
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 27, 2006
(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)

000-50549
(Commission
File Number)

62-1715807
(I.R.S. Employer
Identification No.)

3 N. Dunlap Street
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 (see General Instruction A.2. below):

- 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))
 - 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 July 27, 2006, GTx, Inc. issued an earnings release for the second quarter ended June 30, 2006, 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

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release issued by GTx, Inc. dated July 27, 2006

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 27, 2006

By: /s/ Mark E. Mosteller
Name: Mark E. Mosteller
Title: 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 SECOND QUARTER 2006 FINANCIAL RESULTS

MEMPHIS, TENN. — July 27, 2006—GTx, Inc. (NASDAQ: GTXI), the Men's Health Biotech Company, today reported financial results for the second quarter of 2006. The net loss for the second quarter and six months ended June 30, 2006 was \$10.0 million and \$19.9 million, respectively, compared with a net loss of \$10.0 million and \$19.1 million for the same periods in 2005. At June 30, 2006, GTx had cash and cash equivalents of \$55.6 million.

"We are proud of the substantial progress GTx has made in the second quarter," said Mitchell S. Steiner, M.D., Chief Executive Officer of GTx. "We reached our enrollment goal for our pivotal Phase III PIN clinical trial, we conducted a lipid interim analysis of our pivotal Phase III ADT clinical trial showing that ACAPODENE 80 mg reduced cholesterol and raised HDL, and we initiated and fully enrolled our proof of concept Phase II clinical trial for ostarine, a first in class drug."

Revenues for the quarter and six months ended June 30, 2006 were \$0.6 million and \$1.8 million, respectively, as compared to \$1.8 million and \$2.5 million for the second quarter and first six months of 2005. Revenues in all periods included net sales of FARESTON® (toremifene citrate 60 mg), marketed for the treatment of metastatic breast cancer, and collaboration revenue for andarine from our partner, Ortho Biotech Products, LP, a subsidiary of Johnson & Johnson.

Research and development expenses for the second quarter and first six months of 2006 were \$8.4 million and \$16.9 million, respectively, compared to \$8.6 million and \$16.0 million for the same periods in 2005. Research and development spending was primarily the result of the Company's continued investment in its clinical programs.

General and administrative expenses for the quarter and six months ended June 30, 2006 were \$2.7 million and \$5.6 million, respectively, compared to \$2.6 million and \$5.2 million for the same periods in 2005.

Second quarter 2006 Corporate Highlights

- In June, GTx conducted a lipid interim analysis of the first 197 men to complete one year of treatment in the pivotal Phase III clinical trial evaluating ACAPODENE for the treatment of multiple side effects of androgen deprivation therapy (ADT). Patients treated with ACAPODENE compared to placebo had statistically significantly lower total cholesterol, LDL, triglycerides, and total cholesterol to HDL ratio, and higher HDL. The full lipid data set will be evaluated before conclusions about clinical significance of the findings can be drawn. Final data from the trial is expected in the fourth quarter of 2007.
 - In April, GTx initiated a one year Phase IIIb extension trial of ACAPODENE for the treatment of multiple side effects of ADT. The purpose of this study is to collect additional blinded efficacy and safety data that could further support the current Phase III clinical study. This Phase IIIb clinical study is a separate clinical trial and will not affect the current timeline for the completion of the ongoing Phase III ADT clinical trial in the second half of 2007 nor the potential submission of the new drug application.
 - In May, GTx attained the enrollment goal of 1,260 men in the pivotal Phase III PIN clinical trial evaluating ACAPODENE 20 mg for the prevention of prostate cancer in men with high grade prostatic intraepithelial neoplasia (PIN). Enrollment of the trial began in the first quarter of 2005. The trial is being conducted under a Special Protocol Assessment with the United States Food & Drug Administration. The trial is designed as a 36 month study but provides for an interim efficacy analysis after a sufficient number of prostate cancer events have occurred. GTx believes this interim analysis will occur during the period from the fourth quarter of 2007 to the first quarter of 2008. If the efficacy endpoint is statistically achieved, GTx plans to file a new drug application with the FDA during 2008.
 - In May, GTx initiated a proof of concept Phase II clinical trial of ostarine which was fully enrolled July 20. The three month placebo controlled clinical trial is evaluating multiple doses of ostarine in 60 elderly men and 60 postmenopausal
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women. The trial is designed to evaluate the activity of ostarine on building muscle and promoting bone as well as to assess safety in both elderly men and postmenopausal women. GTX expects to report the data from the Phase II clinical trial in the fourth quarter of 2006. Based on the Phase II clinical data profile of ostarine, GTX will select acute and chronic bone and/or muscle wasting diseases for further development. GTX plans to initiate a Phase IIb or Phase III clinical trial in the first half of 2007.

