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): September 15, 2010

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		38103
(Address of Principal Executive	Offices)	(Zip Code)
Registrant's telephone number, including area code: (901) 523-9700		
(Former nam	e or former address if changed since	e last report.)
Check the appropriate box below if the Fregistrant under any of the following prov	•	eously satisfy the filing obligation of the
o Written communications pursuant to Ru	ale 425 under the Securities Act (17	CFR 230.425)
o Soliciting material pursuant to Rule 14a	-12 under the Exchange Act (17 CF	R 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))		

ITEM 8.01 Other Events.

On September 15, 2010, GTx, Inc. issued a press release announcing that GTx-758, a novel oral selective estrogen receptor alpha agonist being developed to treat advanced prostate cancer, demonstrated the ability to achieve medical castration in a Phase II clinical trial. A copy of the press release is furnished as Exhibit 99.1 to this Current Report.

ITEM 9.01 <u>Financial Statements and Exhibits.</u>

(c) Exhibits

Exhibit Number

99.1

Description

Press Release issued by GTx, Inc. dated September 15, 2010

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: September 15, 2010

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

Secretary

Source: GTx, Inc. McDavid Stilwell, Director of Corporate Communications 901-523-9700

GTx announces that GTx-758, a novel oral selective estrogen receptor alpha agonist being developed to treat advanced prostate cancer, induced medical castration in a Phase II PK/PD clinical trial

· In 2011, GTx plans to initiate clinical studies of GTx-758 for first line treatment of advanced prostate cancer and second line hormonal treatment in prostate cancer patients who have failed LHRH treatment.

Memphis, Tenn. September 15, 2010 — GTx, Inc. (Nasdaq: GTXI) today announced that in a Phase II, open label, pharmacokinetic-pharmacodynamic clinical trial, GTx-758, an oral selective estrogen receptor alpha agonist being developed to treat advanced prostate cancer, suppressed serum total testosterone to castrate levels, increased serum SHBG (sex hormone binding globulin), and markedly reduced serum free testosterone in healthy male volunteers.

60 healthy male volunteer subjects were randomized to receive one of three oral daily doses of GTx-758 (600 mg, 1000 mg or 1500 mg) until the earlier of achieving medical castration or 56 days. Medical castration (levels of serum total testosterone <50 ng/dL) was achieved in subjects receiving both the 1000 mg and 1500 mg treatment.

In the 1500 mg group, compliance with treatment was confirmed by statistical analysis of trough plasma concentrations. The percentage of treatment compliant subjects receiving 1500 mg of GTx-758 who achieved medical castration was comparable to rates of castration observed with LHRH treatment. Castration was achieved in these subjects within three weeks. A surge in serum testosterone levels was not observed in subjects treated with any dose of GTx-758. GTx-758 was well tolerated and no serious adverse events were reported in the study.

"Achieving medical castration in healthy young male volunteers, a population in whom it is more difficult to reduce testosterone to castration levels, provides the scientific evidence of the pharmacologic mechanism of action of GTx-758 and its potential as a new hormonal treatment for advanced prostate cancer," said Mitchell S. Steiner, MD, CEO of GTx.

Additionally, GTx-758 increased serum SHBG, a protein which binds to testosterone, thus further reducing serum free testosterone to levels lower than what is reported to be achievable with LHRH treatment. Free testosterone is the form of testosterone which prostate cancer cells utilize for growth.

"The ability of GTx-758 to reduce serum free testosterone well below levels achieved with standard LHRH therapy may result in improved tumor control in first line therapy as well as allow for the use of GTx-758 for second line hormonal manipulation in men with advanced prostate cancer," said Ronald A. Morton, Jr., Chief Medical Officer of GTx.

In addition to serum levels of total testosterone, SHBG, and free testosterone, GTx also measured luteinizing hormone, follicle stimulating hormone, and bone turnover markers. GTx expects to report full results from this clinical trial at upcoming medical meetings.

In 2011, GTx is planning to initiate additional clinical trials evaluating GTx-758 for first line treatment in men with advanced prostate cancer and second line treatment in men with prostate cancer who have failed LHRH treatment or surgical orchiectomy.

About GTx-758

The standard of care for men with advanced prostate cancer is androgen deprivation therapy (ADT) commonly achieved surgically via bilateral orchiectomy or medically via injection of an LHRH analog. These therapies are associated with symptomatic side effects that can reduce treatment compliance (hot flashes) and result in increased morbidity (bone loss and increased risk of clinical fragility fractures).

As a selective estrogen receptor alpha agonist, GTx-758 has the potential to achieve medical castration by feedback inhibition of the pituitary and hypothalamus without bone loss and hot flashes.

In 2009, GTx evaluated GTx-758 in two Phase I clinical trials. In a single ascending dose study in 96 subjects, GTx-758 was well tolerated and demonstrated a pharmacokinetic profile compatible with daily oral dosing. In a 14 day multiple ascending dose study in 50 subjects, GTx-758 was well tolerated and demonstrated the ability to reduce testosterone and to increase SHBG.

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 and prevention of cancer, the treatment of side effects of anticancer therapy, cancer supportive care, and other serious medical conditions.

In addition to GTx-758, GTx also is developing Ostarine $^{\text{TM}}$ (GTx-024) and other selective androgen receptor modulators, or SARMs, for cancer cachexia and other muscle wasting diseases. GTx is pursuing a partnership for the development of SARMs, which will include our lead SARM, Ostarine, for the treatment of cancer cachexia.

GTx is developing toremifene 80 mg for the reduction of fractures and treatment of other estrogen deficiency side effects of androgen deprivation therapy for prostate cancer. GTx has completed a successful toremifene 80 mg Phase III clinical trial and expects to initiate TREAT2, the second Phase III clinical trial, in the first quarter of 2011.

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 continue to pursue the development of and marketing approval for, and the potential commercialization of, toremifene 80 mg, and the continued development and potential commercialization of GTx's other product candidates. 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 and its collaboration partner will not be able to commercialize their product candidates if clinical trials do not demonstrate safety and efficacy in humans, including in any additional clinical trials that GTx may conduct for toremifene 80 mg to reduce fractures in men with prostate cancer on ADT; (ii) that GTx may not be able to obtain required regulatory approvals to commercialize its product candidates, including toremifene 80 mg to reduce fractures in men with prostate cancer on ADT, in a timely manner or at all; (iii) that clinical trials being conducted or planned to be conducted by GTx and its collaboration partner may not be initiated or completed on schedule, or at all, or may otherwise be suspended or terminated; (iv) related to GTx's dependence on its collaboration partner for product candidate development and commercialization efforts; (v) related to GTx's reliance on third parties to manufacture its product candidates and to conduct its clinical trials; and (vi) 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 SEC on August 9, 2010 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.