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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: **February 16, 2005**
(Date of earliest event reported)

GTx, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**005-79588**	**62-1715807**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

3 N. Dunlap Street
3rd Floor, 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)

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ITEM 2.02 Results of Operations and Financial Condition.

On February 16, 2005, GTx, Inc. issued an earnings release for the fourth quarter and year ended December 31, 2004, 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

Number	Description
99.1	Press Release issued by GTx, Inc. dated February 16, 2005

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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, 2005

By: /s/ Mark E. Mosteller
Name: Mark E. Mosteller
Title: Chief Financial Officer (principal accounting and financial officer)

Exhibit 99.1

Contact:
Carney Duntsch
GTx, Inc.
Investor and Media Relations
901-523-9700

Jonathan M. Nugent
Kathy Nugent, Ph.D
Burns McClellan, Inc.
212-213-0006

GTX, INC. REPORTS FOURTH QUARTER AND YEAR END 2004 FINANCIAL RESULTS

MEMPHIS, Tenn - February 16, 2005--GTx, Inc. (Nasdaq: GTXI), a biopharmaceutical company dedicated to the discovery, development and commercialization of therapeutics for serious men's health conditions and oncology, today reported financial results for the fourth quarter and year ended December 31, 2004. The net loss for the fourth quarter and year ended December 31, 2004 was $6.9 million and $22.3 million, respectively, compared with a net loss of $4.5 million and $14.2 million for the same periods in 2003. At December 31, 2004, GTx had cash and cash equivalents of $64.5 million.

"During 2004, we exceeded our milestones and had an excellent year. We had positive data from our Phase IIb clinical trial of ACAPODENE(R) for the prevention of prostate cancer in high risk men and progressed our second SARM to a Phase I clinical trial," said Mitchell Steiner, M.D., CEO of GTx. "We believe our four promising clinical programs, along with the company's broad discovery pipeline, create attractive long term commercial opportunities for GTx."

Revenue for the quarter and year ended December 31, 2004 was $0.3 million and $1.9 million, respectively, and resulted from the Company's collaboration and license agreement with Ortho Biotech Products L. P., a subsidiary of Johnson & Johnson, for GTx's lead selective androgen receptor modulator (SARM) compound, andarine.

Research and development expenses for the quarter and year ended December 31, 2004 were $5.3 million and $18.0 million, respectively, compared to $3.4 million and $10.8 million during the same periods of 2003. The increase in research and development expenditures for both periods was primarily the result of GTx's growing investment in its lead clinical program for ACAPODENE(R) (toremifene citrate) in an ongoing pivotal Phase III clinical trial for the treatment of serious side effects of androgen deprivation therapy for advanced prostate cancer and in its fourth clinical program, ostarine, which is being developed for andropause and other chronic conditions related to aging.

General and administrative expenses for the quarter and year ended December 31, 2004 were $2.2 million and $7.2 million, respectively, compared to the $1.2 million and $3.6 million for the same periods in 2003. The increase in both periods primarily resulted from the addition of key personnel, increased insurance costs, and higher professional fees to support GTx's growth and reporting obligations as a public company.

2004 CORPORATE HIGHLIGHTS

- Completed a successful initial public offering.
- Partnered GTx's first SARM, andarine, with Ortho Biotech Products, LP, a subsidiary of Johnson & Johnson.
- Formed collaborations with three diagnostic companies, Hybritech, diaDexus and Tessera, to develop a diagnostic prostatic intraepithelial neoplasia (PIN) test.
- Reported positive data from the Phase IIb clinical trial of ACAPODENE(R) for prevention of prostate cancer in high risk men.
- Filed a Special Protocol Assessment with the FDA for its pivotal Phase III clinical trial of ACAPODENE(R) for prevention of prostate cancer in high risk men.
- Purchased from Orion Corporation all remaining rights to toremifene (the active ingredient in ACAPODENE(R)) in the U.S., including FARESTON(R) (toremifene citrate 60mg) for metastatic breast cancer, and additional rights in all other countries.
- Progressed GTx's second SARM compound, ostarine, to a Phase I clinical trial.
- Added to the Russell 3000 Index and NASDAQ Biotechnology Index.

2005 MILESTONES

- Initiated a pivotal Phase III clinical trial of ACAPODENE(R) for the prevention of prostate cancer in high risk men.
- Complete Phase I clinical trials and initiate a Phase II clinical trial of ostarine.
- Report interim analysis of bone mineral density from the ongoing Phase III clinical trial of ACAPODENE(R) for the treatment of side effects of androgen deprivation therapy for advanced prostate cancer.
- Initiate a Phase II clinical trial of andarine with partner Ortho Biotech Products, LP, a subsidiary of Johnson & Johnson.

2005 FINANCIAL GUIDANCE

The Company anticipates that by the end of 2005, it will have two ongoing pivotal Phase III clinical trials and two ongoing Phase II clinical trials for a total of four clinical programs. As a result of these programs, the Company anticipates a net loss for 2005 of approximately $35 million to $45 million.

