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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

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**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 19, 2008**

**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.)

**3 N. Dunlap Street  
Van Vleet Building  
Memphis, Tennessee 38163  
(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)

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 February 19, 2008, GTx, Inc. issued an earnings release for the fourth quarter and year ended December 31, 2007, 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 February 19, 2008

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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: February 19, 2008

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 REPORTS FOURTH QUARTER AND YEAR END 2007 RESULTS**

MEMPHIS, Tenn. — February 19, 2008 — GTx, Inc. (Nasdaq: GTXI), today reported financial results for the fourth quarter and year ended December 31, 2007. The net loss for the three months and year ended December 31, 2007 was \$12.8 million and \$40.4 million, respectively, compared with a net loss of \$4.7 million and \$35.5 million for the same periods in 2006. At December 31, 2007, GTx had cash and cash equivalents and short-term investments of \$110 million. Subsequent to the end of the quarter, GTx received \$40 million from Merck & Co., Inc. (Merck) representing the payment of the upfront license fee for the recently announced global strategic collaboration for selective androgen receptor modulators (SARMs).

"We continued to execute on our business plan in 2007 by advancing ACAPODENE and forging an important strategic SARM collaboration with Merck," said Mitchell Steiner, MD, Chief Executive Officer of GTx. "With our SARMs positioned for success and with our balance sheet strengthened, we are now focused on obtaining the top line results of the ACAPODENE 80 mg Phase III ADT clinical trial and conducting the efficacy interim analysis of the ACAPODENE 20 mg Phase III high grade PIN clinical trial. Positive results from either trial would transform our company."

#### **Fourth Quarter Corporate Highlights**

- In November 2007, GTx and Merck entered into an agreement providing for a research and development and global strategic collaboration for SARMs, a new class of drugs with the potential to treat frailty (age-related muscle loss, sarcopenia), cancer cachexia (muscle wasting in cancer patients), and other musculoskeletal loss conditions. This collaboration includes GTx's lead SARM candidate, Ostarine™, which is currently being evaluated in a Phase II clinical trial for the treatment of cancer cachexia, and establishes a broad SARM collaboration under which GTx and Merck are pooling their programs and compounds and will work together to discover, develop, and commercialize current as
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well as future SARM molecules. Merck agreed to pay GTx an upfront license fee of \$40 million which the company received in January 2008. Merck will also pay GTx an additional \$15 million in research reimbursements over three years beginning in 2008. In addition, Merck has made an equity investment of \$30 million in GTx common stock at a price of \$23.34 per share. GTx is also eligible to receive up to \$422 million in future milestone payments associated with the development and approval of a lead drug candidate if multiple indications receive regulatory approval. Additional milestones may be received for the development and approval of other collaboration drug candidates. GTx will receive royalties on any resulting worldwide product revenue. Merck is responsible for all future costs associated with ongoing development and commercialization of Ostarine and other collaboration SARM products, excluding GTx's ongoing Phase II Ostarine cancer cachexia clinical trial.

- In November 2007, the last patient completed the Phase III ADT clinical trial evaluating ACAPODENE® (toremifene citrate) 80 mg for the treatment of multiple side effects of androgen deprivation therapy (ADT) for prostate cancer. GTx anticipates reporting top line results from the clinical trial by the end of the first quarter of 2008.

### **Annual Product Candidate Portfolio Update**

ACAPODENE® (toremifene citrate) 80 mg for the treatment of multiple serious side effects of ADT:

