



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 22, 2007 (February 20, 2007)**

**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))
-

ITEM 2.02 Results of Operations and Financial Condition.

On February 20, 2007, GTX, Inc. issued an earnings release for the fourth quarter and year ended December 31, 2006, 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 20, 2007

---

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 22, 2007

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 2006 RESULTS**

MEMPHIS, Tenn. — February 20, 2007 — GTx, Inc. (Nasdaq: GTXI), today reported financial results for the fourth quarter and year ended December 31, 2006. The net loss for the three months and year ended December 31, 2006 was \$4.7 million and \$35.5 million, respectively, compared with a net loss of \$7.8 million and \$36.8 million for the same periods in 2005. At December 31, 2006, GTx had cash and cash equivalents of \$119.6 million.

“2006 was an outstanding year for GTx,” said Mitchell Steiner, MD, chief executive officer of GTx. “In the first half of 2006, we obtained positive data in a Phase III ADT lipid interim analysis and attained our enrollment goal in our Phase III high grade PIN clinical trial. In the second half of 2006, GTx licensed ACAPODENE European rights to Ipsen and reported successful results from the Phase II proof of concept clinical trial of ostarine, our first-in-class SARM. We ended 2006 with a registered direct equity offering which raised sufficient cash to see the company through the first quarter of 2009, well beyond the time we expect to receive data from each of our two pivotal Phase III ACAPODENE clinical trials and a Phase IIb ostarine clinical trial.”

---

## Fourth Quarter Corporate Highlights

- GTx advanced ostarine, a first-in-class selective androgen receptor modulator (SARM), through a Phase II proof of concept clinical trial in 120 elderly men and postmenopausal women. Ostarine achieved the primary endpoint of building lean body mass and a key secondary endpoint of improving physical performance.
- GTx completed a registered direct public offering, resulting in net proceeds of approximately \$57 million. GTx projects that it now has sufficient cash to fund its operations through the first quarter of 2009.

## Annual Product Candidate Portfolio Update

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

GTx enrolled nearly 1,400 men 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 ( $p = 0.009$ ). The magnitude of these positive changes in BMD provides more confidence that ACAPODENE should deliver the intended fracture benefit. 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 improvements in BMD, hot flashes, gynecomastia, and lipid profiles. The trial is being conducted under a Special Protocol Assessment (SPA) with the United States Food & Drug Administration (FDA). The last patient will complete

---

the trial at the end of November, 2007. GTx will then evaluate the data and prepare it for public release. If the trial meets its primary endpoint, GTx will file a new drug application in 2008.

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

GTx has enrolled nearly 1,500 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 interim efficacy analysis after a certain number of cancer events have occurred. GTx anticipates that there will be sufficient events to conduct this interim efficacy analysis by the first quarter of 2008. If the interim efficacy analysis reveals that ACAPODENE 20 mg treatment reduces prostate cancer and achieves the pre-specified level of statistical significance, GTx will file a new drug application.

**Ostarine for the treatment of muscle wasting and bone loss diseases:**

In 2006, GTx conducted a double blind, randomized, placebo controlled Phase II proof of concept clinical trial evaluating ostarine in 120 elderly men and postmenopausal women. Without a prescribed diet or exercise regimen, the topline data revealed that all subjects treated with ostarine had a dose dependent increase in total lean body mass (muscle), with the 3 mg cohort achieving an increase of 1.4 kg compared to placebo ( $p < 0.001$ ) after three months of treatment. Treatment with ostarine also resulted in a dose dependent improvement in physical performance measured by a stair climb test, with the 3 mg cohort achieving a clinically significant improvement in both speed ( $p = 0.006$ ) and power ( $p = 0.005$ ). Ostarine had a favorable safety profile, with no serious adverse events reported. Ostarine also exhibited tissue selectivity with beneficial effects on lean body mass and performance with no apparent change in measurements for serum PSA (prostate), sebum production (skin and hair), or serum LH (pituitary). GTx believes ostarine has the potential to treat a variety of indications associated with muscle wasting and bone loss, including cancer

---

cachexia, chronic kidney disease and end stage renal disease muscle wasting, frailty, and osteoporosis. GTx is planning to initiate a Phase IIb ostarine clinical trial for the treatment of cancer cachexia by the summer of 2007. GTx is also planning to initiate a Phase IIb ostarine clinical trial for the treatment of chronic kidney disease and end stage renal disease muscle wasting by the end of the year.

