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 3, 2005

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)

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:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- 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))

ITEM 2.02 Results of Operations and Financial Condition.

On November 3, 2005, GTx, Inc. issued an earnings release for the third quarter ended September 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 99.1

Description

Press Release issued by GTx, Inc. dated November 3, 2005

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 3, 2005 By: /s/ Mark E. Mostelle

By: <u>/s/ Mark E. Mosteller</u> Name: Mark E. Mosteller, CPA

Fitle: Vice President and Chief Financial Officer (principal accounting and financial officer)

Contact:
McDavid Stilwell
GTx, Inc.
Manager, Corporate Communications & Financial Analysis
901-523-9700

GTX, INC. REPORTS THIRD QUARTER 2005 FINANCIAL RESULTS

MEMPHIS, TENN. - Nov. 3, 2005--GTx, Inc. (Nasdaq: GTXI), the Men's Health Biotech Company, today reported financial results for the third quarter of 2005. The net loss for the third quarter and nine months ended September 30, 2005 was \$9.9 million and \$29.0 million, respectively, compared with a net loss of \$5.1 million and \$15.5 million for the same periods in 2004. At September 30, 2005, GTx had cash and cash equivalents of \$37.8 million. In October 2005, GTx received net proceeds of approximately \$45.8 million from the public offering of 6,325,000 shares of its common stock.

"We have received the SPA for our pivotal Phase III clinical trial of ACAPODENE for the prevention of prostate cancer in high risk men. The SPA gives our company regulatory clarity on the trial's design and required endpoints," said Mitchell Steiner, MD, CEO of GTx. "This now means that both of our pivotal Phase III clinical programs for ACAPODENE are proceeding under SPAs."

Revenues for the quarter and nine months ended September 30, 2005 were \$0.6 million and \$3.1 million, respectively, as compared to \$0.4 million and \$1.5 million for the third quarter and first nine months of 2004, respectively. 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 third quarter and first nine months of 2005 were \$8.5 million and \$24.4 million, respectively, compared to \$4.0 million and \$12.6 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 advancing clinical programs:

- 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 (ADT) for advanced prostate cancer.
- ACAPODENE, toremifene citrate 20 mg dose, in a pivotal Phase III clinical trial for the prevention of prostate cancer in high risk men.
- Ostarine in Phase I single and multiple ascending dose clinical trials. Ostarine is being initially developed for acute muscle wasting associated with burns. GTx has 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 nine months ended September 30, 2005 were \$2.3 million and \$7.4 million, respectively, compared to \$1.8 million and \$5.0 million for the same periods in 2004. The increases in both periods primarily resulted from additional personnel and administrative costs to support the company's growth, higher insurance costs and increased patent costs and professional fees.

THIRD QUARTER 2005 CORPORATE HIGHLIGHTS

- Reached patient enrollment goal for the pivotal Phase III trial for the use of ACAPODENE in the treatment of the side effects of ADT on schedule at the end of the third quarter.
- Received a Special Protocol Assessment for our pivotal Phase III clinical trial of ACAPODENE for the prevention of prostate cancer in high risk men. The timing of the analysis of efficacy endpoints for the trial is event driven. GTx believes it will conduct an efficacy analysis within 24 months of completion of enrollment. Once GTx has achieved the efficacy endpoint, it will proceed with a New Drug Application. Enrollment in the trial is on schedule for completion during the first quarter of 2006.
- Completed a Phase I multiple ascending dose trial for ostarine in healthy men and elderly men with truncal obesity. GTx has selected doses of ostarine to advance into Phase II studies, beginning with a Phase II clinical trial for acute muscle wasting in burn patients which the company plans to initiate this quarter.

CONFERENCE CALL

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

- 800-510-9834 from the United States and Canada or
- 617-614-3669 (International)

The access code for the call is 39485009.

A playback of the call will be available from approximately 12:00 p.m., Eastern Time, on November 3 through November 17, and may be accessed by dialing:

- 888-286-8010 from the United States and Canada or
- 617-801-6888 (International), referencing reservation number 95133732.

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 for cancer and serious conditions related to men's health. GTx's lead 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, headquartered in Memphis, Tenn., currently has four clinical programs. GTx is developing ACAPODENE (toremifene citrate), a selective estrogen receptor modulator, or

SERM, in two separate clinical programs 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 with the precancerous prostate lesion called high grade PIN. In its third clinical program, GTx is developing ostarine for the treatment of acute muscle wasting conditions associated with burns and plans to initiate a Phase II clinical trial for ostarine for this indication in the fourth quarter of 2005. GTx is also evaluating clinical development of ostarine for the treatment of chronic muscle wasting conditions, such as testosterone deficiency in aging men, or andropause. In its fourth clinical program, GTx and its collaborator, Ortho Biotech Products, L.P., a subsidiary of Johnson & Johnson, are developing andarine, another one of GTx's SARMs, for the treatment of cancer cachexia. GTx is working with Ortho Biotech to plan a Phase II clinical trial of andarine.

