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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) **July 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)

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ITEM 2.02 Results of Operations and Financial Condition.

On July 28, 2005, GTx, Inc. issued an earnings release for the second quarter ended June 30, 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 July 28, 2005 |

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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: July 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 SECOND QUARTER 2005 FINANCIAL RESULTS

MEMPHIS, TENN. - July 28, 2005 -- GTx, Inc. (Nasdaq: GTXI), a biopharmaceutical company dedicated to the discovery, development and commercialization of therapeutics for cancer and other serious men's health conditions, today reported financial results for the second quarter of 2005. The net loss for the second quarter and six months ended June 30, 2005 was $10.0 million and $19.1 million, respectively, compared with a net loss of $4.5 million and $10.3 million for the same periods in 2004. At June 30, 2005, GTx had cash and cash equivalents of $48.1 million.

"We continue to achieve our objectives for 2005," said Mitchell Steiner, M.D., CEO of GTx. "Both Phase III clinical trials of ACAPODENE for two separate indications are enrolling on schedule. Our ostarine clinical trials are advancing as planned. Ostarine is a SARM to which GTx holds exclusive rights and is the second SARM developed by GTx to enter clinical trials. Next month we will complete the Phase I multiple ascending dose clinical trial for ostarine and will present scientific conclusions from this trial shortly thereafter. Preparations for the ostarine Phase II trials are underway."

Revenues for the quarter and six months ended June 30, 2005 were $1.8 million and $2.5 million, respectively, as compared to $1.1 million for the second quarter and first six months of 2004. Revenues for 2005 included net sales of FARESTON(R) (toremifene citrate 60 mg), marketed for the treatment of metastatic breast cancer, and collaboration revenue from our partner, Ortho Biotech Products, L.P., a subsidiary of Johnson & Johnson, for andarine, one of our proprietary selective androgen receptor modulator (SARM) compounds. Revenues for 2004 consisted of collaboration revenue and reimbursement of development costs from Ortho Biotech Products, L.P.

Research and development expenses for the second quarter and first six months of 2005 were $8.6 million and $16.0 million, respectively, compared to $4.2 million and $8.6 million for the

same periods of 2004. The increase in research and development expenses was primarily the result of the Company's continued investment in the following clinical programs:

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

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

- Ostarine in Phase I single and multiple ascending dose clinical trials. Ostarine is being developed for andropause and other chronic wasting 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 and six months ended June 30, 2005 were $2.6 million and $5.2 million, respectively, compared to $1.6 million and $3.2 million for the same periods in 2004. The increases in both periods primarily resulted from increased personnel costs to support the Company's growth, higher insurance costs and increased patent costs and professional fees.

SECOND QUARTER 2005 CORPORATE HIGHLIGHTS

- The patient enrollment in both pivotal Phase III clinical trials of ACAPODENE for two separate indications is on schedule.

- Presented the ACAPODENE Phase IIb clinical results for the prevention of prostate cancer in high risk men at the annual meeting of the American Society of Clinical Oncology and to the American Urological Association.

- Initiated a second Phase I clinical trial evaluating multiple ascending doses of ostarine in healthy and elderly men.

- Appointed Robert Karr, M.D. to the Board of Directors. Dr. Karr served as Senior Vice President, Strategic Management at Pfizer, Inc. and brings to GTx additional senior executive pharmaceutical industry knowledge and strategic experience in research and development.

CONFERENCE CALL

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

- 800-322-5044 from the United States and Canada or
- 617-614-4927 (International)

  The access code for the call is 83170819.

A playback of the call will be available from approximately 12:00 p.m., Eastern Time, on July 28 through August 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 27915479.

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 cancer and other 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, two essential classes of hormones.

