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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: February 16, 2006**  
**(Date of earliest event reported)**

**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)

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(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 16, 2006, GTX, Inc. issued an earnings release for the fourth quarter and year ended December 31, 2005, 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>Number</u>	<u>Description</u>
99.1	Press Release issued by GTX, Inc. dated February 16, 2006

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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 16, 2006

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.  
Manager, Corporate Communications & Financial Analysis  
901-523-9700

GTX REPORTS FOURTH QUARTER AND YEAR END 2005 RESULTS

MEMPHIS, Tenn - February 16, 2006 -- GTX, Inc. (Nasdaq: GTXI), the Men's Health Biotech Company, today reported financial results for the fourth quarter and year ended December 31, 2005. The net loss for the respective periods was \$7.8 million and \$36.8 million compared with a net loss of \$6.9 million and \$22.3 million for the same periods in 2004. At December 31, 2005, GTX had cash and cash equivalents of \$74.0 million.

"In 2005, GTX met or exceeded each milestone for ACAPODENE that management established at the beginning of the year," said Mitchell Steiner, MD, chief executive officer of GTX. "2006 will be the defining year for SARMS. We should have proof of concept Phase II data for our first-in-class compound, ostarine, in late summer."

GTX has four clinical development programs: First, ACAPODENE(R), toremifene citrate 80 mg dose, is in a pivotal Phase III trial for the treatment of multiple serious side effects of androgen deprivation therapy (ADT) in men with advanced prostate cancer; second, ACAPODENE, toremifene citrate 20 mg dose, is in a pivotal Phase III trial for the prevention of prostate cancer in high risk men who have high grade prostatic intraepithelial neoplasia (PIN); third, ostarine, a first-in-class selective androgen receptor modulator (SARM), will be entering a Phase II clinical trial for the treatment of muscle wasting and bone loss; and fourth, andarine, another GTX SARM, is being developed with our partner Ortho Biotech Products LP (Ortho Biotech), a subsidiary of Johnson & Johnson, for the treatment of cancer cachexia.

## 2005 CORPORATE HIGHLIGHTS

### ACAPODENE for treatment of side effects of ADT:

- Completed enrollment of approximately 1,400 patients in the pivotal Phase III ADT trial.
- Completed an interim analysis of bone mineral density (BMD), a secondary endpoint of the ADT trial, that demonstrated efficacy with highly statistically significant positive changes among men treated with ACAPODENE compared to placebo.

### ACAPODENE for prevention of prostate cancer in men with high grade PIN:

- Presented the ACAPODENE Phase IIb clinical results for the prevention of prostate cancer in men with high grade PIN at the 2005 annual meetings of the American Society of Clinical Oncology (ASCO) and the American Urological Association. The study abstract was selected by peer review for inclusion in Best of ASCO.
- Received a Special Protocol Assessment (SPA) with the United States Food and Drug Administration (FDA) for the pivotal Phase III trial, providing regulatory clarity for this important indication.
- Started patient enrollment for the pivotal Phase III trial in the first quarter of 2005. Enrollment continues in approximately 150 centers in the United States, Canada, Mexico and Argentina.
- Formed a collaboration with a fourth diagnostic company, MacroArray Technologies, Inc., to develop a urine based diagnostic test for high grade PIN.

### Ostarine, our lead SARM:

- Advanced ostarine through two Phase I trials. Results of the Phase I multiple ascending dose trial in 72 subjects showed that ostarine is a selective anabolic agent.

### Andarine:

- Continued preclinical and clinical development of andarine, another GTX SARM, with our partner Ortho Biotech.

Corporate:

- Completed a follow-on public offering of common stock, resulting in net proceeds of approximately \$46 million.
- Appointed to GTX's Board of Directors Robert W. Karr, MD, former Senior Vice President of Strategic Management at Pfizer Global Research and Development and current President of Idera Pharmaceuticals, Inc.

