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) May 11, 2009

GTx, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**000-50549**	**62-1715807**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(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):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o 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 May 11, 2009, GTx, Inc. issued an earnings release for the first quarter ended March 31, 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

Exhibit Number	Description
99.1	Press Release issued by GTx, Inc. dated May 11, 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: May 11, 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 FIRST QUARTER 2009 RESULTS

MEMPHIS, TENN. — May 11, 2009 — GTx, Inc. (NASDAQ: GTXI) today reported financial results for the first quarter of 2009. The net loss for the first quarter was $11.3 million compared with a net loss of $12.7 million for the same period in 2008. At March 31, 2009, GTx had cash, cash equivalents and short-term investments of $81.7 million.

“This is an exciting period for GTx,” said Mitchell S. Steiner, MD, CEO of GTx. “All of our clinical programs are making good progress. We now eagerly await the response from the FDA on the toremifene 80 mg NDA and, once approved, are preparing for the launch of our first product.”

Corporate highlights

- The United States Food and Drug Administration (FDA) accepted for filing and review the New Drug Application (NDA) for toremifene 80 mg for the prevention of bone fractures in men with prostate cancer on androgen deprivation therapy. The FDA has targeted a Prescription Drug User Fee Act (PDUFA) agency action date of October 30, 2009.
- In February, an independent Data Safety Monitoring Board (DSMB) conducted a planned, semi-annual review of unblinded safety data from the approximately 1,590 patients randomized in the Phase III clinical trial evaluating toremifene 20 mg for the prevention of prostate cancer in high risk men with the precancerous lesion known as high grade prostatic intraepithelial neoplasia (PIN) and recommended the clinical trial continue as planned. GTx anticipates conducting an efficacy analysis of the toremifene 20 mg Phase III high grade PIN clinical trial in late summer. The timing of the analysis is determined by the number of cancer events that occur in the clinical trial.
- In February, GTx initiated a Phase I clinical trial for GTx-758, an oral luteinizing hormone (LH) inhibitor for first line treatment of advanced prostate cancer. The Phase I study is evaluating the safety, tolerability and pharmacokinetic profile of GTx-758 using a double

blind, placebo controlled design of single ascending doses in healthy male volunteers. In preclinical *in vitro* and *in vivo* models, GTx-758 has demonstrated the potential to reduce testosterone to castrate levels, increase bone mineral density, and prevent hot flashes. GTx expects to establish proof of concept of testosterone reduction in man in a second Phase I clinical trial later this year.

- Merck & Co., Inc. and GTx are evaluating multiple selective androgen receptor modulator (SARM) product candidates, including Ostarine™ (designated by Merck as MK-2866) and MK-0773 for a variety of musculoskeletal wasting indications including sarcopenia and cancer cachexia. GTx and Merck expect to complete an ongoing Phase II clinical trial evaluating MK-0773 for sarcopenia in the second half of this year.

First quarter 2009 financial highlights

The net loss for the quarter ended March 31, 2009 was $11.3 million, compared with a net loss of $12.7 million for the same period in 2008.

Revenue for the first quarter of 2009 was $3.6 million compared to $4.5 million for the same period in 2008. Net sales of FARESTON® (toremifene citrate) 60 mg, marketed for the treatment of metastatic breast cancer, were $759,000 and $257,000 for the three months ended March 31, 2009 and 2008, respectively. Collaboration revenue for the first quarter of 2009 consisted of approximately $1.5 million and approximately $1.4 million from the amortization of deferred revenue from our collaborations with Ipsen Developments Limited and Merck & Co., Inc., respectively. Collaboration revenue for the first quarter of 2008 consisted of approximately $1.5 million and approximately $1.3 million from the amortization of deferred revenue from Ipsen and Merck, respectively, and approximately $1.5 million from an earned milestone from Ipsen with the achievement of the primary endpoint in the Phase III clinical trial evaluating toremifene 80 mg for the prevention of bone fractures and treatment of other estrogen deficiency side effects of ADT for prostate cancer.

