## 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): September 7, 2006

# GTx, Inc.

(Exact name of registrant as specified in its charter)

#### **Delaware**

(State or other jurisdiction of incorporation)

**Delaware** (State or Other Jurisdiction of Incorporation)

000-50549

(Commission File Number)

**62-1715807** (IRS Employer Identification No.)

3 N. Dunlap Street
Van Vleet Building
Memphis, Tennessee 38163
(Address of principal executive offices, including Zip Code)

Registrant's telephone number, including area code: (901) 523-9700

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)
- 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 1.01. Entry into a Material Definitive Agreement.

Effective September 7, 2006, GTx, Inc. ("GTx") entered into a Collaboration and License Agreement (the "Agreement") with Ipsen Limited ("Ipsen"), a wholly owned subsidiary of the Ipsen Group, pursuant to which GTx granted Ipsen exclusive rights to develop and commercialize ACAPODENE® (toremifene citrate), a selective estrogen receptor modulator, or SERM, and other products containing toremifene in all indications except the treatment and prevention of breast cancer in the European Union, Switzerland, Norway, Iceland, Lichtenstein, and the Commonwealth of Independent States (collectively, the "European Territory"). Each party has also granted to the other a right of first negotiation with respect to the development, marketing, sale and distribution of any new SERM-based products for the field of the prevention and treatment of prostate cancer or related side effects, or any other indication the parties may agree on.

Pursuant to the Agreement, Ipsen has agreed to pay GTx €23.0 million in upfront payments and fees, of which €1.5 million will be paid in equal installments over a three year period. Pursuant to the Agreement, GTx is entitled to receive from Ipsen up to an aggregate of €39.0 million in milestone payments depending on the successful development and launch of ACAPODENE in certain countries of the European Territory for the prostatic intraepithelial neoplasia indication ("HGPIN Indication"), subject to certain conditions, and/or the androgen deprivation therapy indication ("ADT Indication"). Such €39.0 million in aggregate payments may be comprised of up to €9.0 million for the ADT Indication, up to €20.0 million for the HGPIN Indication and up to €10.0 million as additional milestone payments for either the HGPIN Indication or the ADT Indication. Ipsen has agreed to be responsible for and to pay for all clinical development, regulatory and launch activities to commercialize ACAPODENE in the European Territory for both the HGPIN Indication and ADT Indication. GTx will remain similarly responsible for all development and regulatory activities outside of the European Territory. However, Ipsen has agreed to pay a portion of GTx's ACAPODENE development costs in the United States if certain conditions are met. Under the Agreement, Ipsen must elect to retain its rights to commercialize ACAPODENE and other products containing toremifene for the HGPIN Indication. Regardless of whether Ipsen makes this election, Ipsen is responsible for carrying out the development of the HGPIN Indication in the European Territory and must pay for costs associated with Ipsen's development in the European Territory. Depending on when Ipsen exercises this election, Ipsen may be required to pay an additional license fee as well as a premium on its share of the past development and clinical trial expenses incurred by GTx in the United States. If Ipsen does not exercise its election within a certain period, Ipsen will not be obligated to pay GTx for a portion of past development and clinical trial expenses incurred by GTx in the United States in connection with the HGPIN Indication, and GTx may terminate Ipsen's rights to commercialize products for this indication, and all of Ipsen's rights to ACAPODENE for the HGPIN Indication (including all associated clinical trial data and regulatory filings and approvals) will revert to GTx. With respect to royalty obligations, Ipsen has agreed to pay GTx graduating royalty rates on net sales of products containing toremifene (including ACAPODENE) in the mid-teens, which could reach the mid-twenties based on certain sales price thresholds being met, and which rates will be dependent on whether such sales are for the HGPIN Indication or the ADT Indication. GTx will remain responsible for paying upstream royalties to Orion Corporation and the University of Tennessee Research Foundation. The royalty payments provided for under the Agreement are subject to certain reductions in connection with generic drug competition or if Ipsen is required to license third party patent rights in order to commercialize and sell products in a certain country that would otherwise infringe upon such third party patent rights. In addition, in the event that it is not commercially reasonable for Ipsen to launch a product in a particular country, then Ipsen may be released from its obligation to commercialize the product in that country. Ipsen will purchase the bulk material from a third party and is responsible for the packaging and labeling of the final product.

Pursuant to the Agreement, GTx and Ipsen will have equal representation on a joint development committee, which will meet at least once each calendar quarter to discuss each party's development and commercialization plans in their respective territories. The joint development committee will make recommendations regarding each party's initial development plans and associated budgets in their specific territories, as well as regarding joint development plans and associated budgets. In the event that the joint development committee is unable to agree on matters relating to initial development activities conducted by GTx which are intended to support initial development activities conducted by Ipsen in the European Territory, then Ipsen shall have the right not to fund its designated percentage of such joint development expenses. The joint development committee shall also serve as the forum in which the parties may discuss the development and commercialization of subsequent improvements to products licensed under the Agreement.

The development and commercialization portions of the Agreement will terminate when the parties cease to develop and commercialize toremifene-based products in the European Territory, while the provisions relating to commercialization will continue until Ipsen is no longer obligated to pay royalties to GTx. GTx and Ipsen may terminate the Agreement for an uncured material breach by the other party and for certain bankruptcy-related events. Ipsen may also terminate the Agreement upon prior notice under certain other circumstances.

The foregoing summary of the Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the Agreement, which will filed as an exhibit to GTx's Quarterly Report on Form 10-Q for the quarterly period ending September 30, 2006.

### **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: September 12, 2006 By: /s/ Mark E. Mosteller

Mark E. Mosteller,

Vice President and Chief Financial Officer