



**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: November 6, 2008  
(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)

**000-50549**  
(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, and telephone number,  
including area code, of registrant's principal executive offices)

---

(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 2.02 Results of Operations and Financial Condition](#)

[ITEM 9.01 Financial Statements and Exhibits](#)

[SIGNATURE](#)

[EX-99.1](#)

---

## Table of Contents

### ITEM 2.02 Results of Operations and Financial Condition.

On November 6, 2008, GTX, Inc. issued an earnings release for the third quarter ended September 30, 2008, 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 November 6, 2008

---

[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: November 6, 2008

By: /s/ Mark E. Mosteller  
Name: Mark E. Mosteller  
Title: Vice President and Chief Financial Officer  
(principal accounting and financial officer)

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

### **GTX, INC. REPORTS THIRD QUARTER 2008 FINANCIAL RESULTS**

**MEMPHIS, TENN.** — November 6, 2008 — GTx, Inc. (Nasdaq: GTXI) today reported financial results for the third quarter of 2008. The net loss for the third quarter and nine months ended September 30, 2008 was \$11.9 million and \$37.9 million, respectively, compared with a net loss of \$10.2 million and \$27.6 million for the same periods in 2007. At September 30, 2008 GTx had cash, cash equivalents and short-term investments of \$105.3 million.

“We are pleased to report that our registration and launch planning for toremifene 80 mg to prevent fractures in men with prostate cancer on androgen deprivation therapy remains on track,” said Mitchell S. Steiner, M.D., CEO of GTx. “We recently held a pre-NDA meeting with the FDA and anticipate submitting the New Drug Application this quarter. We are also pleased with the progress of the Merck–GTx SARM collaboration and particularly the announcement that Ostarine met the primary endpoint of the Phase II cancer cachexia clinical trial. We are working with Merck on the development program for SARM product candidates for the treatment of sarcopenia, cancer cachexia, and other muscle loss indications.”

#### **Corporate highlights**

*Phase III clinical trial evaluating toremifene 80 mg for the prevention of fractures and treatment of other estrogen deficiency side effects of androgen deprivation therapy (ADT) for prostate cancer:*

- GTx has completed the Phase III ADT clinical trial, held a recent planned pre-NDA meeting with the United States Food and Drug Administration, and is on track to submit the New Drug Application (NDA) in the fourth quarter.
-

- At the Annual Meeting of the American Society for Bone and Mineral Research in September and at the Chicago Supportive Oncology Conference in October, GTx presented a safety analysis from a subset of patients in the Phase III ADT clinical trial with a detectable PSA at baseline demonstrating that fewer men treated with toremifene 80 mg had prostate specific antigen progression over time compared to placebo.

*Phase III clinical trial evaluating toremifene 20 mg for the prevention of prostate cancer in men with high grade prostatic intraepithelial neoplasia (PIN):*

- The Phase III high grade PIN clinical trial is ongoing, and GTx anticipates conducting the efficacy analysis in the summer of 2009.
- In July, an independent Data Safety Monitoring Board (DSMB) conducted a planned, semi-annual review of unblinded safety data from the approximately 1,590 patients participating in the toremifene 20 mg Phase III high grade PIN clinical trial and recommended the clinical trial continue as planned.

*Phase II clinical trial evaluating Ostarine™ (also designated by Merck as MK-2866) for cancer cachexia:*

- In October, GTx announced topline results of the Phase II clinical trial evaluating Ostarine™ in patients with cancer induced muscle loss, also known as cancer cachexia. In the analysis, the study met its primary endpoint of absolute change in total lean body mass (muscle) compared to placebo and the secondary endpoint of muscle function (performance) after 16 weeks of treatment. GTx and Merck & Co., Inc. are collaborating to develop Ostarine™ and other SARMS, a new class of drugs with the potential to treat sarcopenia, which is the loss of skeletal muscle mass resulting in reduced physical strength and ability to perform activities of daily living, as well as cancer cachexia and other musculoskeletal wasting or muscle loss conditions.

### **Third quarter 2008 financial highlights**

The net loss for the quarter ended September 30, 2008 was \$11.9 million, compared with a net loss of \$10.2 million for the same period in 2007.

Revenue for the third quarter of 2008 was \$3.0 million, compared to \$1.7 million for the same period in 2007. Net sales of FARESTON (toremifene citrate) 60 mg, marketed for

---

the treatment of metastatic breast cancer, were \$315,000 and \$268,000 for the three months ended September 30, 2008 and 2007, respectively. Collaboration revenue for the third quarter of 2008 consisted of approximately \$1.5 million and approximately \$1.3 million from the amortization of deferred revenue from our collaborations with Ipsen Limited and Merck, respectively. Collaboration revenue for the third quarter of 2007 consisted of approximately \$1.5 million from the amortization of deferred revenue from Ipsen.

For the three months ended September 30, 2008 research and development expenses were \$9.2 million and general and administrative expenses were \$6.1 million, compared to \$9.9 million and \$3.2 million, respectively, for the same period in 2007. The decrease in research and development expenses resulted from the completion of the toremifene 80 mg Phase III clinical trial for the prevention of fractures and treatment of other estrogen deficiency side effects of ADT for prostate cancer in the first quarter of 2008 and the Ostarine™ Phase II clinical trial for cancer cachexia in the third quarter of 2008. The increase in general and administrative expenses was primarily the result of increased personnel, medical education, and marketing expenses related to the planned commercialization of our toremifene product candidates.