FINANCIAL HIGHLIGHTS FOR THE YEAR AND QUARTER ENDED DECEMBER 31, 2005

Revenue for the quarter and year ended December 31, 2005, was \$0.6 million and \$3.8 million compared to \$0.3 million and \$1.9 million for the same periods in 2004. Revenues for 2005 included net sales of FARESTON(R) (toremifene citrate 60 mg), marketed for the treatment of metastatic breast cancer, and collaboration revenue from our partner, Ortho Biotech, for andarine.

Research and development expenses for the quarter and year ended December 31, 2005, were \$6.5 million and \$30.9 million, compared to \$5.3 million and \$18.0 million for the same periods in 2004. 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, 2005, were \$2.4 million and \$9.8 million, compared to the \$2.2 million and \$7.2 million for the same periods of 2004.



## ANNUAL PRODUCT PORTFOLIO UPDATE

### ACAPODENE for treatment of side effects of ADT:

GTx enrolled nearly 1,400 men in its pivotal Phase III ADT trial at approximately 150 sites in the United States and Mexico. A December 2005 interim analysis of BMD in the first 200 men to complete a full year of treatment resulted in highly statistically significant positive changes in BMD in the treatment arm compared to placebo: +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 will show efficacy in the trial's primary endpoint, a 40% reduction in vertebral fractures at two years. Secondary endpoints include improvements in BMD, hot flashes, gynecomastia, and lipid profiles. The trial is being conducted under a SPA with the FDA. GTx anticipates receiving data from this trial in the second half of 2007, and if the data demonstrates significant fracture benefit, filing a new drug application in 2008.

### ACAPODENE for prevention of prostate cancer in men with high grade PIN:

By the end of the current quarter, GTx anticipates attaining its total enrollment goal of 1,260 patients in the pivotal Phase III trial, which is being conducted under a SPA with the FDA. The primary endpoint of the trial is a reduction in prostate cancer incidence. By the first quarter of 2008, GTx anticipates conducting an interim efficacy analysis, with the timing of the analysis driven by the rate of prostate cancer detected. If successful, GTx will file a new drug application.

### Ostarine:

GTx plans to initiate in the second quarter a proof of concept Phase II trial of ostarine in approximately 120 elderly men and postmenopausal women. The study will evaluate the effects of ostarine on muscle and bone over three months. GTx expects to report data from the trial in late summer 2006. The data from this study is expected to give GTx confidence that ostarine will be a safe and effective treatment for a variety of indications.

including frailty, osteoporosis, muscle wasting in end stage renal disease patients, and treatment of severe burn wounds and associated wasting.

Although GTX has received FDA clearance to commence a Phase II trial of ostarine in burn patients, GTX has decided it can better evaluate ostarine in a larger patient population over the same time period required for the burn study and receive a broader array of relevant data.

Andarine:

GTX is developing a second SARM, andarine, for the treatment of cancer cachexia with its partner, Ortho Biotech. A Phase II trial is being planned.

2006 CORPORATE MILESTONES

- GTX anticipates in the current quarter attaining its enrollment goal of its pivotal Phase III high grade PIN trial.
- GTX intends to secure a partnership for ACAPODENE for treatment of side effects of ADT and ACAPODENE for prevention of prostate cancer in men with high grade PIN.
- Early results of a urine based high grade PIN diagnostic test developed by MacroArray Technologies in collaboration with GTX will be presented at the American Association of Cancer Research's 2006 annual meeting in April.
- The company expects to receive data from its proof of concept Phase II trial of ostarine by the end of the summer of 2006.

2006 FINANCIAL GUIDANCE

By the end of the year, the Company anticipates having two fully enrolled pivotal Phase III clinical trials of ACAPODENE, a completed proof of concept Phase II clinical trial for ostarine, and participating with our partner Ortho Biotech in a Phase II trial for andarine. As a result of these programs, the Company anticipates a net loss for 2006 of \$37 million to \$47 million.

## 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 866-277-1184 from the United States or Canada or 617-597-5360 from outside North America. The access code for the call is 54502054. A playback of the call will be available from approximately 11:00 a.m., Eastern Time today through March 2, 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 64277344. 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>.

