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) May 8, 2012

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** **(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 (*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))

ITEM 8.01 **Other Events.**

On May 8, 2012, GTx, Inc. issued a press release announcing that the Food and Drug Administration (FDA) removed its Full Clinical Hold on the Company's Investigational New Drug application for Capesaris® following the review by the FDA of the Company's complete response and its new Phase II clinical protocol. 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 May 8, 2012

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: May 8, 2012

By: /s/ Henry P. Doggrell

Name: Henry P. Doggrell

Title: Vice President, General Counsel and Secretary

GTx Announces Removal of Full Clinical Hold By FDA for Capesaris®
In Advanced Prostate Cancer

MEMPHIS, TN.—May 8, 2012 — GTx, Inc. (Nasdaq: GTXI) announced today that the Food and Drug Administration (FDA) removed its Full Clinical Hold on the Company's Investigational New Drug application for Capesaris® following the review by the FDA of the Company's complete response and its new Phase II clinical protocol. GTx plans to initiate during the third quarter this Phase II open label clinical study of 75 men with metastatic castration resistant prostate cancer to test three lower doses of Capesaris (125 mg, 250 mg and 500 mg) sequentially in cohorts of 25 patients each.

The Phase II clinical study will evaluate the safety and efficacy of Capesaris as secondary hormonal therapy in men with metastatic castration resistant prostate cancer. The study will assess the effect of oral daily doses of Capesaris on serum prostate specific antigen response and prostate cancer progression in men with metastatic castration resistant prostate cancer maintained on primary androgen deprivation therapy (ADT). The study is also designed to provide confirmation of the mechanism of drug action for Capesaris on lowering serum free testosterone levels by increasing serum SHBG. Other key endpoints that will be evaluated in the study include effects on the levels of adrenal androgen precursors, as well as the incidence and frequency of hot flashes and bone loss, which are estrogen deficiency related side effects of ADT. The safety and tolerability of these lower doses of Capesaris will also be evaluated in these subjects, including the incidence of venous thromboembolic events.

Conference call

There will be a conference call today at 9:00 a.m. Eastern Time to discuss this press release and to provide a Company update. To listen to the conference call, please dial 800-299-6183 from the United States or Canada or 617-801-9713 from other international locations. The access code for the call is 32206083. A playback of the call will be available from approximately 11:00 a.m. Eastern Time today through May 22, 2012 and may be accessed by dialing 888-286-8010 from the United States or Canada or 617-801-6888 from other international locations and referencing reservation number 74903062. 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, 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 involve risks and uncertainties, and include, but are not limited to, statements relating to its planned clinical trial of Capesaris® (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 annual report on Form 10-K filed with the Securities and Exchange Commission on March 2, 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:
Marc Hanover, President
GTx, Inc.
901-523-9700