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): December 14, 2004 (December 13, 2004)

GTx, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

005-79588

(Commission File Number)

62-1715807 (I.R.S. Employer Identification No.)

3 N. Dunlap Street 3rd Floor, Van Vleet Building Memphis, Tennessee 38163 (901) 523-9700

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

(Former name or former address, if changed since last report)

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SIGNATURE

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ITEM 1.01 Entry into a Material Definitive Agreement.

On December 13, 2004, GTx, Inc. entered into a Purchase Agreement with Orion Corporation. GTx and Orion are parties to a Toremifene License and Supply Agreement dated March 30, 2000, as amended, governing the parties' rights and obligations with respect to the research, development, commercialization and manufacture of certain pharmaceutical products based on the toremifene compound.

The Purchase Agreement enables GTx, Inc. to purchase all remaining rights to toremifene in the U.S. and additional rights in all other countries. 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. The acquisition, which is expected to close by year-end, will make GTx the sole licensee of toremifene in the United States. Toremifene has been approved by the FDA for the treatment of metastatic breast cancer and has been marketed under the name FARESTON® (Toremifene Citrate) by Shire Pharmaceuticals Group plc under license from Orion. Additionally, as part of the acquisition, GTx's Toremifene License and Supply Agreement with Orion is being expanded to give GTx exclusive rights to toremifene in all indications in the U.S. and all indications except breast cancer in all other countries.

ITEM 7.01 Regulation FD Disclosure.

On December 14, 2004, GTx, Inc. announced that it has signed an agreement with Orion Corporation to purchase all remaining rights to toremifene in the U.S., including rights to FARESTON®, and additional rights in all other countries. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

ITEM 9.01 Financial Statements and Exhibits.

(c) Exhibits

Exhibit Number	Description
99.1	Press Release issued by GTx, Inc. dated December 14, 2004

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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 14, 2004 By: /s/ Henry P. Doggrell

Name: Henry P. Doggrell

Title: General Counsel/Secretary

Contact: GTx, Inc. Carney Duntsch Investor and Media Relations 901-523-9700 cduntsch@gtxinc.com

Burns McClellan, Inc. Jonathan M. Nugent (investors) Kathy L. Jones-Nugent, Ph.D. (media) 212-213-0006

GTX ACQUIRES EXCLUSIVE RIGHTS IN THE U.S. FOR TOREMIFENE IN ALL INDICATIONS

Memphis, Tenn. -- December 14, 2004 - GTx, Inc. (Nasdaq: GTXI), a biopharmaceutical company dedicated to the discovery, development and commercialization of therapeutics for serious men's health conditions, today announced that it has signed an agreement with Orion Corporation (OMX: ORNAS, ORNBS) to purchase all remaining rights to toremifene in the U.S. and additional rights in all other countries. Toremifene is the active component in ACAPODENE(TM) (Toremifene Citrate), a product candidate that GTx is developing in late stage clinical trials for two separate indications in men's health. The acquisition, which is expected to close by year-end, will make GTx the sole licensee of toremifene in the United States. Toremifene has been approved by the FDA for the treatment of metastatic breast cancer and has been marketed under the name FARESTON(R) (Toremifene Citrate) by Shire Pharmaceuticals Group plc (LSE: SHP, NASDAQ: SHPGY, TSX: SHQ) under license from Orion.

In 2000, GTx in-licensed toremifene from Orion to develop ACAPODENE(TM) for indications in men's health. At the time the partnership was established, Shire had already licensed from Orion the distribution rights in the U.S. to sell toremifene as FARESTON(R) for the treatment of metastatic breast cancer. Under the terms of the purchase agreement, GTx will pay approximately \$5.2 million to Orion to acquire the existing U.S. FARESTON(R) business, including inventory and related license rights. GTx has no current or future financial obligations to Shire. GTx will continue to market FARESTON(R) in the U.S. for the treatment of metastatic breast cancer and will pay a royalty to Orion on FARESTON(R) sales. The royalty rate for FARESTON(R) will be reduced after GTx commercializes a new toremifene based product such as ACAPODENE(TM) for men's health indications. Additionally, as part of the acquisition, GTx's license and supply agreement with Orion is being expanded to give GTx exclusive rights to toremifene in all indications in the U.S. and all indications except breast cancer in all other countries.