GTX, INC.  
CONDENSED STATEMENTS OF OPERATIONS  
(IN THOUSANDS, EXCEPT SHARE AND PER SHARE DATA)  
(UNAUDITED)

	THREE MONTHS ENDED DECEMBER 31,		YEAR ENDED DECEMBER 31,	
	2005	2004	2005	2004
Revenues:				
Product sales, net	\$ 312	\$ --	\$ 2,445	\$ --
Collaboration revenue	334	334	1,337	1,055
Reimbursement of development costs	--	10	--	812
Total revenues	646	344	3,782	1,867
Costs and expenses:				
Cost of product sales	223	--	1,573	--
Research and development expenses	6,504	5,344	30,923	17,950
General and administrative expenses	2,412	2,197	9,845	7,211
Total costs and expenses	9,139	7,541	42,341	25,161
Loss from operations	(8,493)	(7,197)	(38,559)	(23,294)
Interest income	697	314	1,720	946
Net loss	(7,796)	(6,883)	(36,839)	(22,348)
Accrued preferred stock dividends	--	--	--	(455)
Adjustments to preferred stock redemption value	--	--	--	17,125
Net loss attributable to common stockholders	\$ (7,796)	\$ (6,883)	\$ (36,839)	\$ (5,678)
Net loss per share attributable to common stockholders:				
Basic	\$ (0.26)	\$ (0.28)	\$ (1.42)	\$ (0.25)
Diluted	\$ (0.26)	\$ (0.28)	\$ (1.42)	\$ (0.93)
Weighted average shares used in computing net loss per share attributable to common stockholders:				
Basic	29,892,565	24,659,564	25,982,478	22,993,221
Diluted	29,892,565	24,659,564	25,982,478	24,062,271

GTX, INC.  
CONDENSED BALANCE SHEETS  
(IN THOUSANDS)

	DECEMBER 31, 2005	DECEMBER 31, 2004
	----- (unaudited)	----- (1)
<b>ASSETS</b>		
Cash and cash equivalents	\$74,014	\$64,528
Other current assets	1,990	1,624
	-----	-----
Total current assets	76,004	66,152
Property and equipment, net	1,746	1,537
Purchased intangible assets, net	4,978	4,943
Other assets	83	450
	-----	-----
Total assets	\$82,811	\$73,082
	=====	=====
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Accounts payable and accrued expenses	\$ 4,637	\$ 3,517
Deferred revenue, current	1,337	1,337
	-----	-----
Total current liabilities	5,974	4,854
Deferred revenue	2,958	4,295
Other long term liability	280	--
Capital lease obligation	20	24
Total stockholders' equity	73,579	63,909
	-----	-----
Total liabilities and stockholders' equity	\$82,811	\$73,082
	=====	=====

(1) Derived from the audited financial statements included in the Company's annual report on form 10-K for the year ended December 31, 2004.

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## ABOUT GTX

GTX 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, two essential classes of hormones. GTX, headquartered in Memphis, Tenn., currently has four clinical programs. GTX is developing ACAPODENE (toremifene citrate), a selective estrogen receptor modulator, or SERM, in two separate clinical programs in men: (1) a pivotal Phase III clinical trial for the treatment of serious side effects of androgen deprivation therapy for advanced prostate cancer and (2) a pivotal Phase III clinical trial for the prevention of prostate cancer in high risk men with high grade PIN. In its third clinical program, GTX is evaluating ostarine for a variety of indications including frailty, osteoporosis, muscle wasting in end stage renal disease patients, and treatment of severe burn wounds and associated wasting. In its fourth clinical program, GTX and its partner, Ortho Biotech Products, L.P., a subsidiary of Johnson & Johnson, are developing andarine, another of GTX's SARMS, for the treatment of cancer cachexia. GTX is working with Ortho Biotech to plan a Phase II clinical trial of andarine.

### 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 October 12, 2005, 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.