

**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: **April 19, 2004**
(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)

005-79588
(Commission
File Number)

62-1715807
(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)

ITEM 7. Financial Statements and Exhibits.

(c) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated April 19, 2004.

ITEM 12. Results of Operations and Financial Condition

On April 19, 2004, GTx issued an earnings release for the first quarter ending March 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 12 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.

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: April 20, 2004

By: /s/ Mark E. Mosteller

Name: Mark E. Mosteller

Title: Chief Financial Officer
(principal accounting and
financial officer)

Contact:
 Carney Duntsch
 GTx, Inc.
 Manager, Communications
 901-523-9700 170

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 Kathy L. Jones, Ph.D
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GTX, INC. REPORTS FIRST QUARTER 2004 FINANCIAL RESULTS

MEMPHIS, Tenn - April 19, 2004--GTx, Inc. (Nasdaq: GTXI), a biopharmaceutical company dedicated to the development and commercialization of therapeutic products for men's health, today reported financial results for the first quarter ended March 31, 2004. The total net loss for the quarter was \$5.8 million, compared with a net loss of \$2.8 million for the same period in 2003.

Research and development expenses increased 105% to \$4.3 million for the first quarter of 2004 from \$2.1 million for the first quarter of 2003. This increase was mainly attributable to planned expenditures related to the pivotal Phase III clinical trial of ACAPODENE(TM) (Toremifene Citrate) tablets for the treatment of side effects of androgen deprivation therapy, expenses related to the Phase IIb clinical trial of ACAPODENE(TM) for reduction of prostate cancer in men with PIN, continued clinical development of andarine, and continued preclinical development of other product candidates in the company's Selective Androgen Receptor Modulator (SARM) program. General and administrative expenses increased 162% during the quarter to \$1.6 million from \$610,000 for the first quarter of 2003, primarily as a result of increases in personnel and insurance costs, as well as increased professional fees resulting from reporting obligations applicable to public companies.

On February 6, 2004, GTx completed an initial public offering (IPO) of 5.4 million shares of common stock at a price of \$14.50 per share resulting in net proceeds of approximately \$70 million. Concurrent with the IPO, all outstanding shares of preferred stock and accrued dividends were converted into 11,521,075 shares of common stock. At March 31, 2004, GTx had outstanding 24,656,923 shares of common stock.

During the first quarter of 2004, GTx recognized \$52,000 of revenue from amortization of the upfront license fee received from its collaboration and license agreement with Ortho Biotech Products L. P., a subsidiary of Johnson & Johnson. At March 31, 2004, GTx had cash and cash equivalents of approximately \$80.6 million.

Corporate Highlights

On March 17, 2004, GTx announced that it had entered into a joint collaboration and license agreement with Ortho Biotech Products L.P., a subsidiary of Johnson & Johnson, for andarine, GTx's most advanced SARM compound, and specified backup SARM compounds. Under the terms of the agreement, GTx received an upfront licensing fee and will receive reimbursement of expenses in the aggregate of approximately \$6.7 million. Additionally, GTx will receive licensing fees and milestone payments up to \$82 million for andarine and up to \$45 million for each additional specified backup compound achieving specific clinical development decisions or obtaining regulatory approvals. Johnson & Johnson Pharmaceutical Research and Development will be responsible for further clinical development and expenses for collaboration compounds, and Ortho Biotech will be responsible for all commercialization activities and expenses. We anticipate initiating the Phase II for andarine in 2004.

Pending FDA approval of andarine, Ortho Biotech will be exclusively responsible for worldwide marketing. Under the agreement, GTx has the option to co-promote andarine and other specified backup compounds to urologists in the U.S. for uses related to men's health. GTx will receive up to double digit royalties on all sales, as well as additional royalty payments in excess of 20% on all co-promoted sales to urologists in the U.S.

"This agreement combines GTx's expertise in SARMS and men's health with the world class research and marketing capabilities of Ortho Biotech. We believe that andarine could become the first product in this new class of drugs," said Mitchell Steiner, M.D., F.A.C.S., Vice-Chairman and CEO of GTx.

GTx continues to make progress in other clinical programs including its most advanced Selective Estrogen Receptor Modulator (SERM) compound, ACAPODENE(TM). ACAPODENE(TM) is being studied in two indications: (i) the reduction of incidence of prostate cancer in men with high grade PIN (Prostatic Intraepithelial Neoplasia) and (ii) the treatment of side effects of androgen deprivation therapy for those with advanced prostate cancer.

Conference Call

There will be a conference call today at 10:30 a.m. Eastern Time to discuss GTx's first quarter financial results and to provide a company update. If you would like to participate in the call, please dial 800-915-4836 from the United States or Canada or 973-317-5319 from outside North America. A playback of the call will be available today from approximately 12:00 p.m. Eastern Time through April 26, 2004 and may be accessed by dialing 800-428-6051 from the United States or Canada or 973-709-2089 from outside North America. The rebroadcast code is 349402.

About GTx, Inc.