"By gaining the exclusive right to toremifene in the U.S. and expanding our rights globally, GTx has greatly enhanced the value of our asset," said Mitchell Steiner, M.D. CEO of GTx. "We now believe that we will be better positioned to maximize the commercial potential of our toremifene product candidates."

"To Orion the deal means the consolidation of the U.S. rights for toremifene under one, highly committed partner," says Timo Lappalainen, Senior Vice President, Human Pharmaceuticals, Orion Pharma. "We have been very impressed about the progress of toremifene in GTx's pipeline, and we are very confident that the expanded collaboration is most favourable in view of the life cycle potential of the product."

 $\mathsf{GTx's}$ previously announced 2004 financial guidance will not be affected by the $\mathsf{FARESTON}(\mathsf{R})$ acquisition.

Conference Call

There will be a conference call today at 10am Eastern to discuss the FARESTON(R) acquisition. If you would like to participate in the call, please dial 800 289.0529 from the United States or Canada or 913 981.5523 from outside North America. A playback of the call will be available today from approximately 1:00 p.m. Eastern Time through December 21, 2004 and may be accessed by dialing 888 203.1112 from the United States or Canada or 719 457.0820 from outside North America, and referencing reservation number 718187. To access the archived recording, visit the GTx website at http://www.gtxinc.com.

About GTx

GTx is a biopharmaceutical company dedicated to the discovery, development and commercialization of therapeutics for serious men's health conditions. GTx's drug discovery and development programs are focused on small molecules that selectively modulate the effects of estrogens and androgens. GTx currently has two product candidates that are in human clinical trials. The company is developing ACAPODENE(TM), its most advanced product candidate, through clinical trials for two separate indications: (1) a planned pivotal Phase III clinical trial for the reduction in the incidence of prostate cancer in high risk men and (2) a pivotal Phase III clinical trial for the treatment of serious side effects of androgen deprivation therapy for advanced prostate cancer. GTx is developing its second product candidate, andarine, and other specified backup compounds, with its partner, Ortho Biotech Products, L.P., a subsidiary of Johnson & Johnson. It is currently anticipated that andarine will be entering a Phase II clinical trial in 2005. GTx is also developing the compound, ostarine, for andropause and anticipates that a Phase I clinical trial of ostarine will commence in Q1 2005. GTx has a deep pipeline generated from its own discovery program that also includes specific product candidates, prostarine, a SARM for benign prostatic hyperplasia or BPH, and andromustine, an anticancer product candidate, for hormone refractory prostate cancer.

Forward-Looking Information is Subject to Risks and Uncertainty

This press release contains forward-looking statements, including, without limitation, statements related to GTx's marketing efforts for FARESTON(R) for the treatment of metastatic breast cancer, future royalty payments, GTx's ability to maximize the commercial potential of its toremifene product candidates and GTx's current and anticipated clinical trials and research and development programs. These forward-looking statements are based upon GTx's current expectations. Forward-looking statements involve risks and uncertainties. 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, risks that GTx will need substantial additional funding and may be unable to raise capital when needed; GTx will not be able to commercialize its product candidates if preclinical studies do not produce successful results or clinical trials do not demonstrate safety and efficacy in humans; if third parties do not manufacture the Company's product candidates in sufficient quantities and at an acceptable cost, clinical development and commercialization of its product candidates would be delayed; use of third-party manufacturers may increase the risk that the Company will not have adequate supplies of its product candidates; if third parties on whom the Company relies do not perform as contractually required or expected, the Company may not be able to obtain regulatory approval for or commercialize its product candidates; the Company is dependent upon collaborative arrangements to complete the development and

commercialization of some of its product candidates, and these collaborative arrangements may place the development of its product candidates outside its control, may require it to relinquish important rights or may otherwise be on terms unfavorable to the Company; and if the Company is not able to obtain required regulatory approvals, the Company will not be able to commercialize its product candidates. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this press release. The annual report filed on Form 10-K with the U.S. Securities and Exchange Commission (the "SEC") on March 26, 2004 contains under the heading "Additional Factors That Might Affect Future Results" 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.