GTx enrolled 1,389 patients in its pivotal Phase III ADT clinical trial at approximately 150 sites in the United States and Mexico. In December 2005, GTx conducted a Phase III interim analysis of bone mineral density (BMD) in the first 197 men to complete one year of the trial. Patients treated with ACAPODENE 80 mg compared to placebo demonstrated highly statistically significant positive changes in BMD: +2.3% in lumbar spine ( $p < 0.001$ ), +2.0% in hip ( $p = 0.001$ ), and +1.5% in the femoral neck ( $p = 0.009$ ). In June 2006, GTx conducted a Phase III lipid interim analysis in the same patient cohort. The ACAPODENE 80 mg treated group compared to placebo had lower total cholesterol (-7.1%;  $p = 0.001$ ), lower LDL (-9.0%;  $p = 0.003$ ), lower triglycerides (-20.1%;  $p = 0.009$ ), and a reduction in the ratio of total cholesterol to HDL (-11.7%;  $p < 0.001$ ). The full lipid data set will be evaluated before conclusions about the clinical significance of these findings can be drawn. The primary endpoint of the Phase III ADT clinical trial is a reduction in vertebral morphometric fractures. Secondary endpoints include

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improvements in BMD, hot flashes, gynecomastia, and lipid profiles. The last patient completed the trial in November 2007. GTx anticipates releasing top line results of the clinical trial by the end of the first quarter of 2008.

ACAPODENE® 20 mg for the prevention of prostate cancer in high risk men:

GTx enrolled 1,590 patients at over 150 sites in the United States and Canada in the pivotal Phase III clinical trial evaluating ACAPODENE 20 mg for the prevention of prostate cancer in high risk men with high grade prostatic intraepithelial neoplasia (PIN). The primary endpoint of the trial is a reduction in prostate cancer incidence. The trial is being conducted under a SPA with the FDA. The trial is designed as a 36 month study but provides for an efficacy interim analysis after a certain number of cancer events have occurred. GTx anticipates conducting this efficacy interim analysis by the end of the first quarter of 2008. If the efficacy interim analysis reveals that ACAPODENE 20 mg treatment reduces prostate cancer and achieves the prespecified level of statistical significance ( $p \leq 0.001$ ), GTx plans to file a new drug application (NDA) with the FDA. If GTx is able to file a NDA based on the results of the efficacy interim analysis, GTx will continue to conduct the trial during the review process to collect additional safety data in accordance with the SPA.

Ostarine™ and other SARMs for the treatment of muscle wasting and bone loss diseases:

GTx and Merck have established a global strategic collaboration for the discovery, development and commercialization of SARMs, including Ostarine. GTx and Merck intend to develop SARMs for frailty (age related muscle wasting, sarcopenia), as well as other muscle wasting disorders, including cancer cachexia. GTx is currently conducting a Phase II clinical trial evaluating Ostarine for the treatment of cancer cachexia and anticipates results from the trial in the summer of 2008.

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## **GTx Pipeline**

New GTx compounds for clinical development: GTx-758 for advanced prostate cancer and GTx-878 for benign prostatic hyperplasia (BPH) and chronic prostatitis:

GTx has announced two new product candidates for clinical development. The first is GTx-758, an oral luteinizing hormone (LH) inhibitor for advanced prostate cancer. In preclinical models, GTx-758 induced androgen deprivation while minimizing certain unwanted side effects. GTx is planning to initiate Phase I clinical testing by year end.

The second product candidate, GTx-878, is an estrogen receptor beta agonist for BPH. Current BPH drugs either reduce prostate size or relax the prostate smooth muscle tone. In preclinical models, GTx-878 has demonstrated three activities that may be beneficial to treat BPH. GTx believes that GTx-878 has the potential to inhibit prostate growth, relax prostate smooth muscle tone, and reduce inflammation. GTx is planning to initiate Phase I clinical trials in the first half of 2009.

