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 21, 2012

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 38103
(901) 523-9700
(Address of principal executive offices, including zip code)

Registrant's telephone number, including area code:

(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))

ITEM 2.02 Results of Operations and Financial Condition.

On February 21, 2012, GTx, Inc. issued an earnings release for the fourth quarter and year ended December 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

Exhibit Number	Description
99.1	Press Release issued by GTx, Inc. dated February 21, 2012

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 21, 2012

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 2011 FINANCIAL RESULTS

MEMPHIS, Tenn. – February 21, 2012 — GTx, Inc. (Nasdaq: GTXI) today provided a Company update and reported financial results for the fourth quarter and full year 2011.

“Today, in a separate news release, we announced that following our request to discuss changes in our clinical development program because of dose related safety involving venous thromboembolic events, FDA notified the Company in a telephone call on Friday, February 17 that it was placing a clinical hold on our Phase II clinical studies of Capesaris® for first line treatment of advanced prostate cancer and secondary hormonal therapy,” said Mitchell S. Steiner, MD, CEO of GTx. “We believe there may be a path forward to develop Capesaris at lower doses to treat men with metastatic hormone sensitive prostate cancer or castration resistant prostate cancer, and we plan to work with the agency to design appropriate studies for these patient populations.”

“We are pleased with the progress of our clinical development program of enobosarm, formerly known as Ostarine™,” Dr. Steiner said. “Our discussions with lung cancer thought leaders and patient advocates confirm the need for a drug to prevent and treat muscle wasting in patients with advanced non-small cell lung cancer.”

Clinical pipeline updates

• ***Enobosarm (Ostarine™, GTx-024), an oral selective androgen receptor modulator, for the prevention and treatment of muscle wasting in patients with non-small cell lung cancer:*** GTx was granted the generic name “enobosarm” for Ostarine as a first in class agent. GTx has recently commenced two pivotal Phase III clinical trials, POWER1 and POWER2 (Prevention and Treatment Of Muscle Wasting in CancER) in patients with advanced non-small cell lung cancer. These clinical trials were designed based on feedback from the United States

Food and Drug Administration (FDA). In the fourth quarter, GTx met with representatives of the Medicines and Healthcare Products Regulatory Agency (United Kingdom) and Medical Products Agency (Sweden), who confirmed that the design of the POWER1 and POWER2 clinical trials should be sufficient for the European Medicines Agency to support registration in Europe. These international studies are being conducted in clinical sites in the United States, Europe, and South America. In each of the placebo-controlled, double-blind clinical trials, 300 patients with Stage III or IV non-small cell lung cancer will be randomized to placebo or enobosarm 3 mg at the time they are to begin first line chemotherapy. The studies are evaluating as co-primary endpoints after three months of treatment the effect of enobosarm versus placebo on maintaining or improving total lean body mass (muscle) assessed by dual x-ray absorptiometry (DXA) and on improvement of physical function assessed by the Stair Climb Test. Durability of the drug effect is being assessed as a secondary endpoint after five months of treatment. GTx expects data from the POWER1 and POWER2 Phase III clinical studies in the first quarter of 2013.

• ***Capesaris® (GTx-758), an oral selective estrogen receptor alpha agonist, for first and second line hormonal treatment of advanced prostate cancer prior to chemotherapy:*** GTx announced today that the FDA notified the Company in a telephone call on Friday, February 17, 2012, that the agency has placed a clinical hold on clinical trials evaluating Capesaris (GTx-758) for primary (first line) androgen deprivation therapy for advanced prostate cancer and secondary (second line) hormonal treatment. A clinical hold is a notification issued by the FDA to the trial sponsor to delay a clinical trial or suspend an ongoing clinical trial. The Company plans to work with the FDA to determine the appropriate path forward to evaluate Capesaris for the treatment of men with metastatic hormone sensitive prostate cancer or castration resistant prostate cancer.

Financial highlights for the quarter and year ended December 31, 2011

The net loss for the quarter ended December 31, 2011 was $10.7 million compared to a net loss of $7.5 million for the same period in 2010 reflecting increased research and development costs in connection with the Company's enobosarm and Capesaris clinical development programs. The net loss for the year ended December 31, 2011 was $33.3 million compared to net income of $15.3 million for the year ended December 31, 2010.

Revenue was $1.8 million for both of the quarters ended December 31, 2011 and 2010. Revenue for the fourth quarter of 2011 consisted of net sales of FARESTON® (toremifene citrate) 60 mg, approved for the treatment of metastatic breast cancer in postmenopausal women. Revenue for the fourth quarter of 2010 consisted of net sales of FARESTON® of $1.5 million and collaboration revenue of $336,000 from our former collaboration with Ipsen Biopharm Limited.

