

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: **March 3, 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.

| Exhibit No. | Description |
|-------------|------------------------------------|
| 99.1 | Press release dated March 3, 2004. |

ITEM 12. Results of Operations and Financial Condition

On March 3, 2004, GTx issued an earnings release for the quarter and year ended December 31, 2003, 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.

Date: March 3, 2004

GTx, INC.
By: /s/ Mark E. Mosteller

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

GTX, INC. REPORTS FOURTH QUARTER AND YEAR-END 2003 FINANCIAL RESULTS

Memphis, Tennessee. (March 3, 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 fourth quarter and year ended December 31, 2003.

For the fourth quarter ended December 31, 2003, GTX reported a net loss of \$4.5 million compared with a net loss of \$3.5 million for the fourth quarter of 2002. For the year ended December 31, 2003, the Company reported a net loss of \$14.2 million compared with a net loss of \$11.9 million for the year ended December 31, 2002. At December 31, 2003, the Company had cash and cash equivalents of \$14.8 million compared to \$8.9 million at December 31, 2002. As previously reported, on February 6, 2004, the Company completed an initial public offering of 5.4 million shares of common stock at a public offering price of \$14.50 per share, resulting in net proceeds of approximately \$70 million. After the IPO, the Company has outstanding 24,656,923 shares of common stock.

Mitchell Steiner, M.D., F.A.C.S., CEO of GTX, Inc., stated, "2003 was a highly successful year for GTX. We received positive clinical data for our lead product candidate, Acapodene(TM), in two separate indications targeting large markets. We also advanced our second product candidate by completing several Phase I clinical trials for our lead Selective Androgen Receptor Modulator (SARM) compound, Andarine. We believe Andarine represents the first SARM to enter human clinical trials."

2003 ACHIEVEMENTS

- o Completed enrollment and an interim analysis in accordance with the protocol of our Phase IIb clinical trial for Acapodene for the reduction in the incidence of prostate cancer in men with high grade Prostatic Intraepithelial Neoplasia (PIN)
- o Completed two Phase II clinical trials using Acapodene for the treatment of side effects of androgen deprivation therapy for prostate cancer
- o Initiated a pivotal Phase III clinical trial of Acapodene for the treatment of side effects of androgen deprivation therapy for prostate cancer
- o Completed Phase Ia, Ib and Ic clinical trials for the Company's lead SARM compound, Andarine, for the treatment of muscle wasting weight loss, or cachexia, which occurs from various types of cancer
- o Selected several SARM product candidates for clinical testing
- o Completed a \$20 million Series E private equity financing

2003 FOURTH QUARTER AND FULL YEAR HIGHLIGHTS

Research and development expenses represented 73% of total operating expenses for the quarter and year ended December 31, 2003. General and administrative expenses represented 25% and 24% of total operating expenses for the quarter and year ended December 31, 2003, respectively. Depreciation expense accounted for the remaining operating expenses.

For the fourth quarter ended December 31, 2003, research and development expenses increased 16.3% to \$3.3 million from \$2.9 million for the fourth quarter of 2002. For the year ended December 31, 2003, research and development expenses increased 12.7% to \$10.5 million from \$9.3 million for the year ended December 31, 2002. Stock-based compensation expenses accounted for \$413,000 and \$472,000 of research and development expenses for the quarter and year ended December 31, 2003, respectively. Research and development expenses for the fourth quarter and the year included increased expenditures related to the preparation for and initiation of a pivotal Phase III clinical trial of Acapodene for the treatment of side effects of androgen deprivation therapy for prostate cancer. In addition, research and development expenses included the continued development of Andarine and other product candidates in the Company's SARM program.

For the fourth quarter ended December 31, 2003, general and administrative expenses increased 104% to \$1.2 million from \$575,000 for the fourth quarter of 2002. For the year ended December 31, 2003, general and administrative expenses increased 46% to \$3.5 million from \$2.4 million for the year ended December 31, 2002. Stock-based compensation expenses accounted for \$54,000 and \$78,000 of general and administrative expenses for the quarter and year ended December 31, 2003, respectively. The increase in general and administrative expenses for the fourth quarter and the year is due primarily to the Company's expanding operational capabilities.

ANTICIPATED 2004 MILESTONES

The Company plans to achieve the following milestones during 2004:

- o Complete a Phase IIb clinical trial of, and announce results for, Acapodene for the reduction in the incidence of prostate cancer in men with high grade PIN
- o Initiate a pivotal Phase III clinical trial of Acapodene for the reduction in incidence of prostate cancer in men with high grade PIN
- o Initiate a Phase II clinical trial of Andarine for cancer cachexia

2004 FINANCIAL GUIDANCE

- o For the year ended December 31, 2004, the Company anticipates total operating expenses of approximately \$35 million to \$40 million.

CONFERENCE CALL

There will be a conference call today at 10:00 a.m. EST to discuss GTx's fourth quarter and full-year 2003 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 this call will be available today from approximately 12:00 p.m. EST through March 10, 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 access code is 340140.

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 currently has two product candidates that are in human clinical trials. The company is developing Acapodene, its most advanced product candidate, through clinical trials for two separate indications: (1) a Phase IIb clinical trial for the reduction in the incidence of prostate cancer in men with precancerous prostate lesions and (2) a pivotal Phase III clinical trial for the treatment of serious side effects of advanced prostate cancer therapy. GTX is initially developing its second product candidate, Andarine, for the treatment of muscle wasting weight loss, or cachexia, which occurs from various types of cancer.

