GTX INC /DE/
Form 8-K
December 14, 2006

Table of Contents

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 13, 2006**

GTx, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**000-50549**	**62-1715807**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

3 N. Dunlap Street
Van Vleet Building
Memphis, Tennessee 38163
(Address of principal executive offices, including Zip Code)

Registrant s telephone number, including area code: **(901) 523-9700**

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:

¨ 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))

TABLE OF CONTENTS

Table of Contents

Item 1.01. Entry into a Material Definitive Agreement.

On December 13, 2006, GTx, Inc. (the Company) entered into a Placement Agent Agreement with Lazard Capital Markets LLC and Cowen and Company, LLC, as placement agents, relating to the offering, issuance and sale to selected institutional investors (the Investors) of up to 3,799,600 shares (the Shares) of the Company s common stock, par value $0.001 per share, at a purchase price of $16.00 per share. The net offering proceeds to the Company are expected to be approximately $57.4 million after deducting placement agents fees and estimated offering expenses. The sale of the Shares is being made pursuant to Subscription Agreements, dated December 13, 2006, with each of the Investors. The Placement Agent Agreement and form of Subscription Agreement are attached hereto as Exhibits 1.1 and 10.1, respectively, and are each incorporated herein by reference.

A copy of the opinion of Cooley Godward Kronish LLP relating to the valid issuance of the Shares is attached hereto as Exhibit 5.1.

Item 8.01. Other Events.

The Company is providing hereby certain updates to the descriptions of the Company s business from that described under the heading, Item 1. Business Overview in the Company s Annual Report on Form 10-K for the year ended December 31, 2005, filed with the SEC on March 16, 2006, and under the heading Management s Discussion and Analysis of Financial Condition and Results of Operations Overview in the Company s Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2006. The updated descriptions are as follows:

Overview

We are a biopharmaceutical company dedicated to the discovery, development and commercialization of therapeutics for cancer and serious conditions related to men s health. Our 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. We are developing ACAPODENE® (toremifene citrate), a selective estrogen receptor modulator, or SERM, in two separate clinical programs in men: first, a pivotal Phase III clinical trial for the treatment of serious side effects of androgen deprivation therapy, or ADT, for advanced prostate cancer, and second, a pivotal Phase III clinical trial for the prevention of prostate cancer in high risk men with precancerous prostate lesions called high grade prostatic intraepithelial neoplasia, or high grade PIN. We have licensed to Ipsen Limited, or Ipsen, exclusive rights in the European Union, Switzerland, Norway, Iceland, Lichtenstein and the Commonwealth of Independent States to develop and commercialize ACAPODENE® and other products containing toremifene for all indications other than the prevention and treatment of breast cancer. We are also developing ostarine, a selective androgen receptor modulator, or SARM, for the treatment of muscle wasting from various types of cancer, which is known as cancer cachexia, and we plan to initiate a Phase IIb clinical trial evaluating ostarine for the treatment of cancer cachexia by the summer of 2007. We believe that ostarine has the potential to treat a variety of other indications, including muscle wasting and bone loss in frail elderly patients, osteoporosis, muscle wasting in end stage renal disease patients, and severe burn wounds and associated muscle wasting.

In addition, we have an extensive preclinical pipeline generated from our own discovery program that includes the specific product candidates prostarine, a SARM, for benign prostatic hyperplasia, and andromustine, an anticancer product candidate, for hormone refractory prostate cancer.

Our most advanced product candidate, ACAPODENE®, is being developed to treat both the multiple side effects of ADT and to prevent prostate cancer in high risk men with high grade PIN. ADT is the standard medical treatment for patients who have advanced, recurrent or metastatic prostate cancer, and we believe that there will be approximately one million prostate cancer survivors who are expected to be treated with ADT by 2008. The low estrogen levels caused by ADT can lead to serious side effects, including: severe bone loss, or osteoporosis, resulting in skeletal fractures; hot flashes; lipid changes and breast pain and enlargement, or gynecomastia. There are currently no drugs approved by the United States Food and Drug Administration, or FDA, for the treatment of multiple side effects of ADT. We commenced a pivotal Phase III clinical trial of ACAPODENE® under a Special Protocol Assessment, or SPA, with the FDA for this indication in November 2003. A SPA is designed to facilitate the FDA s review and approval of drug products by allowing the agency to evaluate the proposed design and size of clinical trials that are intended to form the primary basis for determining a drug product s efficacy. If agreement is reached with the FDA, a SPA documents the terms and conditions under which the design of the subject trial will be adequate for submission

