Table of Contents

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: **November 2, 2006**
(Date of earliest event reported)

GTx, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**000-50549**	**62-1715807**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(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):

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))

TABLE OF CONTENTS

Table of Contents

ITEM 2.02 Results of Operations and Financial Condition.

On November 2, 2006, GTx, Inc. issued an earnings release for the third quarter ended September 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

Exhibit Number	Description
99.1	Press Release issued by GTx, Inc. dated November 2, 2006

Table of Contents

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 2, 2006

By: /s/ Mark E. Mosteller
Name: Mark E. Mosteller
Title: Vice President and Chief Financial Officer
(principal accounting and financial officer)

Exhibit 99.1

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

GTX, INC. REPORTS THIRD QUARTER 2006 FINANCIAL RESULTS

MEMPHIS, TENN. — November 2, 2006—GTx, Inc. (NASDAQ: GTXI), the Men's Health Biotech Company, today reported financial results for the third quarter of 2006. The net loss for the third quarter and nine months ended September 30, 2006 was $10.9 million and $30.8 million, respectively, compared with a net loss of $9.9 million and $29.0 million for the same periods in 2005. This performance is consistent with GTx's previously stated financial guidance.

"We are proud of the significant progress GTx made in the third quarter. We achieved a major milestone with the execution of our definitive agreement granting Ipsen exclusive European development and marketing rights of ACAPODENE®," said Mitchell S. Steiner, M.D., Chief Executive Officer of GTx. "This partnership allows us to achieve three major corporate objectives. Financially, the partnership's upfront payment yielded GTx sufficient cash to meet our projected operating requirements through the first quarter of 2008, by which time we expect to have received data from our two pivotal Phase III clinical trials. Second, GTx retains exclusive rights to ACAPODENE® in the United States, where we intend to market the drug to physicians treating prostate cancer patients. Third, the transaction places European commercialization of ACAPODENE® in the hands of the partner most capable of successfully marketing prostate cancer drugs. Ipsen already has a solid prostate cancer franchise in Europe with its lead product, Decapeptyl. ACAPODENE® for the treatment of multiple side effects of ADT and ACAPODENE® for the prevention of prostate cancer will further strengthen their product portfolio."

"In the current quarter we will receive important data from our proof of concept Phase II clinical trial of ostarine," Steiner said. "The information from this trial we hope will show the potential of SARMs to build muscle and bone in both men and women. We look forward to reporting top line results toward the end of the year."

Revenues for the quarter and nine months ended September 30, 2006 were $1.1 million and $2.9 million, respectively, as compared to $0.6 million and $3.1 million for the third quarter and first nine 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. Revenues for the third quarter of 2006 also included collaboration revenue for the period September 7, 2006 through September 30, 2006 from our partner, Ipsen Group ("Ipsen"), which has acquired from GTx the exclusive rights to develop and market ACAPODENE® (toremifene citrate) in the European Union, Commonwealth of Independent States and certain other European countries ("European Territory"). GTx is developing ACAPODENE® in two separate indications in men: ACAPODENE® 80 mg for the treatment of multiple side effects of androgen deprivation therapy (ADT) for advanced prostate cancer, and ACAPODENE® 20 mg for the prevention of prostate cancer in men with the precancerous lesion of the prostate, high grade prostatic intraepithelial neoplasia (PIN).

Research and development expenses for the third quarter and first nine months of 2006 were $9.6 million and $26.5 million, respectively, compared to $8.5 million and $24.4 million for the same periods in 2005. The increase in research and development spending was primarily the result of the Company's continued investment in its clinical programs, including increased spending for the development of ostarine in an ongoing Phase II clinical trial.

General and administrative expenses for the quarter and nine months ended September 30, 2006 were $2.9 million and $8.5 million, respectively, compared to $2.3 million and $7.4 million for the same periods in 2005.

At October 7, 2006, with the receipt of the upfront license fee and expense reimbursement from our collaboration with Ipsen, GTx had approximately $70.9 million in cash and cash equivalents.

