

GTX INC /DE/  
Form 8-K  
December 30, 2004

**Table of Contents**

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

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**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):** December 30, 2004 (December 29, 2004)

**GTx, Inc.**

(Exact name of Registrant as specified in its charter)

<b>Delaware</b> (State or other jurisdiction of incorporation or organization)	<b>005-79588</b> (Commission File Number)	<b>62-1715807</b> (I.R.S. Employer Identification No.)
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**3 N. Dunlap Street  
3<sup>rd</sup> Floor, Van Vleet Building  
Memphis, Tennessee 38163  
(901) 523-9700**

(Address, including zip code, of Registrant's principal executive offices  
Registrant's telephone number, including area code,)

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(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))
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**TABLE OF CONTENTS**

Item 1.01 Entry into a Material Definitive Agreement.

SIGNATURE

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**Table of Contents**

**Item 1.01 Entry into a Material Definitive Agreement.**

As previously disclosed in the Current Report on Form 8-K filed with the Securities and Exchange Commission on December 14, 2004 by GTX, Inc. (the Company or GTX), on December 13, 2004, the Company entered into a Purchase Agreement with Orion Corporation enabling GTX to purchase all remaining rights to Toremifene in the United States and additional rights in all other countries. On December 29, 2004 in connection with the closing of the Purchase Agreement, GTX entered into an Amended and Restated License and Supply Agreement ( Agreement ) with Orion Corporation ( Orion ) effective January 1, 2005. The Agreement amends and restates the Toremifene License and Supply Agreement effective March 30, 2000, which was amended and restated on October 22, 2001, and then amended on March 5, 2003, and on December 29, 2003. The following summary description of the Agreement does not purport to be complete, and is qualified in its entirety by reference to the Agreement, which will be filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ending December 31, 2004.

The Agreement governs the parties' rights and obligations with respect to the research, development, commercialization and manufacture of pharmaceutical products based on the Toremifene compound. The Agreement grants GTX the exclusive rights and interests to develop and commercialize Toremifene based products for human use, except products for the prevention and treatment of breast cancer in countries outside of the United States and the use of Toremifene in the animal health field worldwide. Orion has agreed to manufacture and supply GTX's product needs worldwide.

Toremifene is the active component in ACAPODENE (Toremifene Citrate), a product candidate that GTX is developing in late stage clinical trials for two separate indications in men's health. Toremifene has been approved by the FDA for the treatment of metastatic breast cancer and will be marketed under the name FARESTON® (Toremifene Citrate) by GTX, commencing January 1, 2005.

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**Table of Contents**

**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: December 30, 2004

By: /s/ Henry P. Doggrell  
Name: Henry P. Doggrell  
Title: General Counsel/Secretary