
**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) February 17, 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.)

**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 February 17, 2009, GTx, Inc. issued an earnings release for the fourth quarter and year ended December 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 February 17, 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: February 17, 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 REPORTS FOURTH QUARTER AND YEAR END 2008 RESULTS

MEMPHIS, Tenn. — February 17, 2009 — GTx, Inc. (Nasdaq: GTXI), today reported financial results for the fourth quarter and year ended December 31, 2008. The net loss for the quarter and year ended December 31, 2008 was \$13.9 million and \$51.8 million, respectively, compared with a net loss of \$12.8 million and \$40.4 million for the same periods in 2007. At December 31, 2008, GTx had cash, cash equivalents and short-term investments of \$97.7 million.

“2009 will be an exciting, busy year for GTx,” said Mitchell Steiner, MD, Chief Executive Officer of GTx. “The organization is positioning itself to launch toremifene 80 mg if our NDA is approved by FDA. Successful outcome of the toremifene 20 mg Phase III high grade PIN clinical trial this summer could deliver a second near term revenue opportunity. GTx and Merck together are moving forward with clinical development of SARMs for multiple indications. Finally, in the current quarter we will initiate a Phase I clinical trial for GTX-758, a new product candidate that has the potential to be a best in class treatment for advanced prostate cancer.”

Fourth Quarter Corporate and Clinical Highlights

On December 30, 2008 GTx submitted the New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for toremifene 80 mg, an oral selective estrogen receptor modulator (SERM), for the prevention of bone fractures in men with prostate cancer on androgen deprivation therapy (ADT).

GTx announced topline results of a Phase II clinical trial evaluating Ostarine™ (designated by Merck as MK-2866), a selective androgen receptor modulator (SARM), in patients with cancer induced muscle loss, also known as cancer cachexia. The study met the 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, which are a new class of drugs with the potential to treat sarcopenia (the loss of skeletal muscle mass resulting in reduced physical strength and ability to perform activities of daily living), cancer cachexia, and other musculoskeletal loss conditions.

Annual Product Candidate Portfolio Update

Toremifene 80 mg for the prevention of bone fractures in men with prostate cancer on androgen deprivation therapy:

GTx submitted to FDA in late December 2008 the NDA for toremifene 80 mg for the prevention of bone fractures in men with prostate cancer on ADT. The submission is supported by a two year, double blind, placebo controlled, randomized Phase III clinical trial of 1,382 men with advanced prostate cancer on ADT. By early March GTx expects to hear from FDA whether this NDA submission has been accepted for filing and whether it will have priority or standard review. If the NDA is approved by FDA, GTx plans to commercialize toremifene in the United States.

Toremifene 20 mg for the prevention of prostate cancer in high risk men:

GTx enrolled 1,590 patients at over 150 sites in the United States and Canada in the pivotal Phase III clinical trial evaluating toremifene 20 mg for the prevention of prostate cancer in high risk men with the precancerous prostate lesion known as high grade prostatic intraepithelial neoplasia (PIN). The primary endpoint of the trial is a reduction in prostate cancer incidence. The trial is being conducted under a SPA with FDA. GTx anticipates conducting an efficacy analysis of the toremifene 20 mg Phase III high grade PIN clinical trial in the summer of 2009.

Ostarine™ (MK-2866) and other SARMs for the treatment of muscle wasting and bone loss diseases:

GTx and Merck are collaborating on the discovery, development and commercialization of Ostarine™ and other SARMs for the treatment of sarcopenia, which is the loss of skeletal muscle 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 loss conditions. In 2009, GTx and Merck will complete an ongoing Phase II clinical trial in sarcopenia and are planning to initiate a clinical trial in cancer cachexia. GTx and Merck are also evaluating other potential indications for our SARM collaboration.

GTx-758, an oral LH inhibitor for advanced prostate cancer:

GTx is planning to initiate in the first quarter of 2009 a Phase I clinical trial evaluating GTx-758 in healthy volunteers. GTx-758 is an oral LH inhibitor which in preclinical *in vitro* and *in vivo* models has demonstrated the potential to achieve medical castration to treat advanced prostate cancer without bone loss and hot flashes. GTx expects to establish proof of concept for GTx-758 with a Phase I multiple ascending dose clinical trial which GTx is planning to initiate in the second quarter and conclude in the fourth quarter of 2009.

Financial Highlights for the Quarter and Year Ended December 31, 2008

The net loss for the quarter and year ended December 31, 2008 was \$13.9 million and \$51.8 million, respectively, compared to \$12.8 million and \$40.4 million for the same periods in the prior year. Revenue for the quarter and year ended December 31, 2008 was \$3.0 million and \$13.5 million, respectively, compared to \$1.9 million and \$7.1 million for the same periods in 2007.

