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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 (Date of earliest event reported): **November 11, 2004 (November 10, 2004)**

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)

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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o 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 November 11, 2004, GTx, Inc. issued an earnings release for the third quarter ending September 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 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 November 11, 2004

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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: November 11, 2004

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 THIRD QUARTER 2004 FINANCIAL RESULTS

MEMPHIS, Tenn - November 11, 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 three and nine-month periods ended September 30, 2004. The net loss for the three and nine-month periods was $5.1 million and $15.5 million, respectively, compared with a net loss of $3.4 million and $9.6 million for the same periods in 2003. At September 30, 2004, GTx had cash and cash equivalents of $76.1 million.

"We have made significant progress during this quarter for both indications of our lead product candidate, ACAPODENE(TM), through carefully designed clinical plans and dedication to fiscal responsibility." said Mitchell Steiner, M.D., CEO of GTx. "We expect to continue to meet our milestones with the advancement of the Phase III clinical trial for ACAPODENE(TM) for the treatment of serious side effects of androgen deprivation therapy for advanced prostate cancer as well as initiating the pivotal Phase III clinical trial for ACAPODENE(TM) to prevent prostate cancer in high risk men. In addition, we continue to focus on our SARM program, first through our partnership with Johnson and Johnson for andarine, and second by strategically moving other compounds, including ostarine, into Phase I clinical trials."

Revenue for the three and nine-month periods ended September 30, 2004 was $0.4 million and $1.5 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 SARM compound, andarine.

Research and development expenses for the three and nine-month periods ended September 30, 2004 were $3.9 million and $12.3 million, respectively, compared to $2.4 million and $7.1 million during the same periods of 2003. The increase in expenses for both periods was primarily the result of GTx's growing investment in its lead clinical program for ACAPODENE(TM) (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. The increases in research and development expenses also included (1) continuing development of GTx's second clinical program, andarine, (2) preclinical development of its other selective androgen receptor modulator (SARM) compounds, including ostarine and (3) preclinical development of other product candidates including andromustine.

General and administrative expenses for the three and nine-month periods ended September 30, 2004 were $1.8 million and $5.0 million, respectively, compared to the $0.9 million and $2.3 million for the same periods in 2003. The increase in both periods 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.

Diluted net loss per share attributable to common stockholders for the three and nine-month periods ended September 30, 2004 was $0.21 and $0.65, respectively, compared to $11.08 and $11.46 for the same periods in 2003.

Based on our results through the third quarter and our forecasted spending for the fourth quarter, the Company has revised its 2004 financial guidance to reduce its anticipated net loss of $28 to $33 million to $21 to $25 million. This revision is primarily related to the timing of expenditures for the Company's clinical trials, the cost of which the Company anticipates incurring in the first half of 2005. The Company remains on track for completing its clinical trials within the previously announced time frames.

Third Quarter 2004 Corporate Highlights

GTx entered into a collaboration agreement with Tessera, Inc., a diagnostic lab. GTx will provide clinical samples to Tessera, from its completed Phase IIb ACAPODENE(TM) clinical trial for the prevention of prostate cancer in high risk men. This is the third collaboration that GTx has forged with diagnostic companies that have expertise in prostate cancer. The other two companies are Hybritech, a subsidiary of Beckman Coulter, in San Diego and diaDexus in South San Francisco. These collaborations are intended to develop a commercial blood or urine test which could detect high grade prostatic intraepithelial neoplasia (PIN) in the 9.4 million men in the US who unknowingly harbor these precancerous lesions of the prostate and are at high risk for developing prostate cancer.

GTx appointed Timothy R. G. Sear as a new independent board member. Mr. Sear currently serves as Chairman of the board of directors of Alcon, Inc. and recently served as its President and CEO.

Conference Call

There will be a conference call today at 10:00 a.m. Eastern Time to discuss GTx's third quarter financial results and to provide a company update. If you would like to participate in the call, please dial 800-819-9193 from the United States or Canada or 913-981-4911 from outside North America. A playback of the call will be available today from approximately 1:00 p.m. Eastern Time through November 18, 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 923532. 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 for 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. The company is developing ACAPODENE(TM), its most advanced product candidate, through clinical trials for two separate indications: (1) a planned pivotal Phase III clinical trial for the reduction in the incidence 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. GTx is developing its second product candidate, andarine, and other specified backup compounds, with its partner, Ortho Biotech Products, L.P., a subsidiary of

Johnson & Johnson. It is currently anticipated that andarine will be entering a Phase II clinical trial in 2005. GTx is developing another one of its SARMs, ostarine, for andropause. GTx has a deep pipeline generated from its own discovery program which includes specific product candidates prostarine, a SARM for benign prostatic hyperplasia or 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 potential future licensing fees and milestone and royalty payments and GTx's current and anticipated clinical trials and 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 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 SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2004	2003	2004	2003
Collaboration revenue:				
License fees	$ 335	$ --	$ 721	$ --
Reimbursement of development costs	42	--	802	--
Total collaboration revenue	377	--	1,523	--
Operating expenses:				
Research and development	3,859	2,420	12,334	7,123
General and administrative	1,781	928	4,966	2,339
Depreciation	132	89	320	264
Total operating expenses	5,772	3,437	17,620	9,726
Loss from operations	(5,395)	(3,437)	(16,097)	(9,726)
Interest income	270	36	632	79
Net loss	(5,125)	(3,401)	(15,465)	(9,647)
Accrued preferred stock dividends	--	(934)	(455)	(2,300)
Adjustments to preferred stock redemption value	--	(81,402)	17,125	(76,666)
Net income (loss) attributable to common stockholders	$ (5,125)	$ (85,737)	$ 1,205	$ (88,613)
Net income (loss) per share attributable to common stockholders:				
Basic	$ (0.21)	$ (11.08)	$ 0.05	$ (11.46)
Diluted	$ (0.21)	$ (11.08)	$ (0.65)	$ (11.46)
Weighted average shares used in computing net income (loss) per share attributable to common stockholders:				
Basic	24,656,923	7,734,998	22,433,716	7,734,998
Diluted	24,656,923	7,734,998	23,883,264	7,734,998

GTX, INC.

CONDENSED BALANCE SHEETS
(IN THOUSANDS)

	SEPTEMBER 30, 2004 (UNAUDITED)	DECEMBER 31, 2003
ASSETS		
Cash and cash equivalents	$ 76,095	$ 14,769
Other current assets	1,189	255
Total current assets	77,284	15,024
Property and equipment, net	1,523	815
Other assets	348	--
Deferred initial public offering costs	--	1,471
Total assets	$ 79,155	$ 17,310
LIABILITIES, CUMULATIVE REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
Accounts payable and accrued expenses	$ 2,610	$ 2,249
Deferred revenue, current	1,338	--
Total current liabilities	3,948	2,249
Deferred revenue	4,628	--
Cumulative redeemable convertible preferred stock	--	165,292
Total stockholders' equity (deficit)	70,579	(150,231)
Total liabilities and stockholders' equity (deficit)	$ 79,155	$ 17,310

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