### **Financial Highlights for the Year and Quarter Ended December 31, 2006**

The net loss for the three months and year ended December 31, 2006 was \$4.7 million and \$35.5 million, respectively. Revenue for the quarter and year ended December 31, 2006, was \$4.6 million and \$7.5 million compared to \$0.6 million and \$3.8 million for the same periods in 2005. Revenue for the fourth quarter of 2006 included the recognition of the remaining deferred revenue of \$3.3 million from our collaboration with Ortho Biotech Products, L. P., which was terminated by mutual agreement in December 2006. Revenue for the fourth quarter of 2006 also included collaboration income of \$1.5 million from our partner Ipsen Limited ("Ipsen"). Revenue for the year ended December 31, 2006, included collaboration revenue 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® (toremifene citrate 60 mg), marketed for the treatment of metastatic breast cancer. FARESTON net sales for the fourth quarter of 2006 were offset by an increase in the company's reserve for product returns.

Research and development expenses for the quarter and year ended December 31, 2006, were \$7.4 million and \$33.9 million, compared to \$6.5 million and \$30.9 million for the same periods in 2005. 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, 2006, were \$2.8 million and \$11.4 million, compared to the \$2.4 million and \$9.8 million for the same periods of 2005.

### **2007 Milestones**

---

- In January 2007, an independent data safety monitoring board (DSMB) conducted a per protocol interim safety review and recommended that GTx continue clinical development as planned for its two Phase III ACAPODENE clinical trials. The DSMB meets regularly every six months to review unblinded safety data from the two Phase III clinical trials.
  - In February 2007, *Clinical Cancer Research* published results of a polyclonal ELISA urine test able to identify men with high grade PIN. The test was developed by MacroArray Technologies, Inc., one of five diagnostic companies with which GTx is collaborating on the development of a urine or blood test for high grade PIN.
  - Results of the two interim analyses from the Phase III ADT clinical trial will be presented February 23<sup>rd</sup> at the 2007 ASCO Prostate Cancer Symposium in Orlando, Florida.
  - GTx expects the last patient will complete the Phase III ADT clinical trial by the end of November. GTx will then evaluate the data and prepare topline results for public release.
  - GTx will continue to pursue an ACAPODENE partnership for Asia.
  - GTx is planning to initiate a Phase IIb ostarine clinical trial for the treatment of cancer cachexia by the summer of 2007.
  - GTx is planning to initiate a Phase IIb ostarine clinical trial for the treatment of chronic kidney disease and end stage renal disease muscle wasting by the end of the year.
  - Results of the ostarine Phase II proof of concept clinical trial will be presented at the 2007 annual meetings of the American Society of Andrology in April and of the Endocrine Society in June.
  - GTx will host an analyst meeting in New York City on April 17, 2007. The meeting will be available to the public via webcast.
-

**2007 Financial Guidance**

The Company anticipates a net loss for 2007 in the range of \$45 million to \$55 million. The financial projection for 2007 includes the continuation of the two Phase III ACAPODENE clinical trials as well as the two ostarine Phase IIb clinical trials which will be initiated this year.

