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# 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: **September 7, 2006**
(Date of earliest event reported)

# GTx, Inc.

(Exact name of registrant as specified in its charter)

| **Delaware** | **005-79588** | **62-1715807** |
|---|---|---|
| (State or other jurisdiction of incorporation or organization) | (Commission File Number) | (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)

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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):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o 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))

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ITEM 7.01 Regulation FD Disclosure.

On September 7, 2006, GTx publicly announced today that they have entered into a definitive agreement under which Ipsen will have an exclusive license to develop and market GTx's Acapodene® (toremifene citrate) in all indications except breast cancer, in Europe (European Union, Switzerland, Norway, Iceland, Lichtenstein and the Commonwealth of Independent States) ("European Territory"), a copy of which is furnished as Exhibit 99.1 to this Current Report.

This release is furnished by GTx pursuant to Item 2.02 of Form 8-K and is not to be considered "filed" under the Exchange Act, and shall not be incorporated by reference into any previous or future filing by the Registrant under the Securities Act or the Exchange Act.

ITEM 9.01 Financial Statements and Exhibits.

(c) Exhibits

| Exhibit Number | Description |
|---|---|
| 99.1 | Press Release issued by GTx, Inc. dated September 7, 2006 |

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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: September 7, 2006

By: /s/ Henry P. Doggrell
Name: Henry P. Doggrell
Title: Vice President, General Counsel & Secretary

Exhibit 99.1

**Ipsen and GTx enter into partnership agreement for the European rights of Acapodene®**

**GTx conference call & webcast today at 9:00 a.m. Eastern Time**

**Paris (France) and Memphis, Tenn. (USA), 7 September 2006** — Ipsen, a European pharmaceutical group (Euronext: IPN) and GTx, Inc. (Nasdaq: GTXI), the Men's Health Biotech Company announced today that they have entered into a definitive agreement under which Ipsen will have an exclusive license to develop and market GTx's Acapodene® (toremifene citrate) in all indications except breast cancer, in Europe (European Union, Switzerland, Norway, Iceland, Lichtenstein and the Commonwealth of Independent States) ("European Territory").

Acapodene®, a selective estrogen receptor modulator (SERM), is intended to exploit a new strategy of estrogen receptors modulation which could translate into a tangible clinical benefit in both the chemoprevention of prostate cancer in high-risk men and the treatment of multiple side effects from androgen deprivation therapy in advanced prostate cancer.

Acapodene® is currently being developed in separate pivotal Phase III clinical trials for two indications. The first indication is for the treatment of multiple side effects of androgen deprivation therapy (ADT) for advanced prostate cancer (80 mg dose). Final data from the ADT trial is expected in the second half of 2007 with an anticipated New Drug Application filing in the U.S. in 2008. The second indication is for the prevention of prostate cancer in men with high grade prostatic intraepithelial neoplasia (HGPIN)(20 mg dose). GTx expects to conduct an interim efficacy analysis between the second half of 2007 and first quarter of 2008 for the HGPIN indication. If the statistical parameters are achieved, GTx will proceed with the filing of a New Drug Application in the U.S.

Ipsen will pay to GTx €23 million (approximately $30 million based on current exchange rates) upfront payment and fees. In addition, GTx may receive milestone payments from Ipsen of €39 million ($50 million) for Acapodene®, depending on the successful development and European launch of Acapodene® and subject to certain conditions for HGPIN: up to €9 million ($12 million) for the ADT Indication, up to €20 million ($26 million) for the HGPIN Indication and up to €10 million ($13 million) as additional milestone payments. As from execution of the agreement, Ipsen will pay all clinical development, regulatory and launch expenses to commercialize Acapodene® in the European Territory. Ipsen may pay a portion of GTx's Acapodene® development costs in the U.S. if certain conditions are met. Ipsen has agreed to pay GTx a graduating royalty on net sales in the mid-teens which could reach the mid-twenties based on certain sales price thresholds being met. GTx is responsible for paying upstream royalties for Acapodene®. Ipsen will procure the bulk material from a third party and is responsible for the secondary manufacturing of the product.