Revenue for the fourth quarter of 2008 included collaboration income of \$1.3 million and \$1.5 million related to our collaborations with Merck and Ipsen Developments Limited (Ipsen), respectively, and \$242,000 of net sales of FARESTON® (toremifene citrate) 60 mg, marketed for the treatment of metastatic breast cancer in postmenopausal women. Revenue for the year ended December 31, 2008 included collaboration income of \$5.1 million and \$7.3 million from Merck and Ipsen, respectively, and \$1.1 million of net sales of FARESTON®.

Research and development expenses for the quarter and year ended December 31, 2008 were \$10.6 million and \$44.3 million, respectively, compared to \$12.0 million and \$38.5 million for the same periods in 2007. The increase in research and development expenses in 2008 was primarily the result of the company's continued investment in its clinical programs and activities related to the filing of the NDA for toremifene 80 mg for the prevention of bone fractures in men with prostate cancer on ADT.

General and administrative expenses for the quarter and year ended December 31, 2008 were \$6.3 million and \$23.1 million, respectively, compared to \$3.6 million and \$13.5 million for the same periods in 2007. The increase in general and administrative expenses in 2008 was primarily the result of increased personnel, medical education, and marketing expenses related to the planned commercialization of our toremifene product candidates.

At December 31, 2008 GTx had cash, cash equivalents and short-term investments of \$97.7 million. In December 2008 GTx received \$5 million from Merck as the first of three annual installment payments related to cost reimbursements for research and development activities under its collaboration agreement. GTx has no debt and no warrants.

Conference Call

There will be a conference call today at 9:00 a.m. Eastern Time to discuss GTx's fourth quarter and full year 2008 financial results and to provide a company update. To listen to the conference call, please dial 800-299-0433 from the United States or Canada or 617-801-9712 from outside North America. The access code for the call is 29132697. A playback of the call will be available from approximately 11:00 a.m. Eastern Time today through March 3, 2009 and may be accessed by dialing 888-286-8010 from the United States or Canada or 617-801-6888 from outside North America, and referencing reservation number 40020891. 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 bone fractures and treatment of other estrogen side effects in men with prostate cancer on androgen deprivation therapy, 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 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 has submitted a NDA for toremifene 80 mg for the prevention of bone fractures in men with prostate cancer on ADT and, if approved, plans to commercialize toremifene 80 mg in the United States. In December 2007, GTx and Merck 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. Merck and GTx are evaluating multiple SARM product candidates, including Ostarine™ (designated by Merck as MK-2866) for sarcopenia in several Phase I and II clinical development programs. 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 November 6, 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)
(unaudited)

	December 31,	
	2008	2007
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 95,510	\$ 100,178
Short-term investments	2,157	9,810
Accounts receivable, net	487	117
Inventory	92	78
Receivable from collaboration partners	777	40,719
Prepaid expenses and other current assets	1,001	1,362
Total current assets	100,024	152,264
Property and equipment, net	3,988	2,308
Intangible assets, net	4,093	4,430
Other assets	4	728
Total assets	\$ 108,109	\$ 159,730
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 2,821	\$ 1,614
Accrued expenses	6,666	6,784
Deferred revenue — current portion	11,490	10,934
Total current liabilities	20,977	19,332
Deferred revenue, less current portion	54,732	61,245
Other long-term liabilities	382	236
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value: 60,000,000 shares authorized; 36,392,443 shares issued and outstanding at December 31, 2008 and 36,216,263 shares issued and outstanding at December 31, 2007	36	36
Additional paid-in capital	353,900	349,019
Accumulated deficit	(321,918)	(270,138)
Total stockholders' equity	32,018	78,917
Total liabilities and stockholders' equity	\$ 108,109	\$ 159,730

GTx, Inc.
Condensed Statements of Operations
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2008	2007	2008	2007
Revenues:				
Product sales, net	\$ 242	\$ 256	\$ 1,088	\$ 1,076
Collaboration revenue	2,756	1,661	12,440	6,050
Total revenues	2,998	1,917	13,528	7,126
Costs and expenses:				
Cost of product sales	167	158	649	621
Research and development expenses	10,646	12,045	44,259	38,508
General and administrative expenses	6,324	3,593	23,105	13,501
Total costs and expenses	17,137	15,796	68,013	52,630
Loss from operations	(14,139)	(13,879)	(54,485)	(45,504)
Interest income	271	1,089	2,705	5,145
Net loss	\$ (13,868)	\$ (12,790)	\$ (51,780)	\$ (40,359)
Net loss per share:				
Basic and diluted	\$ (0.38)	\$ (0.36)	\$ (1.43)	\$ (1.16)
Weighted average shares used in computing net loss per share:				
Basic and diluted	36,374,895	35,120,383	36,301,558	34,940,151