GTx has four clinical programs. The company is developing ACAPODENE(R) (toremifene citrate 80 mg and 20 mg) for two separate indications in men: (1) a pivotal Phase III clinical trial for the treatment of serious side effects of androgen deprivation therapy for advanced prostate cancer, and (2) a pivotal Phase III clinical trial for the prevention of prostate cancer in high risk men. In its third clinical program, GTx and its partner, Ortho Biotech Products, L.P., a subsidiary of Johnson & Johnson, are developing andarine, a SARM, for cancer cachexia. In its fourth clinical program, GTx is developing its second SARM, ostarine, for andropause and other chronic wasting conditions related to aging, including frailty and sarcopenia. GTx maintains exclusive rights to ostarine. GTx also has a marketed product, FARESTON(R) (toremifene citrate 60mg) tablets, utilizing the same active pharmaceutical ingredient as ACAPODENE(R), for the treatment

of metastatic breast cancer. 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 candidate, for hormone refractory prostate cancer. Additional information can be found at the company's web site, www.gtxinc.com.

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 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 BALANCE SHEETS
(IN THOUSANDS, EXCEPT SHARE DATA)

| | JUNE 30, 2005 (UNAUDITED) | DECEMBER 31, 2004 |
|---|---|---|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | $ 48,082 | $ 64,528 |
| Inventory | 241 | 448 |
| Prepaid expenses and other current assets | 1,577 | 1,176 |
| Total current assets | 49,900 | 66,152 |
| Property and equipment, net | 1,843 | 1,537 |
| Purchased intangible assets, net | 5,027 | 4,943 |
| Other assets | 956 | 450 |
| Total assets | $ 57,726 | $ 73,082 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | $ 2,875 | $ 900 |
| Accrued expenses | 4,595 | 2,617 |
| Deferred revenue | 1,337 | 1,337 |
| Total current liabilities | 8,807 | 4,854 |
| Deferred revenue | 3,626 | 4,295 |
| Capital lease obligation | 21 | 24 |
| Stockholders' equity: | | |
| Common stock, $0.001 par value: 60,000,000 shares authorized; 24,664,716 shares issued and outstanding at June 30, 2005 and December 31, 2004 | 25 | 25 |
| Deferred stock compensation | (2,286) | (2,701) |
| Additional paid-in capital | 224,063 | 224,015 |
| Accumulated deficit | (176,530) | (157,430) |
| Total stockholders' equity | 45,272 | 63,909 |
| Total liabilities and stockholders' equity | $ 57,726 | $ 73,082 |

GTX, INC.
CONDENSED STATEMENTS OF OPERATIONS
(IN THOUSANDS, EXCEPT SHARE AND PER SHARE DATA)
(UNAUDITED)

| | THREE MONTHS ENDED JUNE 30, | | SIX MONTHS ENDED JUNE 30, | |
|---|---|---|---|---|
| | 2005 | 2004 | 2005 | 2004 |
| Revenues: | | | | |
| Product sales, net | $ 1,492 | $ -- | $ 1,845 | $ -- |
| Collaboration revenue | 335 | 334 | 669 | 386 |
| Reimbursement of development costs | -- | 760 | -- | 760 |
| Total revenue | 1,827 | 1,094 | 2,514 | 1,146 |
| Costs and expenses: | | | | |
| Costs of goods sold | 920 | -- | 1,165 | -- |
| Research and development expenses | 8,639 | 4,224 | 15,965 | 8,635 |
| General and administrative expenses | 2,642 | 1,601 | 5,162 | 3,213 |
| Total costs and expenses | 12,201 | 5,825 | 22,292 | 11,848 |
| Loss from operations | (10,374) | (4,731) | (19,778) | (10,702) |
| Interest income | 354 | 212 | 678 | 362 |
| Net loss | (10,020) | (4,519) | (19,100) | (10,340) |
| Accrued preferred stock dividends | -- | -- | -- | (455) |
| Adjustments to preferred stock redemption value | -- | -- | -- | 17,125 |
| Net (loss) income attributable to common stockholders | $ (10,020) | $ (4,519) | $ (19,100) | $ 6,330 |
| Net (loss) income per share attributable to common stockholders: | | | | |
| Basic | $ (0.41) | $ (0.18) | $ (0.77) | $ 0.30 |
| Diluted | $ (0.41) | $ (0.18) | $ (0.77) | $ (0.44) |
| Weighted average shares used in computing net (loss) income per share attributable to common stockholders: | | | | |
| Basic | 24,664,716 | 24,656,923 | 24,664,716 | 21,309,897 |
| Diluted | 24,664,716 | 24,656,923 | 24,664,716 | 23,524,621 |

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