"We are excited to enter into a partnership with Ipsen for European rights to Acapodene®," said Mitchell S. Steiner, M.D., Chief Executive Officer of GTx. "Ipsen has an extensive track record of drug development and commercialization in Europe and has specific expertise marketing to urologists and oncologists. This partnership allows GTx to maintain its rights to Acapodene® in the United States, where we will build a sales force to market it to urologists and medical

oncologists," Steiner said. "The upfront payment will add sufficient cash on our balance sheet to last through the first quarter of 2008, which is beyond the time when we expect to see data from both of our pivotal Phase III Acapodene® trials."

"This partnership with GTx regarding Acapodene®, a product for prostate cancer prevention and for the treatment of side effects of ADT, will further expand Ipsen's franchise of oncology products, one of our targeted therapeutic areas," said Jean-Luc Belingard, Chairman and CEO of the Ipsen Group. "It confirms Ipsen's positioning in the treatment of hormone-dependent diseases, both in oncology and endocrinology and broadens the range of our prostate cancer related product portfolio."

**Acapodene®**
GTx is developing Acapodene® in two pivotal Phase III clinical trials for two separate indications in men:

- GTx is conducting a pivotal Phase III clinical trial evaluating Acapodene® in an 80 mg dose for the treatment of multiple side effects of ADT for advanced prostate cancer. Approximately 1,400 patients are participating in the trial, which is being conducted under a Special Protocol Assessment (SPA) with the United States Food & Drug Administration (FDA). The primary endpoint of the trial is a reduction in vertebral fractures. Other endpoints include improvements in Bone Mineral Density (BMD), hot flashes, lipid profiles and gynecomastia. In December 2005, GTx conducted a planned interim analysis of bone mineral density in the first 197 patients to complete a full year of treatment. In each of three measurements (lumbar spine, hip and femoral neck), highly statistically significant positive changes in BMD were observed in patients on Acapodene®, when compared to patients on placebo, who on average lost bone. In June 2006, GTx conducted a lipid interim analysis of the same 197 patients. Patients treated with Acapodene® had statistically significantly lower levels of total cholesterol, Low Density Lipoproteins (LDL), and triglycerides, a reduction in the ratio of total cholesterol to High Density Lipoproteins (HDL), and higher HDL, when compared to patients on placebo. The full lipid data set will be evaluated before conclusions about clinical significance of the findings can be drawn. GTx expects to receive final data from the trial in the second half of 2007.
- GTx is conducting a separate pivotal Phase III clinical trial evaluating Acapodene® in a 20 mg dose for the prevention of prostate cancer in men with high grade PIN. More than 1,300 patients with high grade PIN are enrolled in the trial, which is being conducted under a SPA with the FDA. The primary endpoint of the trial is a reduction in the incidence of prostate cancer. GTx expects to conduct an interim efficacy analysis between the second half of 2007 and the first quarter of 2008. If the requisite statistical parameters are achieved, GTx will proceed with the filing of a New Drug Application.

**About GTx, Inc.**
GTx, headquartered in Memphis, Tenn., is a biopharmaceutical company dedicated to the discovery, development and commercialization of therapeutics for cancer and serious conditions related to men's health. GTx's lead drug discovery and development programs are focused on small molecules that selectively modulate the effects of estrogens and androgens, two essential classes of hormones. GTx is developing Acapodene® (toremifene citrate), a selective estrogen receptor modulator (SERM), in two separate clinical programs in men: first, a pivotal Phase III clinical trial for the treatment of serious side effects of ADT for advanced prostate cancer, and second, a pivotal Phase III clinical trial for the prevention of prostate cancer in high risk men with high grade prostatic intraepithelial neoplasia, or PIN. Orion Pharma is supplying Acapodene® under its license and supply agreement with GTx. GTx is developing ostarine, a

selective androgen receptor modulator, or SARM, for muscle wasting and bone loss indications. Ostarine is currently being evaluated in a Phase II clinical trial in 120 elderly men and postmenopausal women. GTx expects to have data from the Phase II ostarine trial in the second half of 2006. GTx has licensed to Ortho Biotech Products, L.P., a subsidiary of Johnson & Johnson, another of its SARMs, andarine, under a joint collaboration and license agreement.