Third quarter 2006 Corporate Highlights

- In September, GTx and Ipsen entered into a definitive agreement under which Ipsen has been granted exclusive rights to develop and market in the European

Territory ACAPODENE® for the prevention of prostate cancer in high risk men and for the treatment of multiple side effects of ADT. Ipsen agreed to pay GTx 23 million Euros as a license fee and expense reimbursement. In addition, GTx is entitled to receive milestone payments from Ipsen of approximately 39 million Euros for ACAPODENE®, subject to the successful development and European launch of ACAPODENE® for both the ADT and PIN indications. Ipsen will pay all clinical development, regulatory, and launch expenses, in addition to bulk drug product supply and packaging costs, to commercialize ACAPODENE® in the European Territory, and Ipsen may pay a portion of GTx's ACAPODENE® development costs in the U.S. if certain conditions are met. Ipsen has agreed to pay GTx a royalty equal to a graduating percentage of aggregate net sales of ACAPODENE® in the European Territory in the mid-teens, which could reach the mid-twenties based on certain sales price thresholds being met. GTx is responsible for paying upstream royalties for ACAPODENE®.

- In August, an independent drug safety monitoring board conducted a per protocol interim review of safety data of more than 2,700 patients enrolled in our two pivotal Phase III clinical trials of ACAPODENE® and recommended that GTx continue the two clinical development programs as planned.
- In July, GTx completed recruitment of its proof of concept Phase II clinical trial of its first-in-class drug candidate, ostarine, a selective androgen receptor modulator (SARM). GTx initiated the Phase II clinical trial of ostarine in May 2006. The three month placebo controlled clinical trial is evaluating multiple doses of ostarine in 60 elderly men and 60 postmenopausal 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 trial in the fourth quarter of 2006. Based on ostarine's Phase II clinical data profile, GTx will select specific acute and chronic muscle wasting and/or bone loss diseases for further development. GTx plans to initiate a Phase IIb or Phase III clinical trial in 2007.

Conference Call
There will be a conference call today at 9 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:

- 800-638-4930 from the United States and Canada or
- 617-614-3944 (International)
  The access code for the call is 60274409.

A playback of the call will be available beginning today at 11:00 a.m., Eastern Time through November 16, 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 83047883.

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 has licensed to Ipsen Group exclusive rights in Europe to develop and commercialize ACAPODENE® for the prevention of prostate cancer in high risk men and for the treatment of multiple side effects of androgen deprivation therapy. 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 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 August 9, 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)

	September 30, 2006 (unaudited)	December 31, 2005
ASSETS		
Current assets:		
Cash and cash equivalents	$ 44,551	$ 74,014
Accounts receivable	121	153
Inventory	236	135
Receivable from collaboration partner	27,898	—
Prepaid expenses and other current assets	1,330	1,702
Total current assets	74,136	76,004
Property and equipment, net	1,556	1,746
Purchased intangible assets, net	4,810	4,978
Receivable from collaboration partner, less current portion	1,189	—
Other assets	37	83
Total assets	$ 81,728	$ 82,811
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,344	$ 1,407
Accrued expenses	3,987	3,230
Deferred revenue — current portion	7,189	1,337
Total current liabilities	12,520	5,974
Deferred revenue, less current portion	24,972	2,958
Other long term liability	319	280
Capital lease obligation	16	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 September 30, 2006 and 30,993,967shares issued and outstanding at December 31, 2005	31	31
Deferred stock compensation	—	(1,725)
Additional paid-in capital	268,936	269,542
Accumulated deficit	(225,066)	(194,269)
Total stockholders' equity	43,901	73,579
Total liabilities and stockholders' equity	$ 81,728	$ 82,811

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,	
	2006	2005	2006	2005
Revenues:				
Product sales, net	$ 348	$ 288	$ 1,512	$ 2,133
Collaboration revenue	724	334	1,393	1,003
Total revenues	1,072	622	2,905	3,136
Costs and expenses:				
Cost of product sales	118	185	755	1,350
Research and development expenses	9,614	8,454	26,499	24,419
General and administrative expenses	2,867	2,271	8,509	7,433
Total costs and expenses	12,599	10,910	35,763	33,202
Loss from operations	(11,527)	(10,288)	(32,858)	(30,066)
Interest income	638	345	2,061	1,023
Net loss	$ (10,889)	$ (9,943)	$ (30,797)	$ (29,043)
Net loss per share:				
Basic	$ (0.35)	$ (0.40)	$ (0.99)	$ (1.18)
Diluted	$ (0.35)	$ (0.40)	$ (0.99)	$ (1.18)
Weighted average shares used in computing net loss per share:				
Basic	31,005,717	24,664,950	31,001,292	24,664,794
Diluted	31,005,717	24,664,950	31,001,292	24,664,794