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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 8-K**

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**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 8, 2012**

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**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.)

**175 Toyota Plaza  
7th Floor**

**Memphis, Tennessee 38103  
(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)

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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 8, 2012, GTx, Inc. issued its financial press release for the first quarter ended March 31, 2012, 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.

(d) Exhibits

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release issued by GTx, Inc. dated May 8, 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: May 8, 2012

By: /s/ Mark E. Mosteller

Name: Mark E. Mosteller

Title: Vice President and Chief Financial Officer

Contact:  
Marc Hanover, President  
GTx, Inc.  
901-523-9700

#### GTx PROVIDES CORPORATE UPDATE AND REPORTS FIRST QUARTER 2012 FINANCIAL RESULTS

- **FDA removes Full Clinical Hold on Capesaris® in advanced prostate cancer**
- **DSMB allows pivotal Phase III POWER 1 and POWER 2 clinical trials of enobosarm to continue as planned**

MEMPHIS, TN. – May 8, 2012 — GTx, Inc. (Nasdaq: GTXI) today provided a Company update and reported financial results for the first quarter of 2012.

“Our team successfully addressed FDA’s concerns about Capesaris, and we expect to initiate our Phase II clinical study of Capesaris as secondary hormonal therapy in men with metastatic castration resistant prostate cancer during the third quarter,” said Mitchell S. Steiner, MD, CEO of GTx. “We believe Capesaris can provide a unique treatment for a large number of men who are failing their primary hormonal treatment for advanced prostate cancer.”

#### Clinical updates

• **Enobosarm (Ostarine®, GTx-024), an oral selective androgen receptor modulator, for the prevention and treatment of muscle wasting in patients with advanced non-small cell lung cancer:** GTx is currently enrolling subjects in two pivotal Phase III clinical trials, POWER 1 and POWER 2, in patients with advanced non-small cell lung cancer. After a pre-specified safety review in subjects currently enrolled in these two clinical studies, the independent Data Safety Monitoring Board (DSMB) determined that the studies can continue as planned.

These international pivotal Phase III 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 are being randomized to oral daily doses of 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 and improving 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 POWER 1 and POWER 2 Phase III clinical studies during the first half of 2013.

• **Capesaris® (GTx-758), an oral selective estrogen receptor alpha agonist, for secondary hormonal therapy of advanced prostate cancer:** Today, the Company announced in a separate press release that the Food and Drug Administration (FDA) removed its Full Clinical Hold on the Company's Investigational New Drug application for Capesaris following the review by the FDA of the Company's complete response and its new Phase II clinical protocol. GTx plans to initiate during the third quarter an open-label clinical study of 75 men with metastatic castration resistant prostate cancer to test three lower doses of Capesaris (125 mg, 250 mg and 500 mg) sequentially in cohorts of 25 patients each. The Phase II study is designed to assess the effect of Capesaris on serum prostate specific antigen response and prostate cancer progression. The study is also designed to provide confirmation of the mechanism of drug action for Capesaris on lowering serum free testosterone levels by increasing serum SHBG. The safety and tolerability of lower doses of Capesaris will also be evaluated in these subjects, including the incidence of venous thromboembolic events.

#### **Financial highlights for the quarter ended March 31, 2012**

The net loss for the quarter ended March 31, 2012 was \$11.1 million compared to a net loss of \$2.6 million for the same period in 2011.

Revenue for the first quarter 2012 was \$1.8 million compared to \$9.3 million for the same period in 2011. Revenue for the first quarter of 2012 consisted of net sales of FARESTON® (toremifene citrate) 60 mg, approved for the treatment of metastatic breast cancer in postmenopausal women. Revenue for the first quarter of 2011 included FARESTON net sales of \$1.2 million and \$8.1 million of collaboration revenue as a result of the termination of our license and collaboration agreement with Ipsen Biopharm Limited in March 2011.

Research and development expenses for the quarter ended March 31, 2012 were \$9.8 million compared to \$7.3 million for the same period in 2011. General and administrative expenses for the quarter ended March 31, 2012 were \$2.8 million compared to \$4.7 million for the same period in 2011.

At March 31, 2012, GTx had cash, cash equivalents and short-term investments of \$64.0 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 800-299-6183 from the United States or Canada or 617-801-9713 from other international locations. The access code for the call is 32206083. A playback of the call will be available from approximately 11:00 a.m. Eastern Time today through May 22, 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 74903062. 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 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 its planned clinical trial of Capesaris® (GTX-758). 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 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 annual report on Form 10-K filed with the Securities and Exchange Commission on March 2, 2012 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)

	March 31, 2012 <u>(unaudited)</u>	December 31, 2011 <u></u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 55,909	\$ 63,745
Short-term investments	8,045	10,695
Accounts receivable, net	925	981
Inventory	146	161
Prepaid expenses and other current assets	<u>1,498</u>	<u>1,266</u>
Total current assets	66,523	76,848
Property and equipment, net	890	1,096
Intangible and other assets, net	<u>198</u>	<u>240</u>
Total assets	<u>\$ 67,611</u>	<u>\$ 78,184</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 937	\$ 1,219
Accrued expenses and other current liabilities	<u>4,671</u>	<u>4,857</u>
Total current liabilities	5,608	6,076
Other long-term liabilities	235	234
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value: 120,000,000 shares authorized at both March 31, 2012 and December 31, 2011; 62,803,673 and 62,790,223 shares issued and outstanding at March 31, 2012 and December 31, 2011, respectively	63	63
Additional paid-in capital	458,959	457,985
Accumulated deficit	<u>(397,254)</u>	<u>(386,174)</u>
Total stockholders' equity	61,768	71,874
Total liabilities and stockholders' equity	<u>\$ 67,611</u>	<u>\$ 78,184</u>

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

	Three Months Ended March 31,	
	2012	2011
<b>Revenues:</b>		
Product sales, net	\$ 1,829	\$ 1,229
Collaboration revenue	—	8,066
<b>Total revenues</b>	<b>1,829</b>	<b>9,295</b>
<b>Costs and expenses:</b>		
Cost of product sales	274	205
Research and development expenses	9,835	7,303
General and administrative expenses	2,808	4,684
<b>Total costs and expenses</b>	<b>12,917</b>	<b>12,192</b>
Loss from operations	(11,088)	(2,897)
Other income, net	8	302
<b>Net loss</b>	<b>\$ (11,080)</b>	<b>\$ (2,595)</b>
<b>Net loss per share:</b>		
Basic and diluted	\$ (0.18)	\$ (0.05)
<b>Weighted average shares used in computing net loss per share:</b>		
Basic and diluted	62,798,008	51,719,187