CONFERENCE CALL

There will be a conference call today at 10am 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 800-291-9234 from the United States or Canada or 617-614-3923 from outside North America. The access code for the call is 71909405. A playback of the call will be

available from approximately 12:00 p.m., Eastern Time today through March 2, 2005 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 74169468. 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 is a biopharmaceutical company dedicated to the discovery, development and commercialization of therapeutics primarily related to the treatment of serious men's health conditions and oncology. GTx's 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 has a marketed product and four clinical programs. The marketed product is FARESTON(R) (toremifene citrate 60mg) tablets for the treatment of metastatic breast cancer. In two of its clinical programs, the company is developing the same active compound, toremifene citrate, as ACAPODENE(R) for two separate indications in men: (1) a pivotal Phase III clinical trial for the prevention of prostate cancer in high risk men and (2) a pivotal Phase III clinical trial for the treatment of serious side effects of androgen deprivation therapy for advanced prostate cancer. In its third clinical program, GTx and its partner, Ortho Biotech Products, L.P., a subsidiary of Johnson & Johnson, are developing andarine, a SARM, which is expected to enter a Phase II clinical trial in 2005. In its fourth clinical program, GTx is developing its second SARM, ostarine, for andropause and other chronic conditions related to aging, including sarcopenia. In addition, GTx has an extensive preclinical pipeline generated from its own discovery program which includes the specific product candidates, prostarine, a SARM for benign prostatic hyperplasia (BPH), and andromustine, an anticancer drug, for hormone refractory prostate cancer.

FORWARD-LOOKING INFORMATION IS SUBJECT TO RISK AND UNCERTAINTY

This press release contains forward-looking statements, including, without limitation, statements related to GTx's current and anticipated clinical trials and its other research and development programs and the matters discussed in the "Anticipated 2005 Milestones" and "2005 Financial Guidance" sections. These forward-looking statements are 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, risks that GTx will need substantial additional funding and may be unable to raise capital when needed; GTx will not be able to achieve its milestones within the time period indicated or at all; neither GTx nor its partner will be able to commercialize its product candidates if preclinical studies do not produce successful results or clinical trials do not demonstrate safety and efficacy in humans; if third parties do not manufacture the Company's product candidates in sufficient quantities and at an acceptable cost, clinical development and commercialization of its product candidates would be delayed; use of third-party manufacturers may increase the risk that the Company will not have adequate supplies of its product candidates; if third parties on whom the Company relies do not perform as contractually required or expected, the Company may not be able to obtain regulatory approval for or commercialize its product candidates; the Company is dependent upon collaborative arrangements to complete the development and commercialization of some of its product candidates, and these collaborative arrangements may place the development of its product candidates outside its control, may require it to relinquish important rights or may otherwise be on terms unfavorable to the Company; and if the Company is not able to obtain required regulatory approvals, the Company will not be able to

commercialize its product candidates. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this press release. The annual report filed on Form 10-K with the U.S. Securities and Exchange Commission (the "SEC") on March 26, 2004 contains under the heading "Additional Factors That Might Affect Future Results," 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 STATEMENTS OF OPERATIONS
(IN THOUSANDS, EXCEPT SHARE AND PER SHARE DATA)
(UNAUDITED)

	THREE MONTHS ENDED DECEMBER 31,		FOR THE YEAR ENDED DECEMBER 31,	
	2004	2003	2004	2003
Collaboration revenue:				
License fees	$ 334	$ --	$ 1,055	$ --
Reimbursement of development costs	10	--	812	--
Total collaboration revenue	344	--	1,867	--
Operating expenses:				
Research and development	5,344	3,427	17,950	10,778
General and administrative	2,197	1,184	7,211	3,559
Total operating expenses	7,541	4,611	25,161	14,337
Loss from operations	(7,197)	(4,611)	(23,294)	(14,337)
Interest income	314	64	946	143
Net loss	(6,883)	(4,547)	(22,348)	(14,194)
Accrued preferred stock dividends	--	(1,136)	(455)	(3,436)
Adjustments to preferred stock redemption value	--	(1,178)	17,125	(77,844)
Net loss attributable to common stockholders	$ (6,883)	$ (6,861)	$ (5,678)	$ (95,474)
Net loss per share attributable to common stockholders:				
Basic	$ (0.28)	$ (0.89)	$ (0.25)	$ (12.34)
Diluted	$ (0.28)	$ (0.89)	$ (0.93)	$ (12.34)
Weighted average shares used in computing net loss per share attributable to common stockholders:				
Basic	24,659,564	7,735,125	22,993,221	7,735,125
Diluted	24,659,564	7,735,125	24,062,271	7,735,125

GTX, INC.

CONDENSED BALANCE SHEETS
(IN THOUSANDS)

	DECEMBER 31, 2004	DECEMBER 31, 2003
	(unaudited)	(1)
ASSETS		
Cash and cash equivalents	$ 64,528	$ 14,769
Other current assets	1,624	255
Total current assets	66,152	15,024
Property and equipment, net	1,537	793
Purchased intangible assets, net	4,943	22
Other assets	450	--
Deferred initial public offering costs	--	1,471
Total assets	$ 73,082	$ 17,310
LIABILITIES, CUMULATIVE REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
Accounts payable and accrued expenses	$ 3,517	$ 2,249
Deferred revenue, current	1,337	--
Total current liabilities	4,854	2,249
Deferred revenue	4,295	--
Capital lease obligation	24	--
Cumulative redeemable convertible preferred stock	--	165,292
Total stockholders' equity (deficit)	63,909	(150,231)
Total liabilities and stockholders' equity (deficit)	$ 73,082	$ 17,310

(1) Derived from the audited financial statements included in the Company's annual report on form 10-K for the year ended December 31, 2003.

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