## [GTx LETTERHEAD]

December 21, 2010

## VIA EDGAR

United States Securities and Exchange Commission Division of Corporation Finance 100 F Street, N.E. Washington, D.C. 20549

Attn: Jeffrey Riedler

Johnny Gharib Jennifer Riegel

Re: GTx, Inc. Form 10-K

> Filed March 15, 2010 File No. 000-50549

#### Ladies and Gentlemen:

On behalf of GTx, Inc. (the "Company"), this letter is being transmitted in response to comments received from the staff (the "Staff") of the Securities and Exchange Commission (the "Commission") by letter dated December 15, 2010 (the "Comment Letter") regarding (i) the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2009, filed with the Commission on March 15, 2010 (the "Form 10-K") and (ii) the Company's Definitive Proxy Statement on Schedule 14A, filed with the Commission on March 18, 2010 (the "Proxy Statement"). The text of the Staff's comments has been included in this response letter in italics for your convenience, and the numbering of the paragraphs below correspond to the numbering of the Comment Letter.

## Form 10-K, filed March 15, 2010

### Licenses and Collaborative Relationships, page 14

1. You disclose that you have upfront and milestone payments, annual license fees and/or royalty payments in connection with your license and supply agreement with Orion and your license agreements with UTRF. Although you have been granted confidential treatment for certain provisions of these agreements, the material terms of these agreements should be disclosed in your filing. Please provide draft disclosure to be in included in your 2010 Form 10-K describing the material terms of each agreement, including, but not limited to the aggregate payments to date, a range of royalty rates not to exceed ten percent and the remaining aggregate milestone payments.

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## Response:

The Company respectfully submits that it has disclosed the material terms of its license and supply agreement with Orion and its license agreements with UTRF beginning on page 14 of the Form 10-K, including a description in each case of the aggregate upfront fees and payments made to each of Orion and UTRF. The Company also advises the Staff that the Company does not have any remaining milestone payments due to either Orion or UTRF under these agreements (apart from its royalty payment obligations). In addition, while the Company continues to pay royalties to Orion with respect to FARESTON® net sales, FARESTON® revenue is not significant and therefore disclosure of aggregate royalty payments to Orion with respect to FARESTON® net sales would not provide additional material information relevant to an investor's investment decision with respect to the Company's securities. Likewise, the Company's annual license maintenance fees due to UTRF are not material and disclosure of these amounts would therefore not provide additional material information relevant to an investor's investment decision with respect to the Company's securities. In response to the Staff's comment, however, the Company will revise its disclosure of the Orion and UTRF agreements to describe the royalty rate or range of royalty rates, as applicable, that are payable pursuant to such agreements, as well as the aggregate royalties paid to date on material sublicense revenue or material product revenue (to the extent we have received any such amounts as of the applicable reporting period) in future filings, as reflected in the updated proposed disclosure for the Company's 2010 Form 10-K under the heading "Business—Licenses and Collaborative Relationships" as set forth on Exhibit A attached hereto.

The Company also respectfully notes that it may in the future determine that any of its agreements with Orion or UTRF are no longer material to its business. To the extent that the Company makes such a determination, the Company may determine that it is no longer appropriate or necessary to include disclosure of the material terms of such agreements in its annual reports on Form 10-K or other SEC filings.

# Intellectual Property, page 19

- We note that with respect to the method of use of toremifene 80 mg and the method of use of toremifene 20 mg outside of the United States, you have some patents issued and other pending patent applications. Please provide draft disclosure to be included in your 2010 Form 10-K stating the foreign countries where these patents are issued and where other patent applications are pending and the expiration dates of the issued foreign patents in regard to each product.
- 3. We note that for Ostarine and your other SARMs, you have an exclusive license from UTRF for two sets of its issued patents and pending patent applications in the United States and internationally. Please provide draft disclosure to be included in your 2010 Form 10-K stating the expiration dates for the United States and foreign patents and the countries in which the foreign patents have been issued or patent applications are pending.

