# **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 24, 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		201.02					
Memphis, Tennessee	Office and	38103					
(Address of Principal Executive Offices) (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:							
o Written communications pursuant to Rule	e 425 under the Securities Act (17 CFF	R 230.425)					
o Soliciting material pursuant to Rule 14a-	12 under the Exchange Act (17 CFR 2	40.14a-12)					
o Pre-commencement communications pu	rsuant to Rule 14d-2(b) under the Excl	hange Act (17 CFR 240.14d-2(b))					
o Pre-commencement communications nu	remant to Bule 13e-4(c) under the Evol	hange Δct (17 CER 240 13e-4(c))					

### ITEM 2.02 Results of Operations and Financial Condition.

On February 24, 2011, GTx, Inc. issued an earnings release for the fourth quarter and year ended December 31, 2010, 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 February 24, 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.

Date: February 24, 2011

By: <u>/s/ Mark E. Mosteller</u> 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 2010 FINANCIAL RESULTS

MEMPHIS, Tenn. — February 24, 2011 — GTx, Inc. (Nasdaq: GTXI) today provided a company update and reported financial results for the fourth quarter and full year 2010.

"We are pleased to report that we have made significant progress in the Ostarine and Capesaris clinical development programs," said Mitchell S. Steiner, MD, CEO of GTx. "The ongoing discussions with FDA regarding Ostarine have helped us solidify the indication we will pursue, the prevention and treatment of muscle wasting in patients with non-small cell lung cancer. We expect to initiate a pivotal Phase III clinical trial early in the third guarter."

"We recently confirmed with FDA that the primary endpoint required for approval in the clinical development of Capesaris for first line treatment of prostate cancer is serum total testosterone. We expect to initiate the Phase IIb clinical trial in the second quarter. This study will be an open label study, and we anticipate having efficacy data in the fourth quarter of 2011," Dr. Steiner said.

#### Clinical pipeline updates

•Ostarine<sup>TM</sup> (GTx-024), a selective androgen receptor modulator, for the prevention and treatment of muscle wasting in patients with cancer: GTx held an End of Phase II meeting with the United States Food and Drug Administration (FDA) in December 2010. GTx expects to initiate early in the third quarter of 2011, following additional input from FDA, a pivotal Phase III clinical trial evaluating Ostarine for the prevention and treatment of muscle wasting in patients with non-small cell lung cancer. Muscle wasting is a common cancer related symptom that results in reduced tolerability and response to chemotherapy, decline in physical function, loss of independence, poor cancer outcomes, and reduced survival.

- •Capesaris<sup>TM</sup> (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® (leuprolide acetate), a LHRH agonist treatment, in men with advanced prostate cancer. GTx met with FDA in February 2011 and confirmed that the primary endpoint acceptable for approval for this indication is total testosterone (achieve and maintain total testosterone levels less than 50ng/dL).
- •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 met with FDA, and the Company believes it has agreement with the agency on the protocol for a single clinical trial which would address the two deficiencies cited in the toremifene 80 mg Complete Response Letter. The projected costs of this single clinical trial exceed the level stipulated in the amended March 2010 toremifene collaboration agreement with Ipsen. GTx and Ipsen are evaluating the potential impact of the projected current trial cost on the business prospects of the collaboration. GTx and Ipsen will agree how best to move forward or may mutually agree to terminate their partnership.

#### Financial highlights for the quarter and year ended December 31, 2010

The net loss for the quarter ended December 31, 2010 was \$7.5 million compared to a net loss of \$10.9 million for the same period in 2009. Net income for the year ended December 31, 2010 was \$15.3 million compared to a net loss of \$46.3 million for the year ended December 31, 2009.

Revenue for the quarter ended December 31, 2010 was \$1.8 million compared to revenue of \$3.7 million for the same period in 2009. Revenue for the year ended December 31, 2010 was \$60.6 million compared to revenue of \$14.7 million for the year ended December 31, 2009.

Revenue for the fourth quarter of 2010 included collaboration revenue from our collaboration with Ipsen of \$336,000 and \$1.5 million of net sales of FARESTON® (toremifene citrate) 60 mg, marketed for the treatment of advanced metastatic breast cancer in postmenopausal women. Revenue for the year ended December 31, 2010 included collaboration revenue from Ipsen of \$1.9 million and \$54.9 million from Merck & Co., Inc. As a result of the termination of our license and collaboration agreement with Merck in March 2010, we recognized as collaboration revenue the remaining \$49.9 million of unamortized deferred revenue in the first quarter of 2010, as well as the final payment of \$5.0 million of cost reimbursement for research and development activities that was received from Merck in December 2010. Revenue for the year ended December 31, 2010 also included \$3.8 million of net sales of FARESTON®.

