

GTX INC /DE/
Form 8-K
March 02, 2011

**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): March 1, 2011

GTx, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other Jurisdiction of
Incorporation)

000-50549

(Commission File Number)

62-1715807

(IRS 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:

- 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 1.02. Termination of a Material Definitive Agreement.

Effective March 1, 2011, GTx, Inc. (the “Company”) and Ipsen Biopharm Limited (“Ipsen”) mutually agreed to terminate the Collaboration and License Agreement, dated September 7, 2006, by and between the Company and Ipsen, as amended by the First Amendment to the Collaboration and License Agreement, dated March 22, 2010, by and between the Company and Ipsen (as amended, the “Collaboration Agreement”). Pursuant to the mutual agreement of the parties, the Collaboration Agreement was terminated effective immediately. In connection with the termination of the Collaboration Agreement, and in exchange for the Company reacquiring all of Ipsen’s rights under the Collaboration Agreement, the Company agreed to pay Ipsen a low single digit royalty on net sales of toremifene 80 mg in the United States if approved for commercial sale pursuant to a letter agreement between the parties dated as of February 25, 2011 memorializing the termination (the “Termination Letter Agreement”).

Pursuant to the terms of the Collaboration Agreement, the Company had granted Ipsen exclusive rights initially in the European Union, Switzerland, Norway, Iceland, Lichtenstein, and the Commonwealth of Independent States (the “European Territory”) to develop and commercialize toremifene in all indications (except the treatment and prevention of breast cancer outside of the United States). In accordance with the terms of the Collaboration Agreement, Ipsen paid the Company €23.0 million as a license fee and expense reimbursement. In February 2008, the Company earned a milestone of €1.0 million with the achievement of the primary endpoint in the Company’s Phase III clinical trial of toremifene 80 mg.

In March 2010, the Company and Ipsen amended the Collaboration Agreement primarily to expand the collaboration for the development and commercialization of toremifene 80 mg, and to potentially fund a second pivotal Phase III clinical trial of toremifene 80 mg. In accordance with the terms of the Collaboration Agreement, Ipsen had agreed to pay the Company up to €42.0 million in clinical development milestones for the purpose of conducting a second pivotal Phase III clinical trial evaluating toremifene 80 mg to reduce fractures in men with prostate cancer on androgen deprivation therapy, or ADT. In exchange for Ipsen’s commitment to fund a second toremifene 80 mg ADT Phase III clinical trial, the Company had granted Ipsen certain additional rights, including an expansion of the territory in which Ipsen had the right to develop and commercialize toremifene beyond the European Territory to include Australia and certain countries in North Africa, the Middle East and Asia (excluding Japan), (collectively, the “Ipsen Territory”). In addition, the Company had granted Ipsen the right to co-promote the Company’s toremifene 80 mg product candidate for the ADT indication in the United States or, at Ipsen’s election in lieu of co-promotion, the right to receive a declining, tiered royalty on net sales of the Company’s toremifene 80 mg product candidate for the ADT indication in the United States starting at approximately one-third of net sales. The Company had also granted Ipsen the right of first negotiation, subject to certain conditions, with respect to development, marketing, sale and distribution in the Ipsen Territory of Capesaris™. Ipsen had also agreed to pay a portion of the Company’s toremifene 20 mg development costs in the United States, if certain conditions had been met, and had agreed to pay the Company up to an aggregate of €20.0 million in milestone payments depending on the successful development and launch of toremifene 20 mg in certain countries of the Ipsen Territory, subject to certain conditions and Ipsen’s election to retain its rights to commercialize toremifene and other products containing toremifene for the prevention of prostate cancer in high risk men with high grade prostatic intraepithelial neoplasia (or, in lieu thereof, a reduction in the royalty payable by the Company on net sales of the Company’s toremifene 80 mg product candidate for the ADT indication in the United States). Ipsen had also agreed to pay the Company a royalty equal to a graduating percentage starting in the mid-teens of aggregate net sales in the Ipsen Territory of the Company’s toremifene 20 mg product candidate, and a fixed percentage (12%) of aggregate net sales in the Ipsen Territory of the Company’s toremifene 80 mg product candidate for the ADT indication. As a result of the termination of the Collaboration Agreement, the Company will not any receive any further payments or any royalties from Ipsen provided for under the Collaboration Agreement.

The foregoing is only a brief description of the material terms of Collaboration Agreement and the Termination Letter Agreement, does not purport to be complete, and is qualified in its entirety by reference to (i) the original

Collaboration Agreement and the amendment thereto, which were filed as Exhibit 10.37 to the Company's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission on November 3, 2006, and Exhibit 10.56 to the Company's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission on May 4, 2010, respectively, and (ii) the Termination Letter Agreement which will be filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ending March 31, 2011.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

GTx, Inc.

Dated: March 2, 2011

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