**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 800-638-5439 from the United States or Canada or 617-614-3945 from outside North America. The access code for the call is 12875191. A playback of the call will be available from approximately 11:00 a.m., Eastern Time today through March 6, 2006 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 39602818. 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, headquartered in Memphis, Tenn., is a biopharmaceutical company dedicated to the discovery, development and commercialization of therapeutics for cancer and serious conditions related to men's health. GTx's lead drug discovery and development programs are focused on small molecules that selectively modulate the effects of estrogens and androgens. 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 also is developing ostarine, a first-in-class selective androgen receptor modulator, or SARM. GTx plans to initiate a Phase IIb ostarine clinical trial for cancer cachexia by the summer of 2007. GTx plans to initiate a Phase IIb ostarine clinical trial for the treatment of chronic kidney disease and end stage renal disease muscle wasting by the end of 2007. GTx believes that ostarine also has the potential to treat a variety of other indications associated with muscle wasting and bone loss including frailty and osteoporosis.

### 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. 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; (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; and (iv) 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 prospectus supplement filed with the U.S. Securities and Exchange Commission (the "SEC") pursuant to Rule 424(b)(5) on December 13, 2006, 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)

	<b>December 31,</b> <b>2006</b>	<b>December 31,</b> <b>2005</b>
	(unaudited)	(unaudited)
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 119,550	\$ 74,014
Accounts receivable	61	153
Inventory	207	135
Prepaid expenses and other current assets	1,882	1,702
Total current assets	121,700	76,004
Property and equipment, net	1,448	1,746
Purchased intangible assets:		
License fee, net	4,226	4,524
Other, net	488	454
Other assets	1,393	83
<b>Total assets</b>	<b>\$ 129,255</b>	<b>\$ 82,811</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,336	\$ 1,407
Accrued expenses	3,149	3,230
Deferred revenue — current portion	5,852	1,337
Total current liabilities	10,337	5,974
Deferred revenue, less current portion	21,554	2,958
Other long term liability	300	280
Capital lease obligation	15	20
Stockholders' equity:		
Common stock, \$0.001 par value: 60,000,000 shares authorized; 34,822,362 shares issued and outstanding at December 31, 2006 and 30,993,967 shares issued and outstanding at December 31, 2005	35	31
Deferred stock compensation	—	(1,725)
Additional paid-in capital	326,793	269,542
Accumulated deficit	(229,779)	(194,269)
Total stockholders' equity	97,049	73,579
<b>Total liabilities and stockholders' equity</b>	<b>\$ 129,255</b>	<b>\$ 82,811</b>

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

	Three Months Ended December 31,		Year Ended December 31,	
	2006	2005	2006	2005
<b>Revenues:</b>				
Product sales, net	\$ (155)	\$ 312	\$ 1,357	\$ 2,445
Collaboration revenue	4,755	334	6,148	1,337
Reimbursement of development costs	—	—	—	—
<b>Total revenues</b>	<b>4,600</b>	<b>646</b>	<b>7,505</b>	<b>3,782</b>
<b>Costs and expenses:</b>				
Cost of product sales	18	223	773	1,573
Research and development expenses	7,398	6,504	33,897	30,923
General and administrative expenses	2,843	2,412	11,352	9,845
<b>Total costs and expenses</b>	<b>10,259</b>	<b>9,139</b>	<b>46,022</b>	<b>42,341</b>
<b>Loss from operations</b>	<b>(5,659)</b>	<b>(8,493)</b>	<b>(38,517)</b>	<b>(38,559)</b>
Interest income	946	697	3,007	1,720
<b>Net loss</b>	<b>\$ (4,713)</b>	<b>\$ (7,796)</b>	<b>\$ (35,510)</b>	<b>\$ (36,839)</b>
<b>Net loss per share:</b>				
Basic	\$ (0.15)	\$ (0.26)	\$ (1.14)	\$ (1.42)
Diluted	\$ (0.15)	\$ (0.26)	\$ (1.14)	\$ (1.42)
<b>Weighted average shares used in computing net loss per share:</b>				
Basic	31,591,407	29,892,565	31,150,035	25,982,478
Diluted	31,591,407	29,892,565	31,150,035	25,982,478