At September 30, 2008 GTx had cash, cash equivalents and short-term investments of \$105.3 million. GTx has no debt and no warrants.

#### **Conference Call**

There will be a conference call today at 9 a.m. Eastern Time to discuss GTx's third quarter financial results and to provide a company update. To listen to the conference call, please dial:

- 800-591-6944 from the United States and Canada or
- 617-614-4910 (International)

The access code for the call is 53002004.

A playback of the call will be available beginning today at 11:00 a.m. Eastern Time through November 20, 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 11803665.

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, Inc., headquartered in Memphis, Tenn., is a biopharmaceutical company dedicated to the discovery, development, and commercialization of small molecules that selectively target hormone pathways to treat cancer, osteoporosis and bone loss, muscle loss and other serious medical conditions. GTX is developing toremifene citrate, a selective estrogen receptor modulator, or SERM, in two separate clinical programs in men: first, a completed pivotal Phase III clinical trial evaluating toremifene 80 mg for the prevention of fractures and treatment of other estrogen deficiency side effects of androgen deprivation therapy for prostate cancer, and second, an ongoing pivotal Phase III clinical trial evaluating toremifene 20 mg for the prevention of prostate cancer in high risk men with high grade prostatic intraepithelial neoplasia, or PIN. In 2006, GTX and Ipsen Group entered into a development and collaboration agreement for toremifene citrate in all indications except breast cancer for Europe and the Commonwealth of Independent States (CIS). GTX will submit for marketing approval and, if approved, plans to commercialize toremifene 80 mg in the United States. In December 2007, GTX and Merck & Co., Inc. formed a collaboration to discover and develop selective androgen receptor modulators, or SARMs, a new class of drugs with the potential to treat sarcopenia, which is the loss of skeletal muscle mass resulting in reduced physical strength and ability to perform activities of daily living, as well as cancer cachexia (cancer induced muscle loss) and other musculoskeletal wasting or muscle loss conditions. Merck and GTX are conducting several Phase I and Phase II clinical trials evaluating multiple SARM product candidates including Ostarine™ (also designated by Merck as MK-2866) for sarcopenia. Merck and GTX are evaluating additional muscle loss indications including cancer cachexia for potential SARM clinical development. GTX also is developing its preclinical compound GTX-758, an oral luteinizing hormone inhibitor for advanced prostate cancer.

## **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 and its collaboration partners will not be able to commercialize their 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 product candidates; (iii) clinical trials being conducted by GTX and its collaboration partners 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 August 5, 2008 contains under the heading, "Risk Factors," 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.

---

**GTx, Inc.**  
**CONDENSED BALANCE SHEETS**  
(in thousands, except share data)

	<u>September 30,</u> <u>2008</u>	<u>December 31,</u> <u>2007</u>
	<u>(unaudited)</u>	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 101,784	\$ 100,178
Short-term investments	3,499	9,810
Accounts receivable, net	141	117
Inventory	136	78
Receivable from collaboration partners	833	40,719
Prepaid expenses and other current assets	<u>1,257</u>	<u>1,362</u>
Total current assets	107,650	152,264
Property and equipment, net	4,164	2,308
Intangible assets, net	4,177	4,430
Other assets	9	728
Total assets	<u>\$ 116,000</u>	<u>\$ 159,730</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,329	\$ 1,614
Accrued expenses	5,936	6,784
Deferred revenue – current portion	<u>10,934</u>	<u>10,934</u>
Total current liabilities	18,199	19,332
Deferred revenue, less current portion	53,045	61,245
Other long-term liabilities	175	236
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value: 60,000,000 shares authorized; 36,366,216 shares issued and outstanding at September 30, 2008 and 36,216,263 shares issued and outstanding at December 31, 2007	36	36
Additional paid-in capital	352,595	349,019
Accumulated deficit	<u>(308,050)</u>	<u>(270,138)</u>
Total stockholders' equity	44,581	78,917
Total liabilities and stockholders' equity	<u>\$ 116,000</u>	<u>\$ 159,730</u>

**GTx, Inc.**  
**CONDENSED STATEMENTS OF OPERATIONS**  
(in thousands, except share and per share data)  
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
<b>Revenues:</b>				
Product sales, net	\$ 315	\$ 268	\$ 846	\$ 820
Collaboration revenue	2,734	1,463	9,684	4,389
<b>Total revenue</b>	<b>3,049</b>	<b>1,731</b>	<b>10,530</b>	<b>5,209</b>
<b>Costs and expenses:</b>				
Cost of product sales	192	148	482	463
Research and development expenses	9,244	9,881	33,613	26,463
General and administrative expenses	6,107	3,182	16,781	9,908
<b>Total costs and expenses</b>	<b>15,543</b>	<b>13,211</b>	<b>50,876</b>	<b>36,834</b>
Loss from operations	(12,494)	(11,480)	(40,346)	(31,625)
Interest income	568	1,238	2,434	4,056
<b>Net loss</b>	<b>\$ (11,926)</b>	<b>\$ (10,242)</b>	<b>\$ (37,912)</b>	<b>\$ (27,569)</b>
<b>Net loss per share:</b>				
Basic and diluted	\$ (0.33)	\$ (0.29)	\$ (1.05)	\$ (0.79)
<b>Weighted average shares used in computing net loss per share:</b>				
Basic and diluted	36,348,717	34,910,121	36,277,229	34,879,413