

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: May 12, 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))
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ITEM 2.02 Results of Operations and Financial Condition.

On May 12, 2008, GTx, Inc. issued an earnings release for the first quarter ended March 31, 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 May 12, 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: May 12, 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 FIRST QUARTER 2008 FINANCIAL RESULTS

MEMPHIS, TENN. — May 12, 2008 — GTx, Inc. (Nasdaq: GTXI) today reported financial results for the first quarter of 2008. The net loss for the quarter ended March 31, 2008 was \$12.7 million, compared with a net loss of \$8.1 million for the same period in 2007. At March 31, 2008, GTx had cash, cash equivalents and short-term investments of \$134.7 million.

“Our first quarter announcement that the toremifene 80 mg Phase III ADT clinical trial met its primary endpoint was a transformational event for GTx,” said Mitchell S. Steiner, M.D., CEO of GTx. “We plan to file the New Drug Application with FDA this summer and are preparing for a launch of toremifene 80 mg in 2009. We have initiated the process for conducting the interim efficacy analysis for the toremifene 20 mg high grade PIN clinical trial, and we anticipate receiving results of the analysis soon. The Merck-GTx SARM clinical program is currently pursuing sarcopenia and cancer cachexia, with multiple SARM molecules being evaluated in Phase I and Phase II clinical studies. The ongoing Phase IIb clinical trial evaluating Ostarine, which Merck has designated MK-2866, for cancer cachexia will be completed during the third quarter of this year.”

First quarter 2008 corporate highlights

GTx announced that toremifene 80 mg met the primary and key secondary endpoints of the Phase III ADT clinical trial for the treatment of multiple side effects of androgen deprivation therapy (ADT) for prostate cancer. In a modified intent to treat analysis which included all patients with at least one evaluable study radiograph and a minimum of one dose of study drug or placebo, toremifene 80 mg demonstrated a 54% reduction in new morphometric vertebral fractures, the primary endpoint of the trial. Toremifene 80 mg also increased bone mineral density, reduced hot flashes, improved lipid profiles, and ameliorated gynecomastia. Toremifene 80 mg had a favorable safety profile and was

well tolerated. GTx is planning to file a New Drug Application with the U.S. Food and Drug Administration in the summer of 2008.

First quarter 2008 financial highlights

The net loss for the quarter ended March 31, 2008 was \$12.7 million, compared with a net loss of \$8.1 million for the same period in 2007.

Revenue for the first quarter of 2008 was \$4.5 million, compared to \$1.7 million for the same period in 2007. Revenues for the first quarter of 2008 included \$257,000 of net sales of FARESTON® (toremifene citrate 60 mg), marketed for the treatment of metastatic breast cancer in postmenopausal women, and \$4.2 million of revenue from our collaborations with Ipsen Limited and Merck & Co., Inc. Collaboration revenue included approximately \$1.5 million and approximately \$1.3 million from the amortization of deferred revenue from Ipsen and Merck, respectively. Additionally, the current quarter collaboration revenue included the recognition of approximately \$1.5 million from Ipsen as a result of an earned milestone with the achievement of the primary endpoint in the toremifene 80 mg Phase III ADT clinical trial. Revenues for the first quarter of 2007 included \$192,000 of net sales of FARESTON® and approximately \$1.5 million of collaboration revenue from Ipsen.

For the three months ended March 31, 2008, research and development expenses were \$14.0 million and general and administrative expenses were \$4.3 million, compared to \$8.0 million and \$3.1 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 clinical programs.

At March 31, 2008, GTx had cash, cash equivalents and short-term investments of \$134.7 million. GTx has no debt and no warrants.

2008 Financial Guidance

GTx anticipates a net loss for full year 2008 in the range of \$52 million to \$62 million. This financial projection includes the costs of prelaunch activities for toremifene 80 mg and the ongoing Phase III clinical trial evaluating toremifene 20 mg for the prevention of prostate cancer in men with high grade prostatic intraepithelial neoplasia (PIN). This range does not include the cost of potential prelaunch activities for toremifene 20 mg.

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:

- 866-831-6270 from the United States and Canada or
- 617-213-8858 (International)
The access code for the call is 27771178.

A playback of the call will be available beginning today at 11:00 a.m. Eastern Time through May 26, 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 95259808.

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 ACAPODENE® (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 citrate 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 citrate 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 citrate 80 mg in the United States. 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 age-related muscle loss (a condition generally defined as sarcopenia) as well as other musculoskeletal conditions. Sarcopenia is the loss of skeletal muscle mass resulting in reduced physical strength and ability to perform activities of daily living. The Merck-GTx SARM clinical development program is currently pursuing sarcopenia and cancer cachexia (muscle wasting). Merck and GTX are conducting several Phase I and Phase II clinical trials

evaluating multiple SARM product candidates including Ostarine™ (now designated as MK-2866) for sarcopenia. Ostarine is also in a Phase II clinical trial for cancer cachexia which is due to be completed during the third quarter of 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 annual report on Form 10-K filed March 11, 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>March 31,</u> <u>2008</u>	<u>December 31,</u> <u>2007</u>
	<u>(unaudited)</u>	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 128,313	\$ 100,178
Short-term investments	6,389	9,810
Accounts receivable, net	98	117
Inventory	46	78
Receivable from collaboration partners	2,364	40,719
Prepaid expenses and other current assests	<u>1,945</u>	<u>1,362</u>
Total current assets	139,155	152,264
Property and equipment, net	2,787	2,308
Intangible assets, net	4,346	4,430
Other assets	788	728
Total assets	<u>\$ 147,076</u>	<u>\$ 159,730</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 3,650	\$ 1,614
Accrued expenses	6,678	6,784
Deferred revenue — current portion	<u>10,934</u>	<u>10,934</u>
Total current liabilities	21,262	19,332
Deferred revenue, less current portion	58,512	61,245
Other long term liabilities	216	236
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value: 60,000,000 shares authorized; 36,236,263 shares issued and outstanding at March 31, 2008 and 36,216,263 issued and outstanding at December 31, 2007	36	36
Additional paid-in capital	349,931	349,019
Accumulated deficit	<u>(282,881)</u>	<u>(270,138)</u>
Total stockholders' equity	67,086	78,917
Total liabilities and stockholders' equity	<u>\$ 147,076</u>	<u>\$ 159,730</u>

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

	Three Months Ended	
	March 31,	
	2008	2007
Revenues:		
Product sales, net	\$ 257	\$ 192
Collaboration revenue	4,216	1,463
Total revenues	4,473	1,655
Costs and expenses:		
Costs of product sales	135	109
Research and development expenses	13,999	8,007
General and administrative expenses	4,250	3,117
Total costs and expenses	18,384	11,233
Loss from operations	(13,911)	(9,578)
Interest income	1,168	1,454
Net loss	\$ (12,743)	\$ (8,124)
Net loss per share:		
Basic and diluted	\$ (0.35)	\$ (0.23)
Weighted average shares used in computing net loss per share:		
Basic and diluted	36,224,834	34,842,160