of the efficacy and human safety portion of a New Drug Application, or a NDA. We reached our enrollment goal in the fall of 2005 with approximately 1,400 patients randomized for the trial. The primary endpoint is the incidence of vertebral skeletal fractures measured by x-ray, and the secondary endpoints include bone mineral density, or BMD, hot flashes, gynecomastia and lipid changes. In December 2005, we conducted a planned interim analysis of BMD in the first 197 patients to complete a full year of treatment. Patients treated with ACAPODENE® demonstrated statistically significant increases in BMD compared to placebo in all three skeletal sites measured, with lumbar spine showing an improvement of 2.3 percentage points ($p<0.001$), hip, a 2.0 percentage point improvement ($p=0.001$), and femoral neck, a 1.5 percentage point improvement ($p=0.009$). In June 2006, we conducted a lipid interim analysis of the same 197 patients. Patients treated with ACAPODENE® had statistically significant lower levels of total cholesterol, LDL, and triglycerides, reduction in the ratio of total cholesterol to HDL, and higher levels of HDL, when compared to patients on placebo. However, data on all patients completing the study will need to be evaluated before any conclusions about clinical significance of the lipid findings can be drawn. In addition, investors should note that interim results of a clinical trial do not necessarily predict final results. We anticipate that we will complete this Phase III clinical trial in the fourth quarter of 2007. If the results are favorable, we expect to file a NDA with the FDA in the first half of 2008. We are conducting a voluntary one-year blinded Phase IIIb extension trial for patients from the Phase III study to gather additional fracture and safety data. This Phase IIIb clinical study is a separate clinical trial and will not affect the anticipated timeline for the completion of the ongoing Phase III clinical trial in the fourth quarter of 2007 and the potential submission of the NDA with the FDA.

In the United States, prostate cancer is one of the most commonly diagnosed cancers and the second leading cause of cancer-related deaths in men. Scientific evidence has established that men who have high grade PIN are at high risk of developing prostate cancer (approximately 50% of the men with high grade PIN found on a prostate biopsy develop prostate cancer within three years). In the United States, there are over 115,000 new cases of high grade PIN diagnosed each year and an estimated 14 million men under the age of 80 unknowingly harbor this condition. Currently, there is no approved treatment to prevent prostate cancer in men with high grade PIN. In January 2005, we initiated a pivotal Phase III clinical trial of orally administered ACAPODENE® for the prevention of prostate cancer in men with high grade PIN, which is being conducted under a SPA with the FDA. We reached our enrollment goal of 1,260 patients in May 2006 and expect to enroll approximately 300 additional patients into the trial by the end of 2006, who will also participate in sub-studies requested by the FDA. We will evaluate efficacy endpoints 36 months after completion of enrollment, with an interim efficacy analysis within 24 months of completion of enrollment, which we currently expect will occur either in the fourth quarter of 2007 or the first quarter of 2008. If the efficacy results at 24 months are favorable, we plan to file a NDA with the FDA during 2008. If we are able to file a NDA based on the results of the 24 month interim analysis, we will need to continue to collect safety data during the review process to satisfy the FDA s safety requirements set forth in the SPA. In 2004, we completed a randomized, double-blind, placebo-controlled, dose-finding Phase IIb clinical trial of ACAPODENE® in men with recently diagnosed high grade PIN to determine the efficacy and safety of a daily dose of ACAPODENE® for 12 months. The trial enrolled 514 men and was conducted at 64 clinical sites across the United States. The primary endpoint of this trial was the incidence of prostate cancer at 12 months. We analyzed the results of this trial on a stratified basis, in which we assessed the effect of individual clinical sites on the overall statistical analysis of the trial result, and on an unstratified basis, in which we did not assess such effect. In a stratified analysis of the per protocol population, which is the intent-to-treat population less two patients in the group that received 20 mg of ACAPODENE® who were deemed to be not compliant with the protocol, the cumulative, or overall, risk of prostate cancer was 24.4% in the group that received 20 mg of ACAPODENE compared with 31.2% in the group that received placebo. The p-value for this result was less than 0.05. Thus, the cumulative risk of prostate cancer based on a stratified analysis of the per protocol population was 22.0% lower in the 20 mg treatment group, which would imply an annualized rate of prevention of cancers of 6.8 per 100 men treated. In a stratified analysis of the subgroup of patients who had no biopsy evidence of prostate cancer at their initial screening biopsy or their six-month biopsy and completed the full course of therapy in the trial, the cumulative risk of prostate cancer was 9.1% in the group that received 20 mg of ACAPODENE® compared with 17.4% in the group that received placebo, a 48.2% reduction. For men who were diagnosed with prostate cancer, those treated with ACAPODENE® had similar tumor grades to those of placebo patients, providing evidence that ACAPODENE® does not adversely affect the severity of the tumor in those patients who develop prostate cancer. ACAPODENE® was well tolerated, as the number of adverse events was similar between those patients receiving

ACAPODENE® compared to placebo.

In our third clinical program, ostarine, a SARM, is being developed to treat a variety of medical conditions relating to muscle wasting and/or bone loss in acute and chronic diseases. After approximately age 30, people lose about one-half pound of muscle every year. This muscle loss accelerates in people with chronic illness and other conditions that stress the body, and this muscle loss depletes protein reserves and detrimentally impacts recovery. Testosterone and other anabolic steroids have been proven to reverse involuntary muscle wasting caused by aging, burns and trauma, cancer, end-stage renal