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 "Anticipated 2004 Milestones" and "2004 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 commercialize its 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 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 expects 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 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. The final prospectus filed with the U.S. Securities and Exchange Commission on February 3, 2004 contains under the heading "Risk Factors" 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.

CONTACT: Carney Duntsch, Manager Corporate Communications GTX, Inc. -
901-523-9700 ext.170 or cduntsch@gtxinc.com

---Financial Statements Attached---

GTX, INC.
SUMMARY FINANCIAL INFORMATION
CONDENSED STATEMENTS OF OPERATIONS
(IN THOUSANDS, EXCEPT PER SHARE AMOUNTS)

| | THREE MONTHS ENDED DECEMBER 31, | | FOR THE YEARS ENDED DECEMBER 31, | |
|--|------------------------------------|-------------|-------------------------------------|-------------|
| | 2003 | 2002 | 2003 | 2002 (1) |
| | (UNAUDITED) | (UNAUDITED) | (UNAUDITED) | |
| Operating expenses: | | | | |
| Research and development | \$ 3,345 | \$ 2,877 | \$ 10,468 | \$ 9,285 |
| General and administrative | 1,173 | 575 | 3,512 | 2,405 |
| Depreciation | 93 | 92 | 357 | 332 |
| Total operating expenses | 4,611 | 3,544 | 14,337 | 12,022 |
| Other income: | | | | |
| Interest income | 64 | 51 | 143 | 156 |
| Total other income | 64 | 51 | 143 | 156 |
| Net loss | (4,547) | (3,493) | (14,194) | (11,866) |
| Accrued preferred stock dividends | (1,136) | (681) | (3,436) | (2,147) |
| Adjustments to preferred stock redemption value(2) | (1,178) | (73) | (77,844) | (7,220) |
| Net loss attributable to common stockholders | \$ (6,861) | \$ (4,247) | \$ (95,474) | \$ (21,233) |
| Net loss per share attributable to common stockholders, basic and diluted | \$ (0.89) | \$ (0.55) | \$ (12.34) | \$ (2.75) |
| Weighted average shares used in computing net loss per share attributable to common stockholders, basic and diluted | 7,735,502 | 7,735,000 | 7,735,125 | 7,735,000 |
| Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited) (3) | \$ (0.24) | | \$ (0.83) | |
| Shares used in computing pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited) | 19,032,281 | | 17,018,655 | |

(1) Derived from the audited financial statements included in the Company's registration statement on Form S-1 for the year ended December 31, 2002.

(2) The adjustments to preferred stock redemption value represents the adjustment to the preferred stock carrying value to reflect the redemption value (fair value) at the end of each reporting period.

(3) Pro forma net loss per share for the three months ended December 31, 2003 and the year ended December 31, 2003 is computed using the weighted average number of shares of common stock outstanding, including the pro forma effects of the automatic conversion of the Company's preferred stock and accrued dividends thereon into shares of common stock effective upon the closing of the initial public offering as if such conversion occurred on October 1, 2003 and January 1, 2003 or at the date of the original issuance, if later. The resulting pro forma adjustments include an increase in the weighted average shares used to compute basic and diluted net loss per share attributable to common stockholders of 11,296,779 and 9,283,530 shares for the three months ended December 31, 2003 and the year ended December 31, 2003. The calculation of pro forma net loss per share attributable to common stockholders excludes incremental common stock issuable upon exercise of options, as their effects would be antidilutive.

GTX, INC.

CONDENSED BALANCE SHEETS
(IN THOUSANDS)

| | DECEMBER 31, 2003 | DECEMBER 31, 2002(1) | PRO FORMA DECEMBER 31, 2003(2) |
|--|----------------------|-------------------------|--------------------------------------|
| | ----- (UNAUDITED) | ----- | ----- (UNAUDITED) |
| ASSETS | | | |
| Cash and cash equivalents | \$ 14,769 | \$ 8,925 | \$ 14,769 |
| Other current assets | 255 | 41 | 255 |
| | ----- | ----- | ----- |
| Total current assets | 15,024 | 8,966 | 15,024 |
| Property and equipment, net | 815 | 1,064 | 815 |
| Deferred initial public offering costs | 1,471 | | 1,471 |
| | ----- | ----- | ----- |
| Total assets | \$ 17,310 | \$ 10,030 | \$ 17,310 |
| | ===== | ===== | ===== |
| LIABILITIES, CUMULATIVE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' (DEFICIT) EQUITY | | | |
| Current liabilities | \$ 2,249 | \$ 1,312 | \$ 2,249 |
| Cumulative redeemable convertible preferred stock | 165,292 | 64,026 | |
| Total stockholders' (deficit) equity | (150,231) | (55,308) | 15,061 |
| | ----- | ----- | ----- |
| Total liabilities and stockholders' (deficit) equity | \$ 17,310 | \$ 10,030 | \$ 17,310 |
| | ===== | ===== | ===== |

(1) Derived from the audited financial statements included in the Company's registration statement on Form S-1 for the year ended December 31, 2002.

(2) The pro forma balance sheet at December 31, 2003 includes the pro forma effects of the automatic conversion of the Company's preferred stock and accrued dividends thereon, into shares of common stock effective upon the closing of the initial public offering as if such conversion occurred on December 31, 2003.