Revenue for the year ended December 31, 2011 was $14.7 million compared to revenue of $60.6 million for the year ended December 31, 2010. Revenue for the year ended December 31, 2011 included net sales of FARESTON® of $6.7 million and collaboration revenue from Ipsen of $8.1 million as a result of the termination of our license and collaboration agreement with Ipsen in March 2011. Revenue for the year ended December 31, 2010 consisted of net sales of FARESTON® of $3.8 million, collaboration revenue from Ipsen of $1.9 million, and collaboration revenue from Merck & Co. of $54.9 million resulting from the termination of our license and collaboration agreement with Merck in March 2010.

Research and development expenses for the quarter and year ended December 31, 2011 were $8.9 million and $31.9 million, respectively, compared to $5.8 million and $28.5 million for the same periods in 2010. General and administrative expenses for the quarter and year ended December 31, 2011 were $3.4 million and $15.4 million, respectively, compared to $4.5 million and $17.4 million for the same periods in 2010.

At December 31, 2011, GTx had cash, cash equivalents and short-term investments of $74.4 million.

Conference call

There will be a conference call today at 9:00 a.m. Eastern Time to discuss the latest development regarding Capesaris®, provide a corporate update and discuss the Company's fourth quarter and full year 2011 financial results. To listen to the conference call, please dial 866-356-4279 from the United States or Canada or 617-597-5394 from other international locations. The access code for the call is 91296419. A playback of the call will be available from approximately 11:00 a.m. Eastern Time today through March 6, 2012, 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 84768366. 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.

Please note that the conference call previously announced to provide a corporate update and discuss the Company's fourth quarter and full year 2011 financial results to take place at 9:00 a.m. Eastern Time on Wednesday, February 22, 2012 has been cancelled.

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 involve risks and uncertainties, and include, but are not limited to, statements relating to GTx's clinical trials for enobosarm (also known as Ostarine™ or GTx-024) and Capesaris® (GTx-758), including statements relating to whether there may be a path forward to develop Capesaris at lower doses to treat men with metastatic hormone sensitive prostate cancer or castration resistant prostate cancer, the timing of discussions with the FDA regarding the current clinical hold and whether or under what additional requirements, if any, further clinical development will be permitted. 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 being conducted by GTx may not be completed on schedule, or at all, or may otherwise be suspended, similar to the clinical hold announced today on Capesaris, or terminated; or (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 4, 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, except share and per share data)
(unaudited)

	December 31, 2011	December 31, 2010
ASSETS		
Current assets:		
Cash and cash equivalents	$ 63,745	$ 58,181
Short-term investments	10,695	450
Accounts receivable, net	981	683
Inventory	161	171
Prepaid expenses and other current assets	1,266	875
Total current assets	76,848	60,360
Property and equipment, net	1,096	2,040
Intangible and other assets, net	240	1,850
Total assets	$ 78,184	$ 64,250
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,219	$ 848
Accrued expenses and other current liabilities	4,857	3,112
Deferred revenue – current portion	—	1,345
Total current liabilities	6,076	5,305
Deferred revenue, less current portion	—	6,721
Other long-term liabilities	234	497
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.001 par value: 120,000,000 and 60,000,000 shares authorized at December 31, 2011 and December 31, 2010, respectively; 62,790,223 and 51,719,187 shares issued and outstanding at December 31, 2011 and December 31, 2010, respectively	63	52
Additional paid-in capital	457,985	404,555
Accumulated deficit	(386,174)	(352,880)
Total stockholders' equity	71,874	51,727
Total liabilities and stockholders' equity	$ 78,184	$ 64,250

GTx, Inc.

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

	Three Months Ended December 31,		Year Ended December 31,	
	2011	2010	2011	2010
Revenues:				
Product sales, net	$ 1,770	$ 1,469	$ 6,673	$ 3,827
Collaboration revenue	—	336	8,066	56,786
Total revenues	1,770	1,805	14,739	60,613
Costs and expenses:				
Cost of product sales	275	267	1,055	768
Research and development expenses	8,863	5,775	31,938	28,495
General and administrative expenses	3,380	4,519	15,438	17,419
Total costs and expenses	12,518	10,561	48,431	46,682
(Loss) income from operations	(10,748)	(8,756)	(33,692)	13,931
Other income, net	66	1,227	398	1,363
Net (loss) income	$ (10,682)	$ (7,529)	$ (33,294)	$ 15,294
Net (loss) income per share:				
Basic and diluted	$ (0.17)	$ (0.16)	$ (0.58)	$ 0.39
Weighted average shares used in computing net (loss) income per share:				
Basic and diluted	62,790,223	46,152,093	57,359,466	38,874,721