## **Financial Highlights for the Year and Quarter Ended December 31, 2007**

The net loss for the quarter and year ended December 31, 2007 was \$12.8 million and \$40.4 million, respectively. Revenue for the quarter and year ended December 31, 2007 was \$1.9 million and \$7.1 million, respectively, compared to \$4.6 million and \$7.5 million for the same periods in 2006. Revenue for the fourth quarter of 2007 included collaboration income of \$198,000 and \$1.5 million related to our collaborations with Merck and Ipsen Limited (Ipsen), respectively, and \$256,000 of net sales of FARESTON® (toremifene citrate 60 mg), marketed for the treatment of metastatic breast cancer. Revenue for the fourth quarter of 2006 included collaboration income of \$1.5 million from Ipsen and the remaining deferred revenue of \$3.3 million from our collaboration with Ortho Biotech Products, L. P. (Ortho Biotech), which was terminated by mutual agreement in December 2006. FARESTON net sales for the fourth quarter of 2006 were offset by an increase in the company's reserve for product returns.

Revenue for the year ended December 31, 2007 included collaboration income of \$198,000 and \$5.9 million from Merck and Ipsen, respectively, and \$1.1 million of net sales of FARESTON. Revenue for the year ended December 31, 2006 included collaboration income from Ortho Biotech of \$4.3 million and from Ipsen of \$1.8 million, as well as \$1.4 million of net sales of FARESTON.

Research and development expenses for the quarter and year ended December 31, 2007 were \$12.0 million and \$38.5 million, respectively, compared to \$7.4 million and \$33.9 million for the

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same periods in 2006. The increase in research and development expenses was primarily the result of the company's continued investment in its clinical programs.

General and administrative expenses for the quarter and year ended December 31, 2007 were \$3.6 million and \$13.5 million, respectively, compared to \$2.8 million and \$11.4 million for the same periods in 2006.

At December 31, 2007 GTx had cash and cash equivalents and short-term investments of \$110 million. In January 2008, GTx received \$40 million from Merck representing the payment of the upfront license fee under the exclusive license and collaboration agreement GTx entered into with Merck in November 2007. GTx has no debt and no warrants.

#### **2008 Milestones**

- GTx anticipates releasing top line results of the ACAPODENE 80 mg Phase III ADT clinical trial by the end of the first quarter.
- GTx anticipates conducting an efficacy interim analysis of the ACAPODENE 20 mg Phase III PIN clinical trial by the end of the first quarter.
- GTx anticipates results of the Ostarine Phase II cancer cachexia clinical trial by the end of the summer.
- GTx is planning to initiate Phase I clinical testing of GTx-758, an oral LH inhibitor for advanced prostate cancer, by year end.

#### **Conference Call**

There will be a conference call today at 9:00 a.m. Eastern Time to discuss GTx's fourth quarter and full year financial results and to provide a company update. To listen to the conference call, please dial 800-573-4754 from the United States or Canada or 617-224-4325 from outside North America. The access code for the call is 15873708. A playback of the call will be available from approximately 11:00 a.m., Eastern Time today through March 4, 2008 and may be accessed by dialing 888-286-8010 from the United States or Canada or 617-801-6888 from outside North America, and referencing reservation number 14527179. 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>.

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## 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 to treat cancer, osteoporosis and bone loss, muscle wasting and other serious medical conditions. GTx is developing ACAPODENE® (toremifene citrate), a selective estrogen receptor modulator, or SERM, in two separate clinical programs in men: first, a pivotal Phase III clinical trial for the treatment of serious side effects of androgen deprivation therapy for advanced prostate cancer, and second, a pivotal Phase III clinical trial for the prevention of prostate cancer in high risk men with high grade prostatic intraepithelial neoplasia, or PIN. GTx has licensed to Ipsen Limited exclusive rights in Europe to develop and commercialize ACAPODENE. GTx has formed a strategic collaboration with Merck & Co., Inc. for the development and global commercialization of selective androgen receptor modulators, or SARMS, a new class of drugs with the potential to treat a variety of indications associated with muscle wasting and bone loss including sarcopenia and osteoporosis, cancer cachexia, and chronic kidney disease muscle wasting. GTx is also developing GTx-758, an oral LH inhibitor for advanced prostate cancer, and GTx-878, an estrogen receptor beta agonist for the treatment of benign prostatic hyperplasia and chronic prostatitis.