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. GTx's drug discovery and development programs are focused on small molecules that selectively modulate the effects of estrogens and androgens. GTx currently has two product candidates that are in human clinical trials. GTx is currently conducting clinical trials on ACAPODENE(TM), its most advanced product candidate, for two separate indications: (i) a Phase IIb clinical trial to assess the effect of toremifene in the reduction in the incidence of prostate cancer in men with precancerous prostate lesions and (ii) a pivotal Phase III clinical trial to assess the effect of toremifene in the treatment of serious side effects of advanced prostate cancer therapy. GTx is developing its second product candidate, andarine, and other specified backup compounds, with Ortho Biotech. GTx retains all rights to the discovery, development, and commercialization of the rest of its SARM program including its other specific product candidates ostarine, prostarine and andromustine.

Forward-Looking Statements:

This press release contains forward-looking statements, including without limitation statements related to our current and anticipated clinical trials and the matters discussed in the "Corporate Highlights" section. 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; neither GTx nor its partner will be able to commercialize GTx's product candidates if its preclinical studies do not produce successful results or its clinical trials do not demonstrate safety and efficacy in humans; if third parties do not manufacture GTx'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 GTx will not have adequate supplies of its product candidates; if third parties on whom GTx relies do not perform as contractually required or expected, GTx may not be able to obtain regulatory approval for or commercialize its product candidates; GTx is currently and expects to continue to be 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 GTx; and if GTx is not able to obtain required regulatory approvals, GTx will not be able to commercialize its product candidates. The annual report filed on Form 10-K with the U.S. Securities and Exchange Commission 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 PER SHARE AMOUNTS)
(UNAUDITED)

	THREE MONTHS ENDED MARCH 31,	
	2004	2003
Revenue	\$ 52	\$ --
Operating expenses:		
Research and development	4,336	2,113
General and administrative	1,600	610
Depreciation	87	87
Total operating expenses	6,023	2,810
Loss from operations	(5,971)	(2,810)
Interest income	150	29
Net loss	(5,821)	(2,781)
Accrued preferred stock dividends	(455)	(683)
Adjustments to preferred stock redemption value	17,125(1)	(73)
Net income (loss) attributable to common stockholders	\$ 10,849	\$ (3,537)
Net income (loss) per share attributable to common stockholders:		
Basic	\$ 0.60	\$ (0.46)
Diluted	\$ (0.26)(2)	\$ (0.46)
Weighted average shares used in computing net loss per share attributable to common stockholders:		
Basic	17,962,871(3)	7,734,998
Diluted	22,520,659(2)	7,734,998

(1) The adjustments to preferred stock redemption value, for the three months ended March 31, 2004, represents the adjustment of the preferred stock carrying value to reflect the redemption value (fair value) on the date that all preferred stock and accrued dividends thereon were converted to common stock effective upon the closing of the Company's initial public offering on February 6, 2004.

(2) Diluted net loss per share for the quarter ended March 31, 2004 is calculated as if the conversion of all preferred stock, and accrued dividends thereon, into shares of common stock occurred on January 1, 2004. As a result, diluted net loss per share attributable to common stockholders for the quarter ended March 31, 2004 does not include accrued preferred stock dividends or the adjustments to preferred stock redemption value discussed in Footnote 1. In addition, the weighted average shares used in computing diluted net loss per share for the quarter included an additional 11,456,905 shares to reflect the assumed conversion of preferred stock, and accrued dividends thereon, into common stock and 3,263,736 shares to reflect the weighted average effect during the quarter of 5.4 million shares issued in the IPO.

(3) The weighted average shares used in computing basic net income per share for the quarter ended March 31, 2004 include 3,263,736 shares, which represent the weighted average effect during the quarter of the issuance of 5.4 million shares of common stock in the IPO, and 6,963,287 shares, which represent the weighted average effect during the quarter of the issuance of 11,521,075 shares for the conversion of all preferred stock, and accrued dividends thereon, into common stock at the closing of the IPO. At March 31, 2004, the Company had outstanding

24,656,923 shares of common stock.

GTX, INC.

CONDENSED BALANCE SHEETS
(IN THOUSANDS)

	MARCH 31, 2004 ----- (UNAUDITED)	DECEMBER 31, 2003 -----
ASSETS		
Cash and cash equivalents	\$ 80,620	\$ 14,769
Other current assets	7,903	255
	-----	-----
Total current assets	88,523	15,024
Property and equipment, net	799	815
Deferred initial public offering costs	--	1,471
	-----	-----
Total assets	\$ 89,322 =====	\$ 17,310 =====
LIABILITIES, CUMULATIVE CONVERTIBLE REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities	\$ 4,169	\$ 2,249
Deferred revenue	5,298	--
Cumulative convertible redeemable preferred stock	--(1)	165,292
Total stockholders' equity (deficit)	79,855(1)	(150,231)
	-----	-----
Total liabilities and stockholders' equity (deficit)	\$ 89,322 =====	\$ 17,310 =====

- (1) March 31, 2004 balances reflect the conversion of all outstanding shares of preferred stock, and accrued dividends thereon, into common stock and the proceeds on the Company's initial public offering which closed February 6, 2004.

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