**About Ipsen**
Ipsen is a European pharmaceutical group with over 20 products on the market and a total worldwide staff of nearly 4,000. The company's development strategy is based on a combination of products in targeted therapeutic areas (oncology, endocrinology and neuromuscular disorders), which are growth drivers and primary care products which contribute significantly to its research financing. This strategy is also supported by an active policy of partnerships. The location of its four R&D centers (Paris, Boston, Barcelona and London) gives the Group a competitive edge in gaining access to leading university research teams and highly qualified personnel. In 2005, Research and Development expenditure reached EUR 169 million, i.e. 20.9% of consolidated sales, which amounted to EUR 807 million in the Group's pro forma accounts set up according to the IFRS. Nearly 700 people in R&D are dedicated to the discovery and development of innovative drugs for patient care. Ipsen's shares are traded on Segment A of Eurolist by Euronext (stock code: IPN, ISIN code: FR0010259150). Ipsen's internet website is www.ipsen.com.

**Ipsen in oncology**
Oncology is a key driver for the future of the Ipsen Group, and is also one of its targeted therapeutic area. Ipsen's leading product, Decapeptyl®, a GnRH analogue used in androgen deprivation therapy for prostate cancer, had 2005 sales of €211 million. Ipsen's technology programmes in peptide and protein engineering and medicinal chemistry enable it to explore and develop new approaches in cancer treatment under hormonal control, e.g. like with steroids, growth factors and enzymes regulating cell cycle. For instance:

- Decapeptyl®, a decapeptide analogue of GnRH, a hormone secreted by the hypothalamus, paradoxically act as castration agent in diseases induced by sexual hormones. Decapeptyl® is marketed in monthly or quarterly sustained release formulations, as well as in a daily formulation. Ipsen is developing sustained-release formulations of Decapeptyl® for treatment durations longer than three months and is conducting phase III clinical trials with this product in combination with an aromatase inhibitor in the treatment of breast cancer in premenopausal women.
- BN 83495, a first in class steroid sulfatase inhibitor, is tested in a phase I trial in the treatment of postmenopausal women with breast cancer.
- BN 2629, a DNA minor groove binding agent, is being studied in 3 phase I trials in patients with metastatic refractory solid tumours and leukemias.
- Two patented cytotoxic agents, diflomotecan and elomotecan are respectively in phase II and I clinical trials are being tested in metastatic cancers.

**Forward-Looking Information is Subject to Risk and Uncertainty (GTx)**
This press release contains forward-looking statements 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, the risks that (i) GTx will not be able to commercialize its product candidates if clinical trials do not demonstrate safety and efficacy in humans; (ii) GTx may not able to obtain required regulatory approvals to commercialize its product candidates; (iii) GTx's clinical trials may not be completed on

schedule, or at all, or may otherwise be suspended or terminated; and (iv) GTx could utilize its available cash resources sooner than it currently expects and may be unable to raise capital when needed, which would force GTx to delay, reduce or eliminate its product development programs or commercialization efforts. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this press release. GTx's quarterly report on Form 10-Q filed with the U.S. Securities and Exchange Commission on August 9, 2006, contains 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.

**Forward-looking statements (Ipsen)**
The forward-looking statements and targets contained herein are based on Ipsen's management's current views and assumptions. Such statements involve known and unknown risks and uncertainties that may cause actual results, performance or events to differ materially from those anticipated herein.

Ipsen expressly disclaims any obligation or undertaking to update or revise any forward-looking statements, targets or estimates contained in this press release to reflect any change in events, conditions, assumptions or circumstances on which any such statements are based unless so required by applicable law. Ipsen's business is subject to the risk factors outlined in its information documents filed with the French Autorité des marchés financiers.

**Conference Call Information**
GTx will host a conference call & webcast today at 9:00 a.m. Eastern Time. To listen to the conference call, please dial:

- 800-659-2037 from the United States and Canada or
- 617-614-2713 (International)
  The access code for the call is 47021236.

A playback of the call will be available beginning today at 11:00 a.m., Eastern Time through September 21, and may be accessed by dialing:

- 888-286-8010 from the United States and Canada or
- 617-801-6888 (International)
  The reservation number for the replay is 28701566.

Additionally, you may access the live and subsequently archived webcast of the conference call from the Investor Relations section of GTx's website at http://www.gtxinc.com.

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