

**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: **July 29, 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)

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ITEM 7. Financial Statements and Exhibits.

(c) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated July 29, 2004.

ITEM 12. Results of Operations and Financial Condition

On July 29, 2004, GTx issued an earnings release for the second quarter ending June 30, 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: July 29, 2004

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

Contact:
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 GTX, Inc.
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GTX, INC. REPORTS SECOND QUARTER 2004 FINANCIAL RESULTS

MEMPHIS, Tenn - July 29, 2004--GTX, Inc. (Nasdaq: GTXI), a biopharmaceutical company dedicated to the discovery, development and commercialization of therapeutics for serious men's health conditions, today reported financial results for the second quarter and six months ended June 30, 2004. The net loss for the quarter and six-month period was \$4.5 million and \$10.3 million, respectively, compared with a net loss of \$3.5 million and \$6.2 million for the same periods in 2003.

"We are very pleased to report another positive quarter at GTX with significant progress of our lead clinical program, ACAPODENE," said Mitchell Steiner, M.D., CEO of GTX. "We are focused on continuing the momentum in our clinical trials for both ACAPODENE for prevention of prostate cancer and ACAPODENE for supportive care of patients being treated for advanced prostate cancer. In addition, our SARM program continues to progress successfully."

Revenue for both the second quarter and six months ended June 30, 2004 was \$1.1 million, and resulted from the reimbursement of development costs and the amortization of upfront fees. The revenue was associated with the Company's collaboration and license agreement with Ortho Biotech Products L.P., a subsidiary of Johnson & Johnson, for GTX's lead SARM compound, andarine.

Research and development expenses increased to \$4.1 million for the second quarter of 2004 from \$2.6 million for the second quarter of 2003 and increased to \$8.5 million from \$4.7 million for the first six months of 2004 as compared to the same period in 2003. These increases reflect GTX's growing investment in its lead clinical program for ACAPODENE(TM) (toremifene citrate) which includes an ongoing pivotal Phase III clinical trial for the treatment of side effects of androgen deprivation therapy (ADT) and a recently completed Phase IIB clinical trial for the prevention of prostate cancer in high risk men with high grade prostatic intraepithelial neoplasia (PIN). Increases in research and development expenses also reflect continuing development of GTX's second clinical program, andarine, and preclinical development of its other selective androgen receptor modulator (SARM) compounds, including ostarine and andromustine.

General and administrative expenses increased during the quarter to \$1.6 million from \$0.8 million for the second quarter of 2003 and increased to \$3.2 million for the first six months of 2004 from \$1.4 million for the same period in 2003. The increase primarily resulted from the addition of key personnel, increased insurance costs and professional fees to support GTX's growth and its reporting obligations as a public company.

At June 30, 2004, GTX had 24,656,923 shares of common stock outstanding, and cash and cash equivalents of approximately \$81.4 million.

Corporate Highlights

- o On June 4, 2004, GTx announced positive Phase IIB clinical trial results for its lead program ACAPODENE(TM). This is the largest prospective study to determine the natural history of patients with high grade PIN and the findings suggest that ACAPODENE(TM) may be an effective agent in preventing prostate cancer. Specifically, the trial demonstrated that ACAPODENE(TM) 20mg can produce a clinically significant reduction of prostate cancer cumulative risk over one year. Patients treated with ACAPODENE(TM) 20mg had a lower incidence of prostate cancer compared to placebo, 24.4% vs. 31.2% respectively. The study also revealed that patients who were treated with ACAPODENE(TM) for the entire 12 months had a 48% reduction in prostate cancer incidence. Following discussions with the Food and Drug Administration (FDA), GTx plans to initiate a pivotal Phase III clinical trial to confirm these positive findings.
- o GTx entered into collaboration agreements with diagnostic labs Hybritech, Inc., a wholly owned subsidiary of Beckman Coulter, Inc. and diaDexus, Inc. GTx will provide clinical samples to these diagnostic labs from its now completed Phase IIB ACAPODENE(TM) trial. These collaborations are intended to develop a commercial blood or urine test which could detect high grade PIN in the millions of men who unknowingly harbor this precancerous lesion of the prostate or who may develop prostate cancer.
- o At the 40th Annual Meeting of the American Society of Clinical Oncology (ASCO), results were presented describing data from GTx's Phase II clinical trial for the treatment of side effects associated with ADT and data from a preclinical study designed to demonstrate ACAPODENE's(TM) ability to prevent bone loss as a result of ADT in rats. In addition, presentations on GTx's SARM program were made at the Endocrine Society Meeting and the National Chemistry Symposium.
- o GTx announced the Urology Resident Research Fellowship program, in partnership with the Department of Urology at the University of Tennessee College of Medicine. This program will allow urology residents from the University of Tennessee to spend a research rotation at the GTx research laboratories. This program underscores GTx's commitment to the continued development of drugs to treat serious men's health conditions. By exposing these residents to our scientists and clinicians, we are helping to develop well-rounded urologists who will not only contribute to cutting-edge research during their time in the GTx labs, but will also be better able to treat their patients as they enter their own practices.