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## Response:

In response to the Staff's comment, commencing with the Company's 2010 Form 10-K, the Company will enhance its disclosure under the heading "Business—Intellectual Property" with respect to toremifene and SARMs as reflected in the enhanced proposed disclosure as set forth on **Exhibit B** attached hereto.

The Company also respectfully notes that it may in the future determine to discontinue its development and any commercialization activities related to toremifene or SARMs and therefore determine that such product candidates and the related patents and patent applications are no longer material to its business. To the extent that the Company makes such a determination, the Company may determine that it is no longer appropriate or necessary to include disclosure related to such patents and patent applications in its annual reports on Form 10-K or other SEC filings.

### Proxy Statement on Schedule 14A, filed March 18, 2010

4. We note that you have not included any disclosure in response to Item 402(s) of Regulation S-K. Please advise us of the basis for your conclusion that disclosure is not necessary and describe the process you undertook to reach that conclusion.

### Response:

The Company respectfully advises the Staff that the Company included disclosure in response to Item 402(s) under the caption "Compensation and Risk" on page 46 of the Proxy Statement to describe for investors why the Company believes that its compensation policies and practices do not encourage excessive or inappropriate risk-taking by its employees and are therefore not reasonably likely to have a material adverse effect on the Company. The Company reached this disclosure conclusion in connection with the preparation of the Proxy Statement after consideration of each element of its compensation program and an analysis of whether that element (individually or collectively) would incent Company employees to undertake excessive or inappropriate risk-taking.

Where applicable in future filings, the Company will provide appropriate disclosures pursuant to Item 402(s) of Regulation S-K if the Company determines that the risks arising from its compensation policies and practices for its employees are reasonably likely to have a material adverse effect on the Company.

\* \* \* \*

## The Company further acknowledges that:

- the Company is responsible for the adequacy and accuracy of the disclosure in the filings;
- Staff comments or changes to disclosure in response to Staff comments do not foreclose the Commission from taking any action with respect to the filings; and

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• the Company may not assert Staff comments as a defense in any proceeding initiated by the Commission or any person under the federal securities laws of the United States.

Please do not hesitate to contact me at (901) 507-6916 or Chad Mills at (650) 843-5654 of Cooley LLP, outside counsel to the Company, if you have any questions or would like additional information regarding these matters.

Sincerely,

/s/ Henry P. Doggrell

Henry P. Doggrell Vice President and General Counsel GTx, Inc.

cc: Mitchell S. Steiner, Chief Executive Officer
Marc S. Hanover, President and Chief Operating Officer
Chadwick L. Mills, *Cooley LLP* 

#### **EXHIBIT A**

## **Orion Corporation**

In March 2000, we entered into a license and supply agreement with Orion to develop and commercialize products containing toremifene. Our rights under the original license agreement were limited to specific disease fields pertaining to prostate cancer. In December 2004, we entered into an agreement with Orion to purchase specified FARESTON® related assets which Orion had re-acquired from another licensee. We also entered into an amended and restated license and supply agreement in January 2005 with Orion which replaced the original license agreement. We paid Orion approximately \$5.2 million under the 2004 agreements for the assets and related license rights.

