
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 9, 2011

GTx, Inc.

(Exact name of registrant as specified in its charter)

Delaware

000-50549

62-1715807

(State or other Jurisdiction of
Incorporation)

(Commission File Number)

(IRS Employer Identification No.)

**175 Toyota Plaza
7th Floor**

Memphis, Tennessee

(Address of Principal Executive Offices)

38103

(Zip Code)

Registrant's telephone number, including area code: **(901) 523-9700**

(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:

- 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 9, 2011, GTx, Inc. issued an earnings release for the first quarter ended March 31, 2011, 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 9, 2011

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 9, 2011

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 PROVIDES CORPORATE UPDATE AND REPORTS FIRST QUARTER 2011 FINANCIAL RESULTS

MEMPHIS, Tenn. — May 9, 2011 — GTx, Inc. (Nasdaq: GTXI) today provided a company update and reported financial results for the first quarter of 2011.

“We have made strong progress in both the Ostarine and Capesaris clinical development programs,” said Mitchell S. Steiner, MD, CEO of GTx. “The indication we will pursue for Ostarine is the prevention and treatment of muscle wasting in patients with non-small cell lung cancer. We expect to initiate two pivotal Phase III clinical trials in the third quarter.”

“We are also excited about our Capesaris program. We have met with the FDA and confirmed that the primary endpoint required for approval for Capesaris for first line treatment of advanced prostate cancer will be maintenance of castrate levels of serum total testosterone. We plan to initiate a Phase IIb clinical trial comparing Capesaris to Lupron in advanced prostate cancer patients in the second quarter of 2011. We expect this study to enroll quickly and to have primary efficacy results from this open label study in the fourth quarter of this year,” Dr. Steiner said.

Clinical pipeline updates

• ***OstarineTM (GTx-024), a selective androgen receptor modulator, for the prevention and treatment of muscle wasting in patients with non-small cell lung cancer:*** GTx has held End of Phase II meetings with the U.S. Food and Drug Administration, or FDA, to discuss the proposed Phase III clinical development of Ostarine (GTx-024) for the prevention and treatment of muscle wasting in patients with non-small cell lung cancer. Based upon feedback from the FDA, GTx expects to initiate two pivotal Phase III clinical trials for this indication in the third quarter of 2011. Muscle wasting is a common cancer related symptom that results in the decline in physical function, reduced tolerability and response to chemotherapy, loss of independence, poor cancer outcomes, and reduced survival.

• ***Capesaris™ (GTx-758), an oral selective estrogen receptor alpha agonist, for first line treatment of advanced prostate cancer:***

GTx is planning to initiate in the second quarter of 2011 an open label Phase IIb clinical trial evaluating Capesaris compared to Lupron Depot® (leuprolide acetate for depot suspension) in men with advanced prostate cancer. GTx expects primary efficacy results of the Phase IIb clinical study, which is the proportion of patients who become castrate by 60 days, to be available in the fourth quarter of 2011. GTx has met with the FDA and confirmed that the primary endpoint for Phase III clinical trials required for approval for first line treatment of advanced prostate cancer is the maintenance of castrate levels of serum testosterone (<50 ng/dL) from Day 28 to Day 364.

• ***Toremifene 80 mg for the reduction of fractures and treatment of other estrogen deficiency side effects in men with prostate cancer on androgen deprivation therapy:*** GTx has evaluated the business case for toremifene 80 mg and concluded that the Company cannot justify the expense and time required to conduct a second Phase III clinical trial. Accordingly, GTx is discontinuing development of toremifene 80 mg and allocating its resources to the Ostarine and Capesaris programs.

Financial highlights for the quarter ended March 31, 2011

The net loss for the quarter ended March 31, 2011 was \$2.6 million compared to a net income of \$44.3 million for the same period in 2010.

