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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): November 4, 2011

**GTx, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction  
of incorporation)

**000-50549**

(Commission File Number)

**62-1715807**

(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 November 4, 2011, GTx, Inc. issued an earnings release for the third quarter ended September 30, 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 November 4, 2011

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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: November 4, 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, INC. PROVIDES CORPORATE UPDATE AND REPORTS THIRD QUARTER 2011 FINANCIAL RESULTS**

**MEMPHIS, TENN.** — November 4, 2011 — GTx, Inc. (Nasdaq: GTXI) today reported financial results for the third quarter of 2011. The net loss for the quarter ended September 30, 2011 was \$9.3 million compared with a net loss of \$8.6 million for the quarter ended September 30, 2010, reflecting increased research and development costs in connection with the Company's Ostarine™ and Capesaris™ clinical development programs.

"We continue to make progress with our clinical development programs," said Dr. Mitchell S. Steiner, CEO of GTx. "We have recently commenced the POWER1 and POWER2 Phase III clinical trials evaluating Ostarine for the prevention and treatment of muscle wasting in patients with non-small cell lung cancer. These studies are designed to demonstrate that Ostarine treatment compared to placebo in patients with non-small cell lung cancer receiving chemotherapy will maintain muscle mass, improve physical function, and possibly even prolong survival."

Dr. Steiner continued: "We are currently evaluating Capesaris for both first line hormonal and second line hormonal treatment of advanced prostate cancer. For first line hormonal therapy, two Phase II clinical trials are in progress to identify the optimal dose to achieve and maintain castrate levels of serum total testosterone in men with advanced prostate cancer. For second line hormonal therapy, we are initiating this quarter a Phase II clinical trial evaluating Capesaris in men with castration resistant prostate cancer."

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## Clinical Pipeline Updates

*Ostarine™ (GTx-024), a selective androgen receptor modulator for the prevention and treatment of muscle wasting in patients with non-small cell lung cancer (NSCLC):* GTx has recently commenced two pivotal Phase III Ostarine™ clinical trials, POWER1 and POWER2 (Prevention and Treatment Of Muscle Wasting in CancER). The studies will be conducted at more than 125 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 who are initiating first line chemotherapy will be randomized to placebo or Ostarine™ 3 mg. The studies are evaluating as coprimary endpoints the effect of Ostarine™ versus placebo on total lean body mass (muscle) assessed by dual x-ray absorptiometry (DXA) and on physical function assessed by the Stair Climb Test at three months. Durability of effect is being assessed as a secondary endpoint at five months. GTx expects data from the POWER1 and POWER2 studies in the first quarter of 2013.

*Capesaris™ (GTx-758), a selective ER alpha agonist for first line and second line hormonal treatment of advanced prostate cancer:* For first line hormonal therapy, the primary endpoint of Phase III clinical trials required by FDA for approval is to achieve and maintain castration (serum total testosterone levels <50 ng/dL) from day 28 through day 364. In June 2011, GTx initiated its Phase II maintenance dose finding clinical trial evaluating Capesaris™ 1000 mg and 2000 mg once a day tablets compared to Lupron Depot® (leuprolide acetate for depot suspension) in 156 men with advanced prostate cancer. Enrollment of this clinical trial is complete. GTx has also initiated this quarter a Phase II loading dose finding clinical trial evaluating the optimal dose to castrate men by day 28. The two doses of Capesaris™ being tested are 1000 mg twice a day and 1500 mg twice a day in 102 men with advanced prostate cancer. After day 28, castrate patients will continue treatment on one of three once a day doses of Capesaris™, 2000 mg, 1000 mg or 500 mg, until day 360. The Phase II loading dose finding clinical trial and the Phase II maintenance dose finding clinical trial have a combined objective of assessing efficacy and safety data necessary for the design of Phase III clinical trials, including the determination of the optimal dose of Capesaris™ to achieve and maintain castration. Data from the Phase II maintenance dose finding study will also be used to assess differences in estrogen deficiency side effects between Capesaris™ and Lupron Depot®. GTx expects to release preliminary topline results of the two Phase II Capesaris™ clinical trials together, with the timing of the announcement being subject to patient enrollment in the Phase II loading dose finding clinical trial.

GTx is initiating this quarter a second line hormonal therapy Phase II clinical study evaluating Capesaris™ 1000 mg and 2000 mg once a day tablets in 50 men with castration resistant prostate cancer (CRPC). The objective of the study is to determine the ability of Capesaris™ to reduce serum PSA and the duration of this PSA reduction in men with CRPC who are currently receiving androgen deprivation therapy.

