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) April 4, 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	**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):

☐ 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 April 4, 2012, GTx, Inc. issued a press release announcing that the Company has submitted to the U.S. Food and Drug Administration (FDA) a complete response to the FDA's letter regarding the previously announced Full Clinical Hold of the Company's clinical trials evaluating Capesaris® (GTx-758) for primary (first line hormonal) androgen deprivation therapy for advanced prostate cancer and secondary (second line) hormonal therapy. 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 April 4, 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: April 4, 2012

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

Exhibit 99.1

GTx Submits Clinical Hold Complete Response Letter To FDA For Its Planned Phase II Clinical Study Of Capesaris® For Secondary Hormonal Therapy of Advanced Prostate Cancer

MEMPHIS, Tenn.—April 4, 2012 — GTx, Inc. (Nasdaq: GTXI) announced today that the Company has submitted to the U.S. Food and Drug Administration (FDA) a complete response to the FDA's letter regarding the previously announced Full Clinical Hold of the Company's clinical trials evaluating Capesaris® (GTx-758) for primary (first line hormonal) androgen deprivation therapy for advanced prostate cancer and secondary (second line) hormonal therapy. The FDA's letter specified the information required by the FDA for the Company to resolve the safety related clinical hold deficiency seen in its recent clinical studies before the Company can initiate further clinical studies of Capesaris. The Company's response provides the information requested by the FDA and includes its development plans for Capesaris as a secondary hormonal therapy for advanced prostate cancer at doses lower than those previously tested by the Company. Assuming the FDA determines the Company's response to be a Complete Response to its Full Clinical Hold letter by adequately addressing the FDA's request for information to resolve the clinical hold deficiency, the FDA has stated that it will provide the Company a decision whether to lift the clinical hold on further Capesaris development within thirty (30) days of the Company's submission.

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 as a second line hormonal therapy to treat men with advanced prostate cancer and the timing of discussions with the FDA regarding the current clinical hold on Capesaris clinical development 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 previously announced clinical hold 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 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