
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): February 23, 2009

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
Van Vleet Building
Memphis, Tennessee 38163
(901) 523-9700**

(Address, including zip code, of Registrant's principal executive offices
Registrant's telephone number, including area code.)

(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 8.01 Other Events.

On February 23, 2009, GTx, Inc. issued a press release announcing that it has initiated a Phase I clinical trial for GTX-758, an oral luteinizing hormone (LH) inhibitor to treat men with advanced prostate cancer, a copy of which is furnished as Exhibit 99.1 to this Current Report. The Phase I study will evaluate the safety, tolerability and pharmacokinetic profile of GTX-758 using a single ascending dose, double blind, placebo controlled design in healthy male volunteers.

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 February 23, 2009

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: February 23, 2009

By: /s/ Henry P. Doggrell

Name: Henry P. Doggrell

Title: Vice President, General Counsel and Secretary

GTx Initiates Phase I Clinical Trial for GTx-758, an Oral Luteinizing Hormone Inhibitor for Advanced Prostate Cancer

MEMPHIS, Tenn.—(BUSINESS WIRE)—February 23, 2009—GTx, Inc. (NASDAQ: GTXI) announced today that it has initiated a Phase I clinical trial for GTx-758, an oral luteinizing hormone (LH) inhibitor to treat men with advanced prostate cancer. The Phase I study will evaluate the safety, tolerability and pharmacokinetic profile of GTx-758 using a single ascending dose, double blind, placebo controlled design in healthy male volunteers.

“We are excited to initiate Phase I clinical studies of GTx-758, which was discovered in GTx’s labs and is our fourth clinical development program,” said Mitchell S. Steiner, M.D., CEO of GTx. “We believe GTx-758, with an oral formulation and the potential to treat prostate cancer through suppression of testosterone without also causing bone loss and hot flashes, could become best in class androgen deprivation therapy. We expect to establish proof of concept in man in a second Phase I clinical trial later this year.”

About GTx-758

GTx-758 is an oral LH inhibitor which GTx is developing for the treatment of advanced prostate cancer. Preclinical *in vitro* and *in vivo* data suggest GTx-758 rapidly suppresses secretion of LH, thereby inhibiting production of androgens by the testes. GTx believes GTx-758 has the potential to reduce testosterone, a primary growth factor of prostate cancer, without also causing certain side effects such as bone loss and hot flashes which are common with current androgen deprivation therapies (ADT) for prostate cancer.

About Prostate Cancer

Prostate cancer is the second most common type of cancer diagnosed in men in the U.S. An estimated 186,000 new cases of prostate cancer were diagnosed in the U.S. in 2008.

About ADT for Prostate Cancer

ADT, primary treatment for advanced prostate cancer, has improved survival in men with prostate cancer. Currently, ADT is accomplished either surgically by removal of the testes, or more commonly by injection with LH releasing hormone (LHRH) agents. ADT works by reducing testosterone to castrate levels. The reduction in testosterone from ADT also results in very low estrogen levels, because estrogen is derived from testosterone in men. Estrogen deficiency side effects associated with ADT include high risk of skeletal fractures, adverse lipid changes, hot flashes, gynecomastia, depression, and memory loss. Of patients on ADT, up to 77 percent develop significant bone loss, making them susceptible to fracture. Recent studies indicate that the annual risk of fracture in men on ADT is 5% to 8%, which is three times higher than the risk of fracture for postmenopausal women. Fractures are serious and can reduce survival in men on ADT by more than three years.

Approximately 700,000 men with prostate cancer are being treated with ADT and an estimated 100,000 initiate ADT each year. According to IMS Health data, the annual US sales of drugs for ADT exceeded \$1.7 billion in 2008.

About GTx

GTx, Inc., headquartered in Memphis, Tenn., is a biopharmaceutical company dedicated to the discovery, development, and commercialization of small molecules that selectively target hormone pathways to treat cancer, osteoporosis and bone loss, muscle loss and other serious medical conditions. GTx is developing toremifene citrate, a selective estrogen receptor modulator, or SERM, in two separate clinical programs in men: first, a completed pivotal Phase III clinical trial evaluating toremifene 80 mg for the prevention of bone fractures and treatment of other estrogen side effects in men with prostate cancer on androgen deprivation therapy, and second, an ongoing pivotal Phase III clinical trial evaluating toremifene 20 mg for the prevention of prostate cancer in high risk men with high grade prostatic intraepithelial neoplasia, or PIN. In 2006, GTx and Ipsen entered into a development and collaboration agreement for toremifene citrate in all indications except breast cancer for Europe and the Commonwealth of Independent States (CIS). GTx has applied for marketing approval in the United States for toremifene 80 mg for the prevention of bone fractures in men with prostate cancer on ADT and, if approved, plans to commercialize toremifene 80 mg in the United States. In December 2007, GTx and Merck formed a collaboration to discover and develop selective androgen receptor modulators, or SARMs, a new class of drugs with the potential to treat sarcopenia, which is the loss of skeletal muscle mass resulting in reduced physical strength and ability to perform activities of daily living, as well as cancer cachexia (cancer induced muscle loss) and other musculoskeletal wasting conditions. Merck and GTx are evaluating multiple SARM product candidates, including Ostarine™ (designated by Merck as MK-2866) for sarcopenia in several Phase I and II clinical development programs. Merck and GTx are evaluating additional muscle loss indications including cancer cachexia for potential SARM clinical development. GTx also is developing its preclinical compound GTx-758, an oral luteinizing hormone inhibitor, for advanced prostate cancer.

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 and its collaboration partners will not be able to commercialize their 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 product candidates; (iii) clinical trials being conducted by GTx and its collaboration partners 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 November 6, 2008 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.

Source:

GTx, Inc.

McDavid Stilwell, 901-523-9700

Director, Corporate Communications & Financial Analysis