Under the amended and restated license and supply agreement, we obtained an exclusive license from Orion to develop and commercialize toremifene-based products for all human indications worldwide, except breast cancer outside of the United States. We are required to pay Orion a portion of certain types of upfront and milestone income that we receive from third-party sublicensees, after we recover our clinical development costs, and a low double-digit royalty on sales by us and our affiliates of FARESTON® for breast cancer in the United States. We are also required to pay Orion a low double-digit royalty on sales by us, our affiliates and third-party sublicensees of other toremifene-based products, including toremifene 80 mg and toremifene 20 mg if approved for commercial sale. Our license and supply agreement with Orion requires that Orion will manufacture and supply all of our and our sublicensees' needs for clinical trial and commercial grade material for toremifene-based products developed and marketed in the United States and abroad, including toremifene globally and FARESTON® in the United States. Orion has the right to terminate its supply obligations at its election at any time as a result of our failure to obtain regulatory approval of one of our toremifene product candidates in the United States prior to December 31, 2009, in which event we will have the right to enter into a contract manufacturing agreement with another supplier for toremifene-based products. However, any arrangements we make for an alternative supply would have to be made with a qualified alternative supplier with appropriate FDA approval in order for us to obtain our supply requirements for toremifene. The term of the amended and restated license and supply agreement lasts, on a country-by-country basis, until the later of expiration of our own patents claiming the processes or the methods of use of toremifene for prostate cancer or the end of all marketing or regulatory exclusivity which we may obtain for toremifene-based products. The term of our method of use patents pertaining to toremifene for prostate cancer extend from 2019 to 2022. Orion may terminate the amended and restated license and supply agreement, on a country-by-country basis, as a result of our uncured material breach, including under certain circumstances if we decided not to commercially launch toremifene in any major country after we obtain regulatory approval in such country, or our bankruptcy. Following the termination of the amended and restated license and supply agreement by Orion for our material breach, we will grant a royalty-bearing license to Orion to enable Orion to continue the development and commercialization of toremifene-based products in the countries in which the agreement is terminated.

# University of Tennessee Research Foundation

In July 2007, we and UTRF entered into a consolidated, amended and restated license agreement, or the SARM License Agreement, to consolidate and replace our two previously existing SARM license agreements with UTRF and to modify and expand certain rights and obligations of each of the parties under both license agreements. Pursuant to the SARM License Agreement, we were granted exclusive worldwide rights in all existing SARM technologies owned or controlled by UTRF, including all improvements thereto, and exclusive rights to future SARM technology that may be developed by certain scientists at the University of Tennessee or subsequently licensed to UTRF under certain existing inter-institutional agreements with The Ohio State University. Unless terminated earlier, the term of the SARM License Agreement will continue, on a country-by-country basis, for the longer of 20 years or until the expiration of the last valid claim of any licensed patent in the particular country in which a licensed product is being sold. UTRF may terminate the SARM License Agreement for our uncured breach or upon our bankruptcy.

In September 2007, we and UTRF entered into an amended and restated license agreement, or the SERM License Agreement, to replace our previously existing exclusive worldwide license agreement for toremifene. Pursuant to the SERM License Agreement, we were granted exclusive worldwide rights to UTRF's method of use patents relating to SERMs, including toremifene for chemoprevention of prostate cancer as well as future related SERM technologies that may be developed by certain scientists at the University of Tennessee. Unless terminated earlier, the term of the SERM License Agreement will continue, on a country-by-country basis, in a particular country for the longer of 20 years from the effective date of our previously existing exclusive worldwide license agreement with UTRF for toremifene or until the expiration of the last valid claim of any licensed patent in such country. UTRF may terminate the SERM License Agreement for our uncured breach or upon our bankruptcy.

Under the SARM License Agreement and the SERM License Agreement, or together, the UTRF License Agreements, we paid UTRF a onetime, upfront fee of \$290,000 per UTRF License Agreement as consideration for entering into the UTRF License Agreements. We are also obligated to pay UTRF annual license maintenance fees and low to mid single digit royalties on sublicense revenues and net sales of products. During the year ended December 31, 2007, we paid UTRF a sublicense royalty of approximately \$1.9 million as a result of our previous collaboration with Merck. We also agreed to pay all expenses to file, prosecute and maintain the patents relating to the licensed SARM and SERM technologies, and are obligated to use commercially reasonable efforts to develop and commercialize products based on the licensed SARM and SERM technologies.

In December 2008, we and UTRF amended the UTRF License Agreements, or together, the License Amendments, to, among other things, clarify the treatment of certain payments that we may receive from our current and future sublicensees for purposes of determining sublicense fees payable to UTRF, including the treatment of payments made to us in exchange for the sale of our securities in connection with sublicensing arrangements. In consideration for the execution of the License Amendments, we paid UTRF an aggregate of \$540,000.

