# 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) August 8, 2012

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)

	ck 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 isions (see General Instruction A.2. below):
prov.	isions (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 August 8, 2012, GTx, Inc. issued its financial press release for the second quarter ended June 30, 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

Exhibit

Number Description

99.1 Press Release issued by GTx, Inc. dated August 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: August 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 SECOND QUARTER 2012 FINANCIAL RESULTS

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

"We continue to make progress on our late stage clinical programs. We are enrolling our two pivotal Phase III clinical trials evaluating enobosarm for the prevention and treatment of muscle wasting in non-small cell lung cancer patients," said Mitchell S. Steiner, MD, CEO of GTx. "We expect to receive topline data from these studies during the second quarter of 2013. In addition, we will begin screening patients this month for our Phase II clinical study of Capesaris® as secondary hormonal therapy in men with metastatic castration resistant 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 with advanced non-small cell lung cancer in two pivotal Phase III clinical trials, POWER 1 and POWER 2. These international 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 begin first line standard chemotherapy. The studies are evaluating as co-primary endpoints at three months of treatment the response rates 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 evaluated as a secondary endpoint after five months of treatment. Enrollment for both studies is expected to be completed in the fourth quarter of this year, and topline results should be released during the second quarter of 2013.

Capesaris® (GTx-758), an oral selective estrogen receptor alpha agonist, for secondary hormonal therapy of advanced prostate cancer: GTx is initiating this 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 712 clinical trial is designed to assess the effect of Capesaris on serum prostate specific antigen response and prostate cancer progression. The study is expected to provide confirmation of the mechanism of drug action for Capesaris on lowering serum free testosterone levels by increasing serum SHBG in castrated men who failed primary androgen deprivation therapy. 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 June 30, 2012

The net loss for the quarter ended June 30, 2012 was \$10.4 million compared to a net loss of \$10.7 million for the same period in 2011.

Revenue for both the second quarter of 2012 and 2011 was \$1.6 million and consisted of net sales of FARESTON® (toremifene citrate) 60 mg, approved for the treatment of metastatic breast cancer in postmenopausal women.

Research and development expenses for the quarter ended June 30, 2012 were \$9.2 million compared to \$7.6 million for the same period in 2011. General and administrative expenses for the quarter ended June 30, 2012 were \$2.6 million compared to \$4.5 million for the same period in 2011.

At June 30, 2012, GTx had cash and short-term investments of \$55.9 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 866-356-4281 from the United States or Canada or 617-597-5395 from other international locations. The access code for the call is 90153804. A playback of the call will be available from approximately 11:00 a.m. Eastern Time today through August 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 54291257. 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 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 quarterly report on Form 10-Q filed with the Securities and Exchange Commission on May 10, 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)

	June 30, 2012 (unaudited)	December 31, 2011
ASSETS	, ,	
Current assets:		
Cash and cash equivalents	\$ 47,319	\$ 63,745
Short-term investments	8,610	10,695
Accounts receivable, net	908	981
Inventory	105	161
Prepaid expenses and other current assets	1,223	1,266
Total current assets	58,165	76,848
Property and equipment, net	779	1,096
Intangible and other assets, net	201	240
Total assets	\$ 59,145	\$ 78,184
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,462	\$ 1,219
Accrued expenses and other current liabilities	5,732	4,857
Total current liabilities	7,194	6,076
Other long-term liabilities	262	234
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value: 120,000,000 shares authorized at both June 30, 2012 and December 31, 2011;		
62,809,673 and 62,790,223 shares issued and outstanding at June 30, 2012 and December 31, 2011, respectively	63	63
Additional paid-in capital	459,261	457,985
Accumulated deficit	(407,635)	(386,174)
Total stockholders' equity	51,689	71,874
Total liabilities and stockholders' equity	\$ 59,145	\$ 78,184

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

		Three Months Ended June 30,				Six Months Ended June 30,			
		2012		2011		2012		2011	
Revenues:									
Product sales, net	\$	1,639	\$	1,645	\$	3,468	\$	2,874	
Collaboration revenue		_		_		_		8,066	
Total revenues		1,639		1,645		3,468		10,940	
Costs and expenses:									
Cost of product sales		245		264		519		469	
Research and development expenses		9,237		7,591		19,072		14,894	
General and administrative expenses		2,591		4,470		5,399		9,154	
Total costs and expenses		12,073		12,325		24,990		24,517	
Loss from operations		(10,434)		(10,680)		(21,522)		(13,577)	
Other income, net		53		7		61		309	
Net loss	\$	(10,381)	\$	(10,673)	\$	(21,461)	\$	(13,268)	
Net loss per share:									
Basic and diluted	\$	(0.17)	\$	(0.21)	\$	(0.34)	\$	(0.26)	
Weighted average shares used in computing net loss per share:									
Basic and diluted	62	2,805,662	51	,968,667	62	2,801,835	5	1,844,616	