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 13, 2013**

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.)

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 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))

ITEM 8.01 Other Events.

On February 13, 2013, GTx, Inc. issued a press release announcing that new data from two Phase II studies on the effects of Capesaris® (GTx-758), a selective estrogen receptor alpha agonist, for the treatment of advanced prostate cancer, will be detailed in presentations given by lead author, Evan Yu, MD, Associate Professor of Medicine, Fred Hutchinson Cancer Research Center, Seattle, Washington on February 14 and 15, at the 2013 American Society of Clinical Oncology (ASCO) Genitourinary (GU) Cancer Symposium in Orlando, Florida. A copy of the press release is furnished as Exhibit 99.1 to this Current Report.

ITEM 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	**Description**
99.1	Press Release issued by GTx, Inc. dated February 13, 2013

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 13, 2013

By: /s/ Henry P. Doggrell
Name: Henry P. Doggrell
Title: Vice President, Chief Legal Officer and Secretary

Novel Findings from Clinical Studies Examining the Effects of Capesaris® (GTx-758) for the Treatment of Advanced Prostate Cancer to be Presented at 2013 American Society of Clinical Oncology Genitourinary Cancer Symposium

MEMPHIS, TN.—February 13, 2013—GTx, Inc. (NASDAQ: GTXI) announced today that new data from two Phase II studies on the effects of Capesaris® (GTx-758), a selective estrogen receptor alpha agonist, for the treatment of advanced prostate cancer, will be detailed in presentations given by lead author, Evan Yu, MD, Associate Professor of Medicine, Fred Hutchinson Cancer Research Center, Seattle, Washington on February 14 and 15, at the 2013 American Society of Clinical Oncology (ASCO) Genitourinary (GU) Cancer Symposium in Orlando, Florida.

“These presentations highlight the significant and novel mechanistic findings of Capesaris,” said Mitchell S. Steiner, MD, Chief Executive Officer of GTx. “The attributes demonstrated in these Phase II studies underscore the drug candidate’s potential to not only treat advanced prostate cancer by lowering testosterone in the microenvironment of prostate cancer cells, but also with fewer estrogen deficiency side effects relative to the standard of care for the treatment of advanced prostate cancer.”

GTx-758 Significantly Reduced Free Testosterone and PSA Levels in Phase II Studies (Abstract #104)

In two Phase II clinical studies in men with advanced prostate cancer, patients receiving either 1000 mg or 2000 mg daily doses of GTx-758 demonstrated significant reductions in their serum free (unbound) testosterone (T) levels, with related reductions in their levels of serum prostatic specific antigen (PSA). One of the trials (705) compared the effects of 1000 mg and 2000 mg doses of GTx-758 in newly diagnosed advanced prostate cancer patients with a cohort of patients receiving leuprolide, an established androgen deprivation treatment (ADT). The primary endpoint of the trial was the proportion of men who achieved castration (i.e., a serum total T level less than 50 ng/dL) by Day 60. In hormone naïve advanced prostate cancer patients, 28 days of 1000 mg or 2000 mg daily GTx-758 or leuprolide therapy achieved castration in 49%, 56% and 94%, respectively. Although lesser reductions in serum total T were observed in men receiving either GTx-758 dose, larger decreases in serum free T were observed in these same men, as compared to leuprolide. Observed reductions in serum PSA at 28 days appear to be more strongly associated with the observed changes in free T, rather than total T, with PSA reductions of 84%, 73% and 56% from baseline for the 1000 mg and 2000 mg doses of GTx-758 and leuprolide, respectively. In men treated with GTx-758, sex hormone binding globulin (SHBG) levels increased approximately 400% and were associated with the decreases in serum free T and serum PSA.

Although ADT has been utilized for decades, it has become apparent that, in many men, the levels of serum total T do not reach the levels which some currently consider to be castrate (20 ng/dL vs 50 ng/dL) and that residual levels of serum free T, the biologically active, unbound form of the hormone, remain present at significant levels, potentially promoting clinical progression of their prostate cancer. The literature suggests the concept that a maximal suppression of serum free T would benefit men with advanced prostate cancer. In GTx’s Phase

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II clinical studies, the reductions in free T that were observed with GTx-758 were greater than those observed with leuprolide. Men treated with GTx-758 were shown to have increased levels of SHBG and rapidly lowered free T (within 7 days), as well as decreased PSA values, suggesting that serum levels of free T may be critical to measure as an indicator of therapeutic efficacy in men with advanced prostate cancer. In the studies being presented, GTx-758 lowered free T in both primary and secondary ADT of advanced prostate cancer. These Phase II studies were stopped early due to an undesired rate of venous thromboembolic events (VTEs). Based upon evaluations observed in Phase I and II clinical studies, GTx believes significant increases in SHBG can result from lower doses of GTx-758 to provide a more maximal castration by lowering levels of free T.

GTx-758 Ameliorates Hot Flashes Observed in Men on ADT (Abstract #129)

The effects of GTx-758 and leuprolide on hot flashes, a common side effect in men on ADT, were assessed in 99 evaluable patients (of a total of 159 newly diagnosed patients with advanced prostate cancer) who reached 90 days of treatment. While baseline data showed no significant differences in the number of men reporting hot flashes in any of the treatment groups, the percentage of men experiencing a hot flash while receiving leuprolide increased significantly to 60.4% by day 28, and further increased to 80.9% by day 90. Reports from subjects experiencing hot flashes while receiving GTx-758 were significantly lower, with 18.8% and 5.6% of the men receiving the 1000 mg and 2000 mg doses of GTx-758, respectively, experiencing hot flashes by 90 days. Therefore GTx-758 appears to have a low rate of hot flashes in GTx-758 treated men compared with almost all men on leuprolide experiencing this side effect.