### **EXHIBIT B**

For toremifene in the United States and internationally, we have entered into an amended and restated license and supply agreement with Orion Corporation granting us an exclusive license under Orion's patents covering the composition of matter of toremifene for all uses in humans in the United States, and for all human uses outside the United States other than the treatment and prevention of breast cancer. However, Orion's patent for toremifene expired in the United States in September 2009 and foreign counterparts of this patent also have expired. As a result, we will need to rely primarily on the protection afforded by the method of use patents that either have been already issued or may later issue from our owned or licensed patent applications.

We have licensed from UTRF method of use patents and pending patent applications for specific disease indications and doses in the United States, and have licensed issued and pending patent applications in a number of countries in Europe, Asia and in other jurisdictions internationally related to the use of toremifene 20 mg for the reduction in the incidence of prostate cancer in high risk men with high grade PIN. The method of use patents issued in the United States related to the use of toremifene for this indication that we licensed from UTRF will expire between 2019 and 2022. The method of use patents that we licensed from UTRF related to the use of toremifene for this indication and issued outside of the United States will expire between 2019 and 2020.

We have our own method of use patents and patent applications in the United States and in a number of countries in Europe, Asia and in other jurisdictions internationally related to the use of toremifene 80 mg for the treatment of osteoporosis and reduction of fractures in men with prostate cancer treated by ADT, as well as other side effects from ADT such as gynecomastia and hot flashes. Our method of use patent issued in the United States related to the use of toremifene for the treatment of ADT-induced osteoporosis and fractures in men with prostate cancer will expire in 2022. Our method of use patents issued outside of the United States related to the use of toremifene 80 mg for the treatment of osteoporosis and fractures and other side effects of ADT in men with prostate cancer will also expire in 2022. We own pending patent applications in the United States and a number of countries in Europe, Asia and in other jurisdictions internationally related to the method of use of toremifene 80 mg for the treatment of ADT-induced osteoporosis and fractures in men with prostate cancer that, if issued, would expire between 2022 and 2026.

Even though patents have issued in respect of our owned and licensed pending method of use patent applications, since patents covering the composition of matter of toremifene have expired, competitors could market and sell generic versions of toremifene at doses and in formulations that are bioequivalent to FARESTON® (toremifene citrate 60 mg) for uses other than the indications for toremifene covered by our issued and pending method of use patent applications, and individual physicians would be permitted to prescribe generic versions of toremifene 60 mg for indications that are protected by our or our licensors' method of use patents and pending patent applications. Assuming toremifene receives appropriate marketing approval, if patents do not issue in a particular country on account of our pending method of use patent applications related to the use of toremifene 80 mg for the treatment of osteoporosis and fractures and other side effects of ADT in men with prostate cancer, and the use of toremifene 20 mg for the reduction in the incidence of prostate cancer in high risk men with high grade PIN outside the United States, competitors may be able to market and sell generic versions of toremifene tablets for these indications in that country.

For Ostarine™ and our other SARMs, we have an exclusive license from UTRF under its issued patents and pending patent applications in the United States and in a number of countries in Europe, Asia and in other jurisdictions internationally covering the composition of matter of the active pharmaceutical ingredient in these product indications, pharmaceutical compositions and methods of synthesizing the active pharmaceutical ingredients. We have also exclusively licensed from UTRF issued and pending patent applications in the United States and in a number of countries in Europe, Asia and in other jurisdictions internationally related to methods for building muscle mass and bone in patients, for treating bone related disorders including bone frailty and osteoporosis, and for treating muscle wasting disorders, including cancer cachexia using Ostarine™ and other SARMs. The patents we licensed from UTRF and issued in the United States for Ostarine and our other SARMs expire between 2017 and 2030, and the patents we licensed from UTRF and issued outside of the United States expire between 2017 and 2028.