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 21, 2012

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, including 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 February 21, 2012, GTx, Inc. issued a press release announcing that the U.S. Food and Drug Administration (FDA) notified the Company in a telephone call on Friday, February 17, 2012, that the agency has placed a clinical hold on the Company's clinical trials evaluating Capesaris® (GTx-758) for primary (first line) androgen deprivation therapy for advanced prostate cancer and secondary (second line) hormonal treatment. A clinical hold is a notification issued by the FDA to the trial sponsor to delay a clinical trial or suspend an ongoing clinical trial. A copy of the press release is furnished as Exhibit 99.1 to this Current Report.

ITEM 9.01 Financial Statements and Exhibits.

(c) Exhibits

Exhibit Number	Description
99.1	Press Release issued by GTx, Inc. dated February 21, 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: February 21, 2012

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

GTx Announces Clinical Hold on Clinical Trials Evaluating Capesaris® for First and Second Line Treatments of Advanced Prostate Cancer

MEMPHIS, Tenn.—February 21, 2012—GTx, Inc. (Nasdaq: GTXI) announced today that the U.S. Food and Drug Administration (FDA) notified the Company in a telephone call on Friday, February 17, 2012, that the agency has placed a clinical hold on the Company's clinical trials evaluating Capesaris® (GTx-758) for primary (first line) androgen deprivation therapy for advanced prostate cancer and secondary (second line) hormonal treatment. A clinical hold is a notification issued by the FDA to the trial sponsor to delay a clinical trial or suspend an ongoing clinical trial.

The clinical hold affects GTx's Phase II loading dose finding clinical trial and its Phase IIb maintenance dose finding clinical trial, as well as its Phase II clinical trial in men with castration resistant prostate cancer. The clinical hold, which is effective immediately, follows the Company's reports to the FDA of an increased risk of venous thromboembolic events, or blood clots, in subjects treated with Capesaris at the doses studied (1000 mg and higher) and the Company's request to discuss changes in its clinical development program. GTx has suspended further enrollment into these studies and has notified clinical sites to discontinue treatment of subjects.

The Company believes there may be a path forward to develop Capesaris at lower doses to treat men with metastatic hormone sensitive prostate cancer or castration resistant prostate cancer. The Company will work with the FDA to determine the appropriate course of action to evaluate Capesaris in these patient populations.

Conference call

There will be a conference call today at 9:00 a.m. Eastern Time to discuss this latest development, provide a corporate update and discuss the Company's fourth quarter and full year 2011 financial results. To listen to the conference call, please dial 866-356-4279 from the United States or Canada or 617-597-5394 from other international locations. The access code for the call is 91296419. A playback of the call will be available from approximately 11:00 a.m.

Eastern Time today through March 6, 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 84768366. 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.

Please note that the conference call previously announced to provide a corporate update and discuss the Company's fourth quarter and full year 2011 financial results to take place at 9:00 a.m. Eastern Time on Wednesday, February 22, 2012 has been cancelled.

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 whether there may be a path forward to develop Capesaris® at lower doses to treat men with metastatic hormone sensitive prostate cancer or castration resistant prostate cancer, the timing of discussions with the FDA regarding the current clinical hold and whether or under what additional requirements, if any, further clinical development will be permitted. 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, similar to the clinical hold announced today on Capesaris, 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 4, 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.

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