Conference Call

There will be a conference call today at 10:00 a.m. Eastern Time to discuss GTx's second quarter financial results and to provide a company update. If you would like to participate in the call, please dial 877-847-5346 from the United States or Canada or 719-867-0720 from outside North America. A playback of the call will be available on July 29, 2004 from approximately 1:00 p.m. Eastern Time through August 5, 2004 and may be accessed by dialing 888-203-1112 from the United States or Canada or 719-457-0820 from outside North America, and referencing reservation number 280922. To access the archived recording, visit the GTx website at 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. GTX's drug discovery and development programs are focused on small molecules that selectively modulate the effects of estrogens and androgens. GTX has two clinical programs: In the first clinical program, GTX is developing ACAPODENE(TM), its most advanced product candidate for two separate indications: (1) a pivotal Phase III clinical trial for the treatment of serious side effects of advanced prostate cancer therapy and (2) its completed Phase IIb clinical trial for the reduction in the incidence of prostate cancer in high risk men with precancerous prostate lesions. In the second clinical program, GTX is developing andarine, and other specified backup compounds, with its partner, Ortho Biotech Products, L.P., a subsidiary of Johnson & Johnson. Andarine will be entering a planned Phase II clinical trial this year. 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 GTX's current and anticipated clinical trials of ACAPODENE(TM) 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 neither GTX nor its collaboration partners will not 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 the press release. 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 JUNE 30,		SIX MONTHS ENDED JUNE 30,	
	2004	2003	2004	2003
Collaboration revenue:				
License fees	\$ 334	\$ --	\$ 386	\$ --
Reimbursement of development costs	760	--	760	--
Total collaboration revenue	1,094	--	1,146	--
Operating expenses:				
Research and development	4,139	2,590	8,475	4,703
General and administrative	1,585	801	3,185	1,411
Depreciation	101	88	188	175
Total operating expenses	5,825	3,479	11,848	6,289
Loss from operations	(4,731)	(3,479)	(10,702)	(6,289)
Interest income	212	14	362	43
Net loss	(4,519)	(3,465)	(10,340)	(6,246)
Accrued preferred stock dividends	--	(683)	(455)	(1,366)
Adjustments to preferred stock redemption value	--	4,809	17,125	4,736
Net income (loss) attributable to common stockholders	\$ (4,519)	\$ 661	\$ 6,330	\$ (2,876)
Net income (loss) per share attributable to common stockholders:				
Basic	\$ (0.18)	\$ 0.09	\$ 0.30	\$ (0.37)
Diluted	\$ (0.18)	\$ (0.22)	\$ (0.44)	\$ (0.39)
Weighted average shares used in computing net loss per share attributable to common stockholders:				
Basic	24,656,923	7,734,998	21,309,897	7,734,998
Diluted	24,656,923	15,982,982	23,524,621	15,886,677

GTX, INC.
CONDENSED BALANCE SHEETS
(IN THOUSANDS)

	JUNE 30, 2004 ----- (UNAUDITED)	DECEMBER 31, 2003 -----
ASSETS		
Cash and cash equivalents	\$81,444	\$ 14,769
Other current assets	1,928	255
	-----	-----
Total current assets	83,372	15,024
Property and equipment, net	1,439	815
Other assets	231	--
Deferred initial public offering costs	--	1,471
	-----	-----
Total assets	\$85,042	\$ 17,310
	=====	=====
LIABILITIES, CUMULATIVE CONVERTIBLE REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
Accounts payable and accrued expenses	\$ 3,221	\$ 2,249
Deferred revenue, current	1,338	--
	-----	-----
Total current liabilities	4,559	2,249
Deferred revenue	4,963	--
Cumulative redeemable convertible preferred stock	--	165,292
Total stockholders' equity (deficit)	75,520	(150,231)
	-----	-----
Total liabilities and stockholders' equity (deficit)	\$85,042	\$ 17,310
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