
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): June 20, 2011

GTx, Inc.

(Exact name of registrant as specified in its charter)

Delaware

000-50549

62-1715807

(State or other Jurisdiction of
Incorporation)

(Commission File Number)

(IRS Employer Identification No.)

**175 Toyota Plaza
7th Floor**

Memphis, Tennessee

(Address of Principal Executive Offices)

38103

(Zip Code)

Registrant's telephone number, including area code: **(901) 523-9700**

(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))
 - 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 June 20, 2011, GTx, Inc. issued a press release announcing that it has initiated a Phase IIb clinical trial for Capesaris, a selective estrogen receptor alpha agonist for first line treatment of advanced prostate cancer, a copy of which is furnished as Exhibit 99.1 to this Current Report.

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 June 20, 2011

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: June 20, 2011

By: /s/ Henry P. Doggrell
Name: Henry P. Doggrell
Title: Vice President, General Counsel
and Secretary

Source:
GTx, Inc.
McDavid Stilwell, Director, Corporate Communications and Financial Analysis
901-523-9700

GTx Initiates Phase IIb Clinical Trial Evaluating Oral Capesaris™ Tablets Versus Lupron Depot® for First Line Treatment of Advanced Prostate Cancer

MEMPHIS, Tenn.—(BUSINESS WIRE)—June 20, 2011—GTx, Inc. (Nasdaq: GTXI), announced today that it initiated a Phase IIb clinical trial evaluating Capesaris™, a selective estrogen receptor alpha agonist, compared to Lupron Depot® (leuprolide acetate for depot suspension) for first line treatment of advanced prostate cancer.

“Acting selectively through estrogen receptor α , Capesaris has the potential to achieve medical castration without also causing several well documented problems of androgen deprivation therapy for prostate cancer such as hot flashes, bone loss and metabolic syndrome,” said Thomas Keane, MD, Chairman and Professor of Urology at the Medical University of South Carolina, and lead investigator of the multicenter Capesaris Phase IIb clinical trial. “A new form of first line hormonal treatment that avoids some of the side effects of current ADT would be an important development.”

“We are excited to have initiated the Phase IIb Capesaris clinical trial,” said Ronald A. Morton, Jr., M.D., Chief Medical Officer of GTx. “Because of the tremendous interest to find a better ADT, we expect this trial to enroll quickly and to have primary efficacy results from the study in the fourth quarter 2011.”

The Phase IIb clinical trial is an open label study comparing oral Capesaris tablets to Lupron Depot®, a luteinizing hormone releasing hormone (LHRH) agonist. One hundred and fifty six men with advanced prostate cancer will be randomized to receive one of two doses of Capesaris (2000 mg orally each day or 1000 mg orally each day) or Lupron Depot® injection every 3 months. The purpose of this study is to establish the dose of Capesaris required to maintain medical castration. The primary endpoint of the study is the proportion of patients that achieve castration by day 60. Secondary endpoints include maintenance of castration beyond 60 days, levels of free testosterone, sex hormone binding globulin (SHBG), luteinizing hormone, and prostate specific antigen (PSA), as well as safety endpoints of Capesaris compared to leuprolide such as hot flashes, libido changes, lipid profile, body composition, bone turnover markers, and bone mineral density.

“Now that we have an oral tablet that has been shown to achieve medical castration, the next step is to conduct dose finding studies to select the appropriate loading and maintenance doses to advance into Phase III clinical trials,” said Mitchell Steiner, MD, Chief Executive Officer of GTx. “This Phase IIb clinical trial will help us answer the question of finding the lowest effective dose to maintain castration and to assess the clinical impact of avoiding estrogen deficiency by measuring the safety endpoints compared to Lupron.”

GTx plans to initiate an additional Phase II study in advanced prostate cancer patients in second half of 2011 to determine the loading dose of Capesaris required to achieve medical castration in greater than 90% of patients within 28 days. In addition, GTx plans to advance Capesaris into a Phase II study for second line therapy for patients with castration resistant prostate cancer who have failed LHRH therapy.

About Capesaris™ (GTx-758)

The standard of care for men with advanced prostate cancer is androgen deprivation therapy (ADT) commonly achieved by surgical orchiectomy or medically by injection of a luteinizing hormone releasing hormone (LHRH) agonist or antagonist. These therapies can result in serious estrogen deficiency related side effects which include hot flashes, loss of libido, bone loss and increased risk of clinical fractures, metabolic syndrome, increased body fat, and increase in cardiovascular events.

As a selective estrogen receptor agonist, Capesaris has the potential to achieve medical castration by feedback inhibition of the pituitary and hypothalamus with the potential to avoid these estrogen deficiency side effects. Capesaris also directly increases SHBG which has the potential to further lower serum free testosterone.

In 2010, GTx evaluated three doses (600 mg, 1000 mg and 1500 mg) of oral Capesaris solution in a Phase II pharmacokinetic and pharmacodynamic clinical trial. Patients receiving 1000 mg and 1500 mg of Capesaris achieved medical castration. In the 1500 mg cohort, 91% of treatment compliant subjects (10 of 11) met the endpoint of castration with a total serum testosterone <50ng/dL. In the 1000 mg dose group, 71% of treatment compliant subjects (10 of 14) achieved castration. Castration was not achieved in men treated with 600 mg of Capesaris. Capesaris was generally well tolerated in this study. The most common adverse events observed in the study were headache, upper respiratory tract infection, nipple pain, and nausea.

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 for the treatment of cancer, cancer supportive care, and other serious medical conditions.

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 include, but are not limited to, statements relating to GTx's plans to conduct clinical trials for Capesaris™ (GTx-758), statements related to anticipated clinical trial initiation, enrollment and timing of results, and statements related to the therapeutic potential of Capesaris™. 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 (i) that GTx will not be able to commercialize its product candidates if clinical trials do not demonstrate safety and efficacy in humans; (ii) that GTx may not be able to obtain required regulatory approvals to commercialize its product candidates in a timely manner or at all; (iii) that clinical trials planned to be conducted by GTx may not be initiated or completed on schedule, or at all, including as a result of registration or enrollment delays, or may otherwise be suspended or terminated; (iv) that GTx could observe serious or other adverse effects in its ongoing and planned clinical trials; and (v) that 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 candidate 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 Securities and Exchange Commission on May 9, 2011, 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.