

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: **March 18, 2004**
(Date of earliest event reported)

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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ITEM 9. Regulation FD Disclosure.

On March 17, 2004, GTx publicly announced that it had entered into a joint collaboration with Ortho Biotech Products L.P. for andarine and specified backup SARM compounds. The full text of the press release announcing the agreement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

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: March 18, 2004

By: /s/ Henry P. Doggrell

Name: Henry P. Doggrell

Title: General Counsel/Secretary

GTX, INC. ENTERS INTO A WORLDWIDE COLLABORATION, LICENSE AND CO-PROMOTION AGREEMENT WITH ORTHO BIOTECH PRODUCTS, L.P., FOR ANDARINE, A SELECTIVE ANDROGEN RECEPTOR MODULATOR (SARM)

Memphis, Tenn. - March 17, 2004 -- GTX Inc. (Nasdaq: GTXI), a biopharmaceutical company dedicated to the development and commercialization of therapeutic products for men's health, announced today that GTX has entered into a joint collaboration and license agreement with Ortho Biotech Products L.P. for andarine, its most advanced SARM (Selective Androgen Receptor Modulator) compound, and specified backup SARM compounds. SARMs bind to testosterone receptors in the body and have the potential to affect muscle, bone, sexual function and mood. Andarine is currently being tested in human clinical trials.

"This agreement combines GTX's expertise in SARMs and men's health with the world class research and marketing capabilities of Ortho Biotech. Andarine could become the first product in this new class of drugs," said Mitchell Steiner, MD, FACS, Vice-Chairman and CEO of GTX.

Under the terms of the agreement, GTX will receive an upfront licensing fee, additional licensing fees and milestone payments up to \$82 million based on andarine and up to \$45 million for each additional licensed compound achieving specific clinical development decisions or obtaining regulatory approvals. Johnson & Johnson Pharmaceutical Research & Development will be responsible for further clinical development and expenses, and Ortho Biotech will be responsible for commercialization and expenses.

Once approved, Ortho Biotech will exclusively market andarine in the U.S. and markets outside the U.S. Under the agreement, GTX has the option to co-promote andarine and the other licensed SARM compounds to urologists in the U.S. for uses specifically related to men's health. GTX will receive up to double digit royalties on all sales, as well as additional royalty payments in excess of 20% on all co-promoted sales to urologists in the U.S.

"We believe that andarine is the first SARM to have successfully entered human clinical trials in the U.S.," said Dr. Steiner. "To date, GTx has completed several Phase I clinical trials, and with its new partner, plans to initiate a Phase II clinical trial of andarine in 2004."

Androgen receptors, to which testosterone binds, are found throughout the body in both men and women. The binding of testosterone to these receptors has potential effects of building muscle and bone, improving sexual function and positively effecting mood and libido. The unwanted effects of testosterone are the potential for increased risk to the prostate, liver and cardiovascular systems. GTx has designed its SARMS to bind to the androgen receptor in a manner that maximizes the beneficial effects and minimizes the unwanted effects of testosterone.

Conference Call

There will be a conference call today at 11:00 a.m. EST to discuss GTx's agreement with Ortho Biotech. If you would like to participate in the call, please dial 800-915-4836 from the United States or Canada or 973-317-5319 from outside North America. A playback of this call will be available today from approximately 1:00 p.m. EST through March 23, 2004 and may be accessed by dialing 800-428-6051 from the United States or Canada or 973-709-2089 from outside North America. The rebroadcast access code is 34480.

About GTx

GTx is a biopharmaceutical company dedicated to the discovery, development and commercialization of therapeutics primarily related to the treatment of 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 currently conducting clinical trials on ACAPODENE(TM) (Toremifene Citrate) tablets, its most advanced product candidate, for two separate indications: (1) a Phase IIb clinical trial to assess the effect of toremifene in the reduction in the incidence of prostate cancer in men with precancerous prostate lesions and (2) a pivotal Phase III clinical trial to assess the effect of toremifene in the treatment of serious side effects of advanced prostate cancer therapy. GTx is initially developing its second product candidate, andarine, for the treatment of muscle wasting weight loss, or cachexia, which occurs from various types of cancer and other chronic diseases.

This press release contains forward-looking statements, including, without limitation, statements related to potential future licensing fees and milestone and royalty payments 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 neither GTx nor its partner will 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. The final prospectus filed with the U.S. Securities and Exchange Commission on February 4, 2004 contains under the heading "Risk Factors," and reports that GTx will file with the U.S. Securities and Exchange Commission will contain, 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.

CONTACT: Carney Duntsch, Manager Corporate Communications GTx, Inc. -
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