For the three months ended March 31, 2009 and 2008, research and development expenses were $8.3 million and $14.0 million, respectively. The decrease in research and development expenses resulted from the completion of the toremifene 80 mg Phase III ADT clinical trial in the first quarter of 2008 and completion of the Phase II clinical trial evaluating Ostarine™ (designated by Merck as MK-2866) for the treatment of cancer cachexia in the third quarter of 2008. For the three months ended March 31, 2009, general and administrative expenses were

$6.5 million compared to $4.3 million for the same period in 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 March 31, 2009, GTx had cash, cash equivalents and short-term investments of $81.7 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 first quarter financial results and to provide a company update. To listen to the conference call, please dial:

- 866-271-6130 from the United States and Canada or
- 617-213-8894 (International)

  The access code for the call is 14165481.

A playback of the call will be available beginning today at 11:00 a.m. Eastern Time through May 25, and may be accessed by dialing:

- 888-286-8010 from the United States and Canada or
- 617-801-6888 (International)

  The access code for the replay is 67067092.

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 citrate, a selective estrogen receptor modulator, or SERM, at an 80 mg dose for the prevention of bone fractures and treatment of other estrogen deficiency side effects of androgen deprivation therapy in men with prostate cancer. GTx has applied for marketing approval in the United States for toremifene 80 mg and, if approved, plans to commercialize toremifene 80 mg in the U.S. GTx is also developing toremifene citrate at a 20 mg dose in a Phase III clinical trial for the prevention of prostate cancer in high risk men with high grade prostatic intraepithelial neoplasia, or PIN. GTx and Ipsen have 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). 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 conditions. 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 including sarcopenia and cancer cachexia. In the second half of 2009, Merck and GTx expect to complete an ongoing Phase II clinical trial evaluating MK-0773 in sarcopenia. GTx also is conducting a Phase I clinical trial evaluating GTx-758, an oral luteinizing hormone inhibitor, for first line treatment of 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 annual report on Form 10-K filed March 3, 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)

	March 31, 2009 (unaudited)	December 31, 2008
ASSETS		
Current assets:		
Cash and cash equivalents	$ 80,174	$ 95,510
Short-term investments	1,553	2,157
Accounts receivable, net	436	487
Inventory	59	92
Receivable from collaboration partners	756	777
Prepaid expenses and other current assets	1,970	1,001
Total current assets	84,948	100,024
Property and equipment, net	3,708	3,988
Intangible and other assets, net	4,010	4,097
Total assets	$ 92,666	$ 108,109
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,610	$ 2,821
Accrued expenses	5,486	6,666
Deferred revenue — current portion	11,490	11,490
Total current liabilities	18,586	20,977
Deferred revenue, less current portion	51,860	54,732
Other long term liabilities	383	382
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.001 par value: 60,000,000 shares authorized; 36,411,509 shares issued and outstanding at March 31, 2009 and 36,392,443 shares issued and outstanding at December 31, 2008	36	36
Additional paid-in capital	355,020	353,900
Accumulated deficit	(333,219)	(321,918)
Total stockholders' equity	21,837	32,018
Total liabilities and stockholders' equity	$ 92,666	$ 108,109

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

	Three Months Ended March 31,	
	2009	2008
Revenues:		
Product sales, net	$ 759	$ 257
Collaboration revenue	2,872	4,216
Total revenues	3,631	4,473
Costs and expenses:		
Cost of product sales	348	135
Research and development expenses	8,312	13,999
General and administrative expenses	6,542	4,250
Total costs and expenses	15,202	18,384
Loss from operations	(11,571)	(13,911)
Interest income	76	1,168
Loss before income taxes	(11,495)	(12,743)
Income tax benefit	194	—
Net loss	$ (11,301)	$ (12,743)
Net loss per share:		
Basic and diluted	$ (0.31)	$ (0.35)
Weighted average shares used in computing net loss per share:		
Basic and diluted	36,404,608	36,224,834