
**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) August 10, 2009

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.)

**175 Toyota Plaza
7th Floor
Memphis, Tennessee 38103
(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))
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ITEM 2.02 Results of Operations and Financial Condition.

On August 10, 2009, GTX, Inc. issued an earnings release for the second quarter ended June 30, 2009, 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 10, 2009

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 10, 2009

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 2009 CORPORATE RESULTS

MEMPHIS, TENN. — August 10, 2009 — GTx, Inc. (Nasdaq: GTXI) today reported financial results for the second quarter of 2009. The net loss for the second quarter and six months ended June 30, 2009 was \$11.3 million and \$22.6 million, respectively, compared with a net loss of \$13.2 million and \$26.0 million for the same periods in 2008. At June 30, 2009 GTx had cash, cash equivalents and short-term investments of \$68.9 million.

“We are pleased with the progress of our clinical development programs,” said Mitchell S. Steiner, M.D., CEO of GTx. “Our commercial plans are on track and we are looking forward to launching toremifene 80 mg for patients on ADT, once approved.”

Corporate Updates

- Toremifene 80 mg to reduce the risk of fractures in men with prostate cancer on androgen deprivation therapy:
GTx is working closely with the United States Food and Drug Administration as they review the New Drug Application for toremifene 80 mg to reduce the risk of fractures in men with prostate cancer on androgen deprivation therapy. The agency has targeted a Prescription Drug User Fee Act (PDUFA) agency action date of October 30, 2009. Commercial plans are on track to launch toremifene 80 mg following approval by the FDA.
 - Phase III clinical trial evaluating toremifene 20 mg for the prevention of prostate cancer in high risk men with high grade prostatic intraepithelial neoplasia (PIN):
Following our review of results of recent clinical trials evaluating other potential treatments for the prevention of prostate cancer in low risk and medium risk patients, GTx believes that full three year efficacy and safety data can further differentiate toremifene 20 mg, which is being evaluated in high risk men. GTx has therefore decided not to conduct the event-based efficacy analysis which had been anticipated for late
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summer of 2009 with results to have been available in the fourth quarter. We will instead, following the conclusion of the study in the first quarter of 2010, conduct the final analyses of the clinical trial. GTx plans to announce results of the study and, if successful, the company's plans to submit a New Drug Application in 2010.

- The GTx and Merck & Co., Inc. collaboration for the discovery, development and commercialization of oral selective androgen receptor modulators (SARMs):

The GTx and Merck SARM collaboration is planning to advance in the following indications in 2009 and 2010: chronic sarcopenia and muscle loss in patients with chronic obstructive pulmonary disease (COPD). GTx and Merck are finalizing plans to evaluate Ostarine™ (designated by Merck as MK-2866) for the treatment of chronic sarcopenia with the goal of initiating a Phase IIb clinical trial in 2010. GTx and Merck have selected muscle loss in patients with COPD as an additional indication for Ostarine clinical development with a goal of initiating a Phase II clinical trial in the first quarter of 2010. GTx and Merck are evaluating additional indications for SARM clinical development.

- GTx-758, an oral luteinizing hormone inhibitor for first line treatment of advanced prostate cancer:

GTx expects results from the ongoing Phase I multiple ascending dose clinical trial of GTx-758 in the fourth quarter of 2009. In the second quarter of 2009, GTx completed a Phase I single ascending dose clinical trial evaluating GTx-758 in healthy male volunteers. GTx-758 was well tolerated. The company has initiated a Phase I multiple ascending dose clinical trial evaluating GTx-758 in healthy male volunteers in which it expects to establish the proof of concept of the ability of GTx-758 to reduce testosterone blood concentrations to castrate levels. GTx expects to conclude this trial in the fourth quarter of 2009 and to initiate a Phase II clinical trial in 2010.

Second quarter 2009 financial highlights

The net loss for the quarter ended June 30, 2009 was \$11.3 million compared with a net loss of \$13.2 million for the same period in 2008.

Revenue for the second quarter of 2009 was \$3.8 million compared to \$3.0 million for the same period in 2008. Revenues included net sales of FARESTON® (toremifene citrate) 60 mg, marketed for the treatment of metastatic breast cancer in postmenopausal women, and collaboration revenue from our collaborations with Ipsen Developments Limited and Merck & Co., Inc. Net sales of FARESTON® were \$949,000 and \$274,000 for the three months ended June 30, 2009 and 2008, respectively. Collaboration revenue was \$2.9 million and \$2.7 million for the second quarter of 2009 and 2008, respectively.

For the three months ended June 30, 2009 and 2008, research and development expenses were \$7.7 million and \$10.4 million, respectively. General and administrative expenses increased during the three months ended June 30, 2009 to \$6.9 million from \$6.4 million for the three months ended June 30, 2008.