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### **Third quarter 2011 financial highlights**

The net loss for the quarter ended September 30, 2011 was \$9.3 million compared with a net loss of \$8.6 million for the same period in 2010, reflecting increased research and development costs in connection with the Company's Ostarine™ and Capesaris™ clinical development programs.

Revenue for the third quarter of 2011 was \$2.0 million compared to \$1.3 million for the same period in 2010. Revenue for the third quarter of 2011 consisted of net sales of FARESTON® (toremifene citrate) 60 mg, marketed for the treatment of metastatic breast cancer in postmenopausal women. Revenue for the third quarter of 2010 consisted of net sales of FARESTON® of \$960,000 and collaboration revenue of \$336,000 from our former collaboration with Ipsen Biopharm Limited.

For the three months ended September 30, 2011 and 2010, research and development expenses were \$8.2 million and \$5.6 million, respectively. General and administrative expenses for the third quarter of 2011 were \$2.9 million compared to \$4.1 million for the same period in 2010.

At September 30, 2011, GTX had cash, cash equivalents and short-term investments of \$83.0 million.

### **Conference Call**

There will be a conference call today at 9 a.m. Eastern Time to discuss GTX's third quarter financial results and to provide a company update. To listen to the conference call, please dial:

- 866-831-6243 from the United States and Canada or
- 617-213-8855 (International)

The access code for the call is 26953667.

A playback of the call will be available beginning today at 12:00 p.m. Eastern Time through November 18, and may be accessed by dialing:

- 888-286-8010 from the United States and Canada or
- 617-801-6888 (International)

The reservation number for the replay is 70702629.

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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 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 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 August 9, 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.*

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**GTx, Inc.**  
**CONDENSED BALANCE SHEETS**  
(in thousands, except share data)

	<b>September 30,</b>	<b>December 31,</b>
	<b>2011</b>	<b>2010</b>
	<u>(unaudited)</u>	<u></u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 73,296	\$ 58,181
Short-term investments	9,715	450
Accounts receivable, net	830	683
Inventory	150	171
Prepaid expenses and other current assets	<u>1,351</u>	<u>875</u>
Total current assets	85,342	60,360
Property and equipment, net	1,302	2,040
Intangible and other assets, net	264	1,850
Total assets	<u>\$ 86,908</u>	<u>\$ 64,250</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 829	\$ 848
Accrued expenses and other current liabilities	4,367	3,112
Deferred revenue — current portion	<u>—</u>	<u>1,345</u>
Total current liabilities	5,196	5,305
Deferred revenue, less current portion	—	6,721
Other long-term liabilities	240	497
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value: 120,000,000 and 60,000,000 shares authorized at September 30, 2011 and December 31, 2010, respectively; 62,790,223 and 51,719,187 shares issued and outstanding at September 30, 2011 and December 31, 2010, respectively	63	52
Additional paid-in capital	456,901	404,555
Accumulated deficit	<u>(375,492)</u>	<u>(352,880)</u>
Total stockholders' equity	81,472	51,727
Total liabilities and stockholders' equity	<u>\$ 86,908</u>	<u>\$ 64,250</u>



**GTx, Inc.**  
**CONDENSED STATEMENTS OF OPERATIONS**  
(in thousands, except share and per share data)  
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
<b>Revenues:</b>				
Product sales, net	\$ 2,029	\$ 960	\$ 4,903	\$ 2,358
Collaboration revenue	—	336	8,066	56,450
<b>Total revenues</b>	<b>2,029</b>	<b>1,296</b>	<b>12,969</b>	<b>58,808</b>
<b>Costs and expenses:</b>				
Cost of product sales	311	216	780	501
Research and development expenses	8,181	5,593	23,075	22,720
General and administrative expenses	2,904	4,066	12,058	12,900
<b>Total costs and expenses</b>	<b>11,396</b>	<b>9,875</b>	<b>35,913</b>	<b>36,121</b>
(Loss) income from operations	(9,367)	(8,579)	(22,944)	22,687
Other income, net	23	4	332	136
<b>Net (loss) income</b>	<b>\$ (9,344)</b>	<b>\$ (8,575)</b>	<b>\$ (22,612)</b>	<b>\$ 22,823</b>
<b>Net (loss) income per share:</b>				
Basic and diluted	\$ (0.15)	\$ (0.24)	\$ (0.41)	\$ 0.63
<b>Weighted average shares used in computing net (loss) income per share:</b>				
Basic and diluted	62,778,575	36,424,971	55,529,320	36,422,273