Revenue for the first quarter of 2011 was \$9.3 million compared to \$56.6 million for the same period in 2010. Revenue for both periods included net sales of FARESTON® (toremifene citrate) 60 mg, marketed for the treatment of advanced metastatic breast cancer in postmenopausal women, and collaboration revenue from Ipsen Biopharm Limited. Net sales of FARESTON were \$1.2 million and \$799,000 for the three months ended March 31, 2011 and 2010, respectively. Revenue for the first quarter of 2011 included \$8.1 million of collaboration revenue as a result of the termination of our license and collaboration agreement with Ipsen during March 2011. Revenue for the first quarter of 2010 included collaboration revenue of \$922,000 from Ipsen and the recognition of \$54.9 million of revenue due to the termination that quarter of a license and collaboration agreement for our SARM program.

Research and development expenses for the quarter ended March 31, 2011 were \$7.3 million compared to \$7.7 million for the same period in 2010. Research and development expenses for the three months ended March 31, 2011 included a non-cash impairment charge of \$1.6 million related to our toremifene 80 mg intangible asset following the decision to discontinue development of toremifene 80 mg. General and administrative expenses for the quarter were \$4.7 million compared to \$4.5 million for the same period in 2010.

At March 31, 2011, GTx had cash, cash equivalents and short-term investments of \$49.4 million.

Conference call

There will be a conference call today at 8:00 a.m. Eastern Time. To listen to the conference call, please dial 866-831-6247 from the United States or Canada or 617-213-8856 from other international locations. The access code for the call is 97712705. A playback of the call will be available from approximately 12:00 p.m. Eastern Time today through May 23, 2011 and may be accessed by dialing 888-286-8010 from the United States or Canada or 617-801-6888 from other international locations and referencing reservation number 42500165. 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 for the treatment of cancer, cancer supportive care, and other serious medical conditions.

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 include, but are not limited to, statements relating to GTx's plans to initiate clinical trials for Ostarine™ (GTx-024) and Capesaris™ (GTx-758) and statements related to the therapeutic potential of GTx's product candidates. 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 (i) that GTx will not be able to commercialize its product candidates if clinical trials do not demonstrate safety and efficacy in humans; (ii) that GTx may not be able to obtain required regulatory approvals to commercialize its product candidates in a timely manner or at all; (iii) that clinical trials planned to be conducted by GTx may not be initiated or completed on schedule, or at all, or may otherwise be suspended or terminated; (iv) that 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 candidate 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 with the Securities and Exchange Commission on March 8, 2011, 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)

	March 31, 2011	December 31, 2010
	<u>(unaudited)</u>	<u></u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 42,790	\$ 58,181
Short-term investments	6,575	450
Accounts receivable, net	680	683
Inventory	164	171
Prepaid expenses and other current assets	1,666	875
Total current assets	51,875	60,360
Property and equipment, net	1,764	2,040
Intangible and other assets, net	223	1,850
Total assets	<u>\$ 53,862</u>	<u>\$ 64,250</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 658	\$ 848
Accrued expenses and other current liabilities	2,576	3,112
Deferred revenue — current portion	—	1,345
Total current liabilities	3,234	5,305
Deferred revenue, less current portion	—	6,721
Other long-term liabilities	246	497
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value: 60,000,000 shares authorized; 51,719,187 shares issued and outstanding at March 31, 2011 and December 31, 2010	52	52
Additional paid-in capital	405,805	404,555
Accumulated deficit	(355,475)	(352,880)
Total stockholders' equity	50,382	51,727
Total liabilities and stockholders' equity	<u>\$ 53,862</u>	<u>\$ 64,250</u>

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

	Three Months Ended	
	March 31,	
	<u>2011</u>	<u>2010</u>
Revenues:		
Product sales, net	\$ 1,229	\$ 799
Collaboration revenue	8,066	55,778
Total revenues	<u>9,295</u>	<u>56,577</u>
Costs and expenses:		
Cost of product sales	205	151
Research and development expenses	7,303	7,650
General and administrative expenses	4,684	4,509
Total costs and expenses	<u>12,192</u>	<u>12,310</u>
(Loss) income from operations	(2,897)	44,267
Other income, net	302	72
Net (loss) income	<u>\$ (2,595)</u>	<u>\$ 44,339</u>
Net (loss) income per share:		
Basic and diluted	<u>\$ (0.05)</u>	<u>\$ 1.22</u>
Weighted average shares used in computing net (loss) income per share:		
Basic and diluted	<u>51,719,187</u>	<u>36,420,901</u>