At June 30, 2009 GTx had cash, cash equivalents and short-term investments of \$68.9 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:

- 866-711-8198 from the United States and Canada or
- 617-597-5327 (International)

The access code for the call is 56156529.

A playback of the call will be available beginning today at 11:00 a.m. Eastern Time through August 24, 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 77179556.

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 prevent and treat cancer, fractures and bone loss, muscle loss and other serious medical conditions. GTx has completed a pivotal Phase III clinical trial evaluating toremifene 80 mg to reduce the risk of fractures and to treat other estrogen deficiency side effects of androgen deprivation therapy, or ADT, in men with prostate cancer. In December 2008, GTx submitted a New Drug Application, or NDA, for toremifene 80 mg to reduce the risk of fractures in men with prostate cancer on ADT, which has been accepted for filing and review by the U.S. Food and Drug Administration, or FDA. The FDA has informed us that it has targeted October 30, 2009 as the Prescription Drug User Fee Act, or PDUFA, date by which it will respond to our toremifene 80 mg NDA. GTx is also developing toremifene 20 mg in an ongoing pivotal Phase III clinical trial for the prevention of prostate cancer in high risk men with high grade prostatic intraepithelial neoplasia. GTx has licensed to Ipsen Developments Limited exclusive rights in the European Union, Switzerland, Norway, Iceland, Lichtenstein, and the Commonwealth of Independent States to develop and commercialize toremifene for all indications which GTx has licensed from Orion Corporation. In December 2007, GTx and Merck & Co., Inc. entered into a collaboration to discover and develop selective androgen receptor modulators, or SARMs, a new class of drugs with the potential to treat chronic sarcopenia, which is the loss of skeletal muscle mass resulting in reduced physical strength and ability to perform activities of daily living and other musculoskeletal wasting or muscle loss conditions, including muscle loss in patients with chronic obstructive pulmonary disease. GTx and Merck are evaluating multiple SARM product candidates, including Ostarine™ (designated by Merck as MK-2866) and MK-0773, for a variety of musculoskeletal wasting indications. GTx is also developing GTx-758, an oral luteinizing hormone inhibitor for the treatment of advanced prostate cancer which is in a Phase I multiple ascending dose clinical trial.

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 11, 2009 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>June 30,</u> <u>2009</u>	<u>December 31,</u> <u>2008</u>
	<u>(unaudited)</u>	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 67,498	\$ 95,510
Short-term investments	1,413	2,157
Accounts receivable, net	411	487
Inventory	115	92
Receivable from collaboration partners	916	777
Prepaid expenses and other current assets	1,723	1,001
Total current assets	<u>72,076</u>	<u>100,024</u>
Property and equipment, net	3,528	3,988
Intangible and other assets, net	3,924	4,097
Total assets	<u>\$ 79,528</u>	<u>\$ 108,109</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,499	\$ 2,821
Accrued expenses	5,338	6,666
Deferred revenue — current portion	11,522	11,490
Total current liabilities	<u>18,359</u>	<u>20,977</u>
Deferred revenue, less current portion	49,026	54,732
Other long term liabilities	447	382
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value: 60,000,000 shares authorized; 36,418,234 shares issued and outstanding at June 30, 2009 and 36,392,443 shares issued and outstanding at December 31, 2008	36	36
Additional paid-in capital	356,139	353,900
Accumulated deficit	<u>(344,479)</u>	<u>(321,918)</u>
Total stockholders' equity	<u>11,696</u>	<u>32,018</u>
Total liabilities and stockholders' equity	<u>\$ 79,528</u>	<u>\$ 108,109</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,	
	2009	2008	2009	2008
Revenues:				
Product sales, net	\$ 949	\$ 274	\$ 1,708	\$ 531
Collaboration revenue	2,873	2,734	5,745	6,950
Total revenue	3,822	3,008	7,453	7,481
Costs and expenses:				
Cost of product sales	431	155	779	290
Research and development expenses	7,746	10,370	16,058	24,369
General and administrative expenses	6,940	6,424	13,482	10,674
Total costs and expenses	15,117	16,949	30,319	35,333
Loss from operations	(11,295)	(13,941)	(22,866)	(27,852)
Interest income	35	698	111	1,866
Loss before income taxes	(11,260)	(13,243)	(22,755)	(25,986)
Income tax benefit	—	—	194	—
Net loss	\$ (11,260)	\$ (13,243)	\$ (22,561)	\$ (25,986)
Net loss per share:				
Basic and diluted	<u>\$ (0.31)</u>	<u>\$ (0.37)</u>	<u>\$ (0.62)</u>	<u>\$ (0.72)</u>
Weighted average shares used in computing net loss per share:				
Basic and diluted	<u>36,417,056</u>	<u>36,256,681</u>	<u>36,410,866</u>	<u>36,240,893</u>