

---

**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: August 5, 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))
- 
-

ITEM 2.02 Results of Operations and Financial Condition.

On August 5, 2008, GTx, Inc. issued an earnings release for the second quarter ended June 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 August 5, 2008

---

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: August 5, 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 SECOND QUARTER 2008 FINANCIAL RESULTS**

**MEMPHIS, TENN.** — August 5, 2008 — GTx, Inc. (Nasdaq: GTXI) today reported financial results for the second quarter of 2008. The net loss for the second quarter and six months ended June 30, 2008 was \$13.2 million and \$26.0 million, respectively, compared with a net loss of \$9.2 million and \$17.3 million for the same periods in 2007. At June 30, 2008 GTx had cash, cash equivalents and short-term investments of \$118.0 million.

“In the second quarter, we continued to make strong progress towards the filing of the NDA and planning the commercialization for toremifene 80 mg for the prevention of fractures and treatment of other key estrogen related serious side effects of ADT in men with advanced prostate cancer,” said Mitchell S. Steiner, M.D., CEO of GTx. “We are eager to receive the results of the toremifene 20 mg Phase III PIN clinical trial next year. As for our SARM collaboration with Merck, multiple Phase I and II clinical trials for the treatment of sarcopenia and cancer cachexia are ongoing. We are quickly approaching the end of the Phase II cancer cachexia clinical trial, and we look forward to updating you in the fall.”

#### **Corporate highlights**

In the second quarter GTx announced that an external data group recommended that the Phase III clinical trial evaluating toremifene 20 mg to prevent prostate cancer in men with high grade prostatic intraepithelial neoplasia, or PIN, should continue as planned following an interim efficacy analysis. GTx will make a final determination about the toremifene 20 mg Phase III PIN clinical trial after an efficacy analysis is conducted in the summer of 2009.

---

GTx expects to file the toremifene 80 mg New Drug Application in the fourth quarter following a pre-NDA meeting with the U.S. Food and Drug Administration in October.

The last patient completed the Ostarine™ (MK-2866) Phase II cancer cachexia clinical trial in early August, and GTx anticipates receiving top line data from the clinical trial in the fall. Merck & Co., Inc. (Merck) and GTx are evaluating multiple SARM candidates for the treatment of sarcopenia in Phase I and Phase II clinical trials to select molecules to advance in later stage clinical trials.

### **Second quarter 2008 financial highlights**

The net loss for the quarter ended June 30, 2008 was \$13.2 million, compared with a net loss of \$9.2 million for the same period in 2007.

Revenue for the second quarter of 2008 was \$3.0 million, compared to \$1.8 million for the same period in 2007. Net sales of FARESTON® (toremifene citrate) 60 mg, marketed for the treatment of metastatic breast cancer in postmenopausal women, were \$274,000 and \$360,000 for the three months ended June 30, 2008 and 2007, respectively. Collaboration revenue for the second 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 second quarter of 2007 consisted of approximately \$1.5 million from the amortization of deferred revenue from Ipsen.

For the three months ended June 30, 2008 research and development expenses were \$10.4 million and general and administrative expenses were \$6.4 million, compared to \$8.6 million and \$3.6 million, respectively, for the same period in 2007. The increase in research and development expenses was primarily the result of the company's continued investment in its preclinical and clinical programs, including spending related to the planned filing of a new drug application for toremifene 80 mg. 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 June 30, 2008 GTx had cash, cash equivalents and short-term investments of \$118.0 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 second quarter financial results and to provide a company update. To listen to the conference call, please dial:

- 866-770-7120 from the United States and Canada or
- 617-213-8065 (International)

The access code for the call is 83987063.

A playback of the call will be available beginning today at 11:00 a.m. Eastern Time through August 19, 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 67989165.

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 wasting 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 treatment of serious side effects of androgen deprivation therapy for advanced 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 file 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 (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, cancer cachexia (muscle wasting), as well as other musculoskeletal conditions. Merck and GTx

---

are conducting several Phase I and Phase II clinical trials evaluating multiple SARM product candidates including Ostarine™ (also designated as MK-2866) for sarcopenia. Ostarine is also in a Phase II clinical trial for cancer cachexia which will be completed in 2008. Merck and GTx are evaluating additional muscle loss indications for potential SARM clinical development. GTx also is developing its preclinical compounds, GTx-758, an oral LH inhibitor for advanced prostate cancer, and GTx-878, an estrogen receptor beta agonist for the treatment of benign prostatic hyperplasia and chronic prostatitis.

***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 May 12, 2008 and its most recent Form 10-Q filed August 5, 2008 contain 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>June 30,</u> <u>2008</u>	<u>December 31,</u> <u>2007</u>
	<u>(unaudited)</u>	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 112,937	\$ 100,178
Short-term investments	5,040	9,810
Accounts receivable, net	121	117
Inventory	175	78
Receivable from collaboration partners	785	40,719
Prepaid expenses and other current assets	<u>1,515</u>	<u>1,362</u>
Total current assets	120,573	152,264
Property and equipment, net	3,967	2,308
Intangible assets, net	4,262	4,430
Other assets	<u>782</u>	<u>728</u>
Total assets	<u>\$ 129,584</u>	<u>\$ 159,730</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,483	\$ 1,614
Accrued expenses	6,078	6,784
Deferred revenue — current portion	<u>10,934</u>	<u>10,934</u>
Total current liabilities	18,495	19,332
Deferred revenue, less current portion	55,778	61,245
Other long-term liabilities	195	236
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value:		
60,000,000 shares authorized; 36,311,490 shares issued and outstanding at June 30, 2008 and 36,216,263 shares issued and outstanding at December 31, 2007	36	36
Additional paid-in capital	351,204	349,019
Accumulated deficit	<u>(296,124)</u>	<u>(270,138)</u>
Total stockholders' equity	55,116	78,917
Total liabilities and stockholders' equity	<u>\$ 129,584</u>	<u>\$ 159,730</u>



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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2007	2008	2007
<b>Revenues:</b>				
Product sales, net	\$ 274	\$ 360	\$ 531	\$ 552
Collaboration revenue	2,734	1,463	6,950	2,926
<b>Total revenue</b>	<b>3,008</b>	<b>1,823</b>	<b>7,481</b>	<b>3,478</b>
<b>Costs and expenses:</b>				
Cost of product sales	155	206	290	315
Research and development expenses	10,370	8,575	24,369	16,582
General and administrative expenses	6,424	3,609	10,674	6,726
<b>Total costs and expenses</b>	<b>16,949</b>	<b>12,390</b>	<b>35,333</b>	<b>23,623</b>
Loss from operations	(13,941)	(10,567)	(27,852)	(20,145)
Interest income	698	1,364	1,866	2,818
<b>Net loss</b>	<b>\$ (13,243)</b>	<b>\$ (9,203)</b>	<b>\$ (25,986)</b>	<b>\$ (17,327)</b>
<b>Net loss per share:</b>				
Basic and diluted	\$ (0.37)	\$ (0.26)	\$ (0.72)	\$ (0.50)
<b>Weighted average shares used in computing net loss per share:</b>				
Basic and diluted	36,256,681	34,885,213	36,240,893	34,863,807