Forward-Looking Information is Subject to Risk and Uncertainty

This press release contains forward-looking statements 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, the risks that (i) GTx will not be able to commercialize its product candidates if clinical trials do not demonstrate safety and efficacy in humans; (ii) GTx may not able to obtain required regulatory approvals to commercialize its product candidates; (iii) GTx's clinical trials may not be completed on schedule, or at all, or may otherwise be suspended or terminated; and (iv) GTx could utilize its available cash resources sooner than its currently expects and may be unable to raise capital when needed, which would force GTx to delay, reduce or eliminate its product development programs or commercialization efforts. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this press release. GTx's prospectus supplement filed with the U.S. Securities and Exchange Commission (the "SEC") pursuant to Rule 424(b)(5) on October 12, 2005, 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.

$\begin{array}{c} {\sf GTX,\ INC.} \\ {\sf CONDENSED\ BALANCE\ SHEETS} \\ ({\sf IN\ THOUSANDS,\ EXCEPT\ SHARE\ DATA}) \end{array}$

SEPTEMBER 30, DECEMBER 31, 2005 2004 ----------(UNAUDITED) **ASSETS** Current assets: Cash and cash equivalents \$ 37,808 \$ 64,528 Inventory 175 448 Prepaid expenses and other current assets 2,497 1,176 ----------Total current assets 40,480 66,152 Property and equipment, net 1,865 1,537 Purchased intangible assets, net 5,037 4,943 Other assets 312 450 --------------Total assets \$ 47,694 \$ 73,082 ========= ========= LIABILITIES AND STOCKHOLDERS' **EQUITY** Current liabilities: Accounts payable \$ 1,955 \$ 900 Accrued expenses 5,585 2,617 Deferred revenue 1,337 1,337 ------ Total current liabilities 8,877 4,854 Deferred revenue 3,292 4,295 Capital

lease

obligation 20 24 Stockholders' equity: Common stock, \$0.001 par value: 60,000,000 shares authorized; 24,666,133 shares issued and outstanding at September 30, 2005 and 24,664,716 shares issued and outstanding at December 31, 2004 25 25 Deferred stock compensation (1,884) (2,701) Additional paid-in capital 223,837 224,015 Accumulated deficit (186, 473)(157, 430) --Total stockholders' equity 35,505 63,909 ----Total liabilities and stockholders' equity \$ 47,694 \$ 73,082 ========= ==========

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

THREE MONTHS ENDED NINE MONTHS ENDED SEPTEMBER 30, SEPTEMBER 30, -------- ----------- 2005 2004 2005 2004 ------- ------- ------ Revenues: Product sales, net \$ 288 \$ -- \$ 2,133 \$ --Collaboration revenue 334 335 1,003 721 Reimbursement of development costs -- 42 -- 802 ------- --------- -------- ------- Total revenue 622 377 3,136 1,523 Costs and expenses: Costs of goods sold 185 -- 1,350 -- Research and development expenses 8,454 3,971 24,419 12,606 General and administrative expenses 2,271 1,801 7,433 5,014 -Total costs and expenses 10,910 5,772 33,202 17,620 ---------------Loss from operations (10,288)(5,395)

(30,066)

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(16,097)
  Interest
 income 345
270 1,023 632
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----- Net
loss (9,943)
   (5, 125)
  (29,043)
  (15,465)
   Accrued
  preferred
    stock
dividends --
 -- -- (455)
 Adjustments
to preferred
    stock
 redemption
value -- -- -
- 17,125 ----
-----
-----
-----
  ---- Net
(loss) income
attributable
  to common
stockholders
 $ (9,943) $
  (5,125)$
  (29,043)$
    1,205
  =======
=========
 ========
=========
 Net (loss)
 income per
    share
attributable
  to common
stockholders:
   Basic $
  (0.40) $
  (0.21) $
(1.18) \pm 0.05
  ========
=========
 ========
========
  Diluted $
  (0.40)$
  (0.21) $
  (1.18) $
   (0.65)
  =======
=========
 ========
========
  Weighted
  average
 shares used
in computing
 net (loss)
 income per
    share
attributable
  to common
stockholders:
   Basic
 24,664,950
 24,656,923
 24,664,794
 22,433,716
 ========
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 ========
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Diluted
24,664,950
24,656,923
24,664,794
23,883,264

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