Research and development expenses for the quarter and year ended December 31, 2010 were \$5.8 million and \$28.5 million, respectively, compared to \$8.2 million and \$32.3 million for the same periods in 2009. General and administrative expenses for the quarter and year ended December 31, 2010 were \$4.5 million and \$17.4 million, respectively, compared to \$6.3 million and \$27.8 million for the same periods in 2009.

Additionally, net income for the fourth quarter and year ended December 31, 2010 included other income of \$1.2 million from grants awarded to the Company by the United States Government under the Qualifying Therapeutic Discovery Project Program, which was established under the Patient Protection and Affordable Care Act.

At December 31, 2010, GTx had cash, cash equivalents and short-term investments of \$58.6 million.

#### Conference call

There will be a conference call today at 9:00 a.m. Eastern Time. To listen to the conference call, please dial 866-804-6923 from the United States or Canada or 857-350-1669 from other international locations. The access code for the call is 30495097. A playback of the call will be available from approximately 12:00 p.m. Eastern Time today through March 10, 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 11542545. 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 and the side effects of anticancer therapy, 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 OstarineTM (GTx-024), Capesaris™ (GTx-758), toremifene 80 mg, 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 Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission on November 9, 2010, 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.

# Condensed Balance Sheets (in thousands) (unaudited)

	December 31,			
	2010		2009	
ASSETS				
Current assets:				
Cash and cash equivalents	\$	58,181	\$	40,219
Short-term investments		450		8,825
Accounts receivable, net		683		406
Inventory		171		116
Receivable from collaboration partners		_		189
Prepaid expenses and other current assets		875		920
Total current assets		60,360		50,675
Property and equipment, net		2,040		3,291
Intangible and other assets, net		1,850		3,755
Total assets	\$	64,250	\$	57,721
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)				
Current liabilities:				
Accounts payable	\$	848	\$	1,268
Accrued expenses and other current liabilities		3,112		4,730
Deferred revenue — current portion		1,345		9,954
Total current liabilities		5,305		15,952
Deferred revenue, less current portion		6,721		49,898
Other long-term liabilities		497		621
Commitments and contingencies				
Stockholders' equity (deficit):				
Common stock, \$0.001 par value: 60,000,000 shares authorized; 51,719,187 shares				
issued and outstanding at December 31, 2010 and 36,420,901 shares issued and				
outstanding at December 31, 2009		52		36
Additional paid-in capital		404,555		359,388
Accumulated deficit		(352,880)		(368,174)
Total stockholders' equity (deficit)		51,727		(8,750)
Total liabilities and stockholders' equity (deficit)	\$	64,250	\$	57,721

GTx, Inc.

# Condensed Statements of Operations (in thousands, except share and per share data) (unaudited)

	Three Months Ended December 31,			Year Ended December 31,				
		2010		2009		2010		2009
Revenues:								
Product sales, net	\$	1,469	\$	862	\$	3,827	\$	3,289
Collaboration revenue		336		2,815		56,786		11,441
Total revenue		1,805		3,677		60,613		14,730
Costs and expenses:								
Cost of product sales		267		167		768		1,290
Research and development expenses		5,775		8,163		28,495		32,344
General and administrative expenses		4,519		6,284		17,419		27,778
Total costs and expenses		10,561		14,614		46,682		61,412
Income (loss) from operations		(8,756)		(10,937)		13,931		(46,682)
Other incomé, net		1,227		18		1,363		188
Income (loss) before income taxes		(7,529)		(10,919)		15,294		(46,494)
Income tax benefit		` —'		44		· —		238
Net income (loss)	\$	(7,529)	\$	(10,875)	\$	15,294	\$	(46,256)
Net income (loss) per share:								
Basic and diluted	\$	(0.16)	\$	(0.30)	\$	0.39	\$	(1.27)
Weighted average shares used in computing net income (loss) per share:								
Basic and diluted	46	5,152,093	30	5,420,901	38	3,874,721	36	5,415,379