Conference Call

There will be a conference call today at 9 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:

- 866-362-4666 from the United States and Canada or
- 617-597-5313 (International)

The access code for the call is 12638081.

A playback of the call will be available beginning today at 11:00 a.m., Eastern Time through August 11, and may be accessed by dialing:

- 888-286-8010 from the United States and Canada or
- 617-801-6888 (International)

The reservation number for the replay is 16098503.

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, headquartered in Memphis, Tenn., 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 is developing ACAPODENE® (toremifene citrate), a selective estrogen receptor modulator, or SERM, in two separate clinical programs in men: first, a pivotal Phase III clinical trial for the treatment of serious side effects of androgen deprivation therapy for advanced prostate cancer, and second, a pivotal Phase III clinical trial for the prevention of prostate cancer in high risk men with high grade PIN. GTX is developing ostarine, a selective androgen

receptor modulator, or SARM, for muscle wasting and bone loss indications. Ostarine is currently being evaluated in a Phase II clinical trial in 120 elderly men and postmenopausal women. GTX expects to have data from the Phase II ostarine trial in the fourth quarter of 2006. GTX has licensed to Ortho Biotech Products, L.P., a subsidiary of Johnson & Johnson, another of its SARMS, andarine, under a joint collaboration and license agreement.

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 be 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 it 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 quarterly report on form 10-Q filed with the U.S. Securities and Exchange Commission on May 5, 2006, contains 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)

	<u>June 30, 2006</u> (unaudited)	<u>December 31, 2005</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 55,561	\$ 74,014
Accounts receivable	63	153
Inventory	214	135
Prepaid expenses and other current assets	1,575	1,702
Total current assets	57,413	76,004
Property and equipment, net	1,665	1,746
Purchased intangible assets, net	4,804	4,978
Other assets	39	83
Total assets	<u>\$ 63,921</u>	<u>\$ 82,811</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 990	\$ 1,407
Accrued expenses	4,522	3,230
Deferred revenue — current portion	1,337	1,337
Total current liabilities	6,849	5,974
Deferred revenue, less current portion	2,289	2,958
Other long term liability	338	280
Capital lease obligation	17	20
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value: 60,000,000 shares authorized; 31,005,717 shares issued and outstanding at June 30, 2006 and 30,993,967 shares issued and outstanding at December 31, 2005	31	31
Deferred stock compensation	—	(1,725)
Additional paid-in capital	268,574	269,542
Accumulated deficit	(214,177)	(194,269)
Total stockholders' equity	54,428	73,579
Total liabilities and stockholders' equity	<u>\$ 63,921</u>	<u>\$ 82,811</u>

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,	
	2006	2005	2006	2005
Revenues:				
Product sales, net	\$ 288	\$ 1,492	\$ 1,164	\$ 1,845
Collaboration revenue	335	335	669	669
Total revenue	623	1,827	1,833	2,514
Costs and expenses:				
Cost of product sales	170	920	637	1,165
Research and development expenses	8,444	8,639	16,885	15,965
General and administrative expenses	2,692	2,642	5,642	5,162
Total costs and expenses	11,306	12,201	23,164	22,292
Loss from operations	(10,683)	(10,374)	(21,331)	(19,778)
Interest income	699	354	1,423	678
Net loss	\$ (9,984)	\$ (10,020)	\$ (19,908)	\$ (19,100)
Net loss per share:				
Basic	\$ (0.32)	\$ (0.41)	\$ (0.64)	\$ (0.77)
Diluted	\$ (0.32)	\$ (0.41)	\$ (0.64)	\$ (0.77)
Weighted average shares used in computing net loss per share:				
Basic	31,002,338	24,664,716	30,999,044	24,664,716
Diluted	31,002,338	24,664,716	30,999,044	24,664,716