Table of Contents

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) **April 28, 2005**

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)

TABLE OF CONTENTS

Table of Contents

ITEM 2.02 Results of Operations and Financial Condition.

On April 28, 2005, GTx, Inc. issued an earnings release for the first quarter ended March 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

Exhibit Number	Description
99.1	Press Release issued by GTx, Inc. dated April 28,2005

Table of Contents

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 28, 2005

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

Exhibit 99.1

Contact:
Marc S. Hanover
GTx, Inc.
President and Chief Operating Officer
901-523-9700

GTX, INC. REPORTS FIRST QUARTER 2005 FINANCIAL RESULTS

MEMPHIS, TENN. - April 28, 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 first quarter of 2005. The net loss for the first quarter ended March 31, 2005 was $9.1 million compared with a net loss of $5.8 million for the same period in 2004. At March 31, 2005, GTx had cash and cash equivalents of $55.6 million.

"We continue to meet our Company's stated goals, and we are particularly pleased to have the opportunity to showcase our latest clinical results for our lead drug, ACAPODENE(R) (toremifene citrate), at the upcoming annual meeting of the American Society of Clinical Oncology," said Mitchell Steiner, M.D., CEO of GTx. "Our team, along with our physician investigators, has done an excellent job advancing our four clinical programs and consistently achieving our medical and commercial objectives."

Revenues for the quarter ended March 31, 2005 were $687,000 as compared to $52,000 for the first quarter of 2004. The first quarter revenues for 2005 were comprised of net sales of FARESTON(R) (toremifene citrate 60 mg), marketed for the treatment of metastatic breast cancer, and collaboration income from our partner, Ortho Biotech, L.P., a subsidiary of Johnson & Johnson, for andarine, one of our proprietary selective androgen receptor modulator (SARM) compounds. FARESTON net sales were $353,000 and cost of goods sold was $245,000 while the collaboration income from Ortho Biotech, L.P. was $334,000.

Research and development expenses for the first quarter of 2005 were $7.3 million, compared to $4.4 million for the same period of 2004. The $2.9 million increase in research and development expenses was primarily the result of the Company's continued investment in the following clinical programs:

- ACAPODENE (toremifene citrate 20 mg) in a pivotal Phase III clinical trial for the prevention of prostate cancer in high risk men.

- ACAPODENE (toremifene citrate 80 mg) in a pivotal Phase III clinical trial for the treatment of serious side effects of androgen deprivation.

- Ostarine in a recently completed Phase I single ascending dose clinical trial in 96 volunteers, which is being developed for andropause and other chronic conditions related to aging. GTx retains the exclusive rights to ostarine, which is the second SARM that GTx has developed from discovery into clinical trials.

General and administrative expenses for the quarter ended March 31, 2005 were $2.5 million, compared to $1.6 million for the same period in 2004. The difference primarily resulted from increased personnel costs to support the Company's growth, higher insurance costs and increased patent costs and professional fees.

FIRST QUARTER 2005 CORPORATE HIGHLIGHTS

- Initiated a pivotal Phase III clinical trial of ACAPODENE for the prevention of prostate cancer in high risk men.

- Completed a Phase I single ascending dose clinical trial for ostarine, GTx's second SARM compound to enter clinical trials.

CONFERENCE CALL

There will be a conference call today at 10 a.m. Eastern Time today to discuss GTx's first quarter financial results and to provide a company update. To listen to the conference call, please dial:

- 800-638-5495 from the United States and Canada or

- 617-614-3946 (International)
  The access code for the call is 66040231.

A playback of the call will be available from approximately 12:00 p.m., Eastern Time, on April 28 through May 5, 2005 and may be accessed by dialing:

- 888-286-8010 from the United States and Canada or

- 617-801-6888 (International),
  referencing reservation number 76732232.

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 (toremifene citrate 60mg) tablets for the treatment of metastatic breast cancer. The company is developing the same active compound, toremifene citrate, as ACAPODENE in two of its clinical programs for 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 they are working to progress to a Phase II clinical trial in the second half of 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. 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 24, 2005 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 MARCH 31,	
	2005	2004
Revenues:		
Product sales, net	$ 353	$ --
Collaboration revenue	334	52
Total revenues	687	52
Costs and expenses:		
Cost of goods sold	245	--
Research and development expenses	7,326	4,411
General and administrative expenses	2,520	1,612
Total costs and expenses	10,091	6,023
Loss from operations	(9,404)	(5,971)
Interest income	324	150
Net loss	(9,080)	(5,821)
Accrued preferred stock dividends	--	(455)
Adjustments to preferred stock redemption value	--	17,125
Net (loss) income attributable to common stockholders	$ (9,080)	$ 10,849
Net (loss) income per share attributable to common stockholders:		
Basic	$ (0.37)	$ 0.60
Diluted	$ (0.37)	$ (0.26)
Weighted average shares used in computing net (loss) income per share attributable to common stockholders:		
Basic	24,664,716	17,962,871
Diluted	24,664,716	22,456,489

GTX, INC.

CONDENSED BALANCE SHEETS
(IN THOUSANDS)

	MARCH 31, 2005 (UNAUDITED)	DECEMBER 31, 2004
ASSETS		
Cash and cash equivalents	$55,578	$64,528
Other current assets	2,908	1,624
Total current assets	58,486	66,152
Property and equipment, net	1,612	1,537
Purchased intangible assets, net	4,901	4,943
Other assets	672	450
Total assets	$65,671	$73,082
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable and accrued expenses	$ 5,249	$ 3,517
Deferred revenue	1,337	1,337
Total current liabilities	6,586	4,854
Deferred revenue	3,961	4,295
Capital lease obligation	23	24
Total stockholders' equity	55,101	63,909
Total liabilities and stockholders' equity	$65,671	$73,082

# # #