GTx-758 Has a Positive Effect on Biomarkers of Bone Turnover (Abstract #222)

As a result of advanced prostate cancer patients being treated for longer periods of time with ADT, estrogen deficiency side effects, including a loss of bone and a higher incidence of fractures, has become a serious side effect of ADT. The effects of GTx-758 and leuprolide on markers of bone turnover, C-terminal telopeptides (CTX) and bone specific alkaline phosphatase, were evaluated in men with advanced prostate cancer in a Phase II study. In men receiving GTx-758 1000 mg or 2000 mg daily dose treatment compared with the standard leuprolide ADT, the 1000 mg and 2000 mg doses of GTx-758 had reductions of greater than 50% for CTX levels, as compared to an almost 50% increase in the men receiving leuprolide. Similarly, bone specific alkaline phosphate levels were lower by approximately 20% in men treated with GTx-758, compared with an increase of 8% in the leuprolide treated group. These findings indicate that not only was bone maintained in the men treated with GTx-758, but improved during their course of treatment, as opposed to those treated with leuprolide, in which most of whom, despite the relatively short course of treatment, appear to have significant bone turnover and therefore bone loss.

“Since changes in bone mineral density are a significant side effect that can negatively affect the health of men on ADT, improvements in bone turnover observed in men treated with GTx-758 could be significant,” said Dr. Steiner.

GTx-758 Decreases Serum IGF-1 levels in Men with Advanced Prostate Cancer (Abstract #171)

Serum insulin-like growth factor-1 (IGF-1) has been implicated in the development of prostate cancer as serum IGF-1 levels have been associated with advanced disease, and IGF-1 is an indirect measure of metabolic syndrome. IGF-1 levels were measured and compared among

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patients receiving the 1000 and 2000 mg doses of GTx-758 and leuprolide (n=159), in a Phase II study of men with advanced prostate cancer. Through day 90, men receiving the 1000 mg and 2000 mg doses of GTx-758 showed IGF-1 levels decreased from baseline by more than 70 ng/ml (greater than 50%),

while levels stayed constant or increased in men being treated with leuprolide.

New GTx-758 Phase II Study Underway

GTx is currently conducting a Phase II clinical trial (G200712) to evaluate the safety and effectiveness of lower doses of GTx-758 to treat men with metastatic castration resistant prostate cancer. Seventy-five men with metastatic castration resistant prostate cancer will be randomized into one of three cohorts to receive a 125 mg, 250 mg or 500 mg daily dose of GTx-758. Each arm will have 25 subjects, and the enrollment will be conducted sequentially, with the 125 mg cohort currently being enrolled. The enrollment into the next higher dose of GTx-758 will commence if an acceptable incidence of VTEs is observed among randomized patients for 30 days following enrollment of the last patient in the previous cohort. The primary endpoint will be to lower serum PSA by $\geq$ 50% by day 90. Other key endpoints include free T levels, SHBG levels, serum PSA progression as well as time to tumor progression and progression free survival, in these study subjects. In addition, the study will evaluate the ability of GTx-758 to treat certain estrogen deficiency side effects associated with medical castration such as hot flashes, bone loss, and insulin resistance.

General Poster Session
Thursday, February 14, 2013
11:45am-1:15pm and 5:05 pm – 6:35 pm
Gatlin Ballroom B
Presenter: Evan Yu

Abstract #104
GTx-758, an ERα Agonist, Reduces Serum Free Testosterone and Serum PSA in Men with Advanced Prostate Cancer Yu EY, Gittelman M, Keane T, Tutrone R, Belkoff L, Given R, Bass J, Chu F, Gambla M, Gaylis F, Bailen J, Getzenberg RH, Coss CC, Hancock ML, Dalton JT, Steiner MS

Abstract #129
Advanced prostate cancer patients treated with GTx-758 have a significantly lower rate of hot flashes
Yu EY, Gittelman M, Keane T, Tutrone R, Belkoff L, Given R, Bass J, Chu F, Gambla M, Gaylis F, Bailen J, Getzenberg RH, Coss CC, Hancock ML, Dalton JT, Steiner MS

Abstract # 171
Serum IGF-1 levels are decreased in men with advanced prostate cancer treated with the ERα agonist, GTx-758
Yu EY, Gittelman M, Keane T, Tutrone R, Belkoff L, Given R, Bass J, Chu F, Gambla M, Gaylis F, Bailen J, Getzenberg RH, Coss CC, Hancock ML, Dalton JT, Steiner MS

General Poster Session
Friday, February 15, 2013
12:15pm-1:45pm and 5:15 PM-6:45 PM
Gatlin Ballroom B
Presenter: Evan Yu

Abstract #222
The ERα agonist, GTx-758, decreases bone turnover markers in men with advanced prostate cancer
Yu EY, Gittelman M, Keane T, Tutrone R, Belkoff L, Given R, Bass J, Chu F, Gambla M, Gaylis F, Bailen J, Getzenberg RH, Coss CC, Hancock ML, Dalton JT, Steiner MS

About GTx

GTx, Inc., headquartered in Memphis, Tenn., is a biopharmaceutical company dedicated to the discovery, development and commercialization of small molecules 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 involve risks and uncertainties, and include, but are not limited to, statements relating to clinical studies of GTx-758. 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 being conducted by GTx may not be completed on schedule, or at all, or may otherwise be suspended or terminated; or (iv) 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 November 8, 2012 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.

GTx, Inc.
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