### Forward-Looking Information is Subject to Risk and Uncertainty

This press release contains forward-looking statements based upon GTx's current expectations, including statements related to clinical development, regulatory timelines, clinical trial results and the expected timing thereof, and statements related to GTx's collaboration with Merck & Co., Inc. 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 that (i) GTx will not be able to commercialize its product candidates if clinical trials do not demonstrate safety and efficacy in humans and even though GTx may receive positive interim results from a clinical trial, interim results of a clinical trial do not necessarily predict final results; (ii) GTx may not be able to obtain required regulatory approvals to commercialize its product candidates; (iii) GTx's clinical trials may not be completed on schedule, or at all, or may otherwise be suspended or terminated; (iv) GTx may not realize the anticipated benefits from its collaboration with Merck & Co., Inc., including the risk that GTx may not receive any future milestone or other payments provided for under the collaboration; and (v) 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 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 registration statement on Form S-3 (File No. 333-148325) filed with the U.S. Securities and Exchange Commission (the "SEC") on December 26, 2007, 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)

	<b>December 31,</b> <b>2007</b>	<b>December 31,</b> <b>2006</b>
	(unaudited)	(unaudited)
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 100,178	\$ 119,550
Short-term investments	9,810	—
Accounts receivable, net	117	61
Inventory	78	207
Receivable from collaboration partners	40,719	660
Prepaid expenses and other current assets	<u>1,362</u>	<u>1,222</u>
Total current assets	152,264	121,700
Property and equipment, net	2,308	1,936
Intangible assets, net	4,430	4,226
Other assets	728	1,393
Total assets	<u>\$ 159,730</u>	<u>\$ 129,255</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,614	\$ 1,336
Accrued expenses	6,784	3,149
Deferred revenue — current portion	<u>10,934</u>	<u>5,852</u>
Total current liabilities	19,332	10,337
Deferred revenue, less current portion	61,245	21,554
Capital lease obligation	10	15
Other long term liability	226	300
Stockholders' equity:		
Common stock, \$0.001 par value: 60,000,000 shares authorized; 36,216,263 shares issued and outstanding at December 31, 2007 and 34,822,362 shares issued and outstanding at December 31, 2006	36	35
Additional paid-in capital	349,019	326,793
Accumulated deficit	<u>(270,138)</u>	<u>(229,779)</u>
Total stockholders' equity	78,917	97,049
Total liabilities and stockholders' equity	<u>\$ 159,730</u>	<u>\$ 129,255</u>

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

	Three Months Ended December 31,		Year Ended December 31,	
	2007	2006	2007	2006
<b>Revenues:</b>				
Product sales, net	\$ 256	\$ (155)	\$ 1,076	\$ 1,357
Collaboration revenue	1,661	4,755	6,050	6,148
<b>Total revenues</b>	<b>1,917</b>	<b>4,600</b>	<b>7,126</b>	<b>7,505</b>
<b>Costs and expenses:</b>				
Cost of product sales	158	18	621	773
Research and development expenses	12,045	7,398	38,508	33,897
General and administrative expenses	3,593	2,843	13,501	11,352
<b>Total costs and expenses</b>	<b>15,796</b>	<b>10,259</b>	<b>52,630</b>	<b>46,022</b>
Loss from operations	(13,879)	(5,659)	(45,504)	(38,517)
Interest income	1,089	946	5,145	3,007
<b>Net loss</b>	<b>\$ (12,790)</b>	<b>\$ (4,713)</b>	<b>\$ (40,359)</b>	<b>\$ (35,510)</b>
<b>Net loss per share:</b>				
Basic and diluted	\$ (0.36)	\$ (0.15)	\$ (1.16)	\$ (1.14)
<b>Weighted average shares used in computing net loss per share:</b>				
Basic and diluted	35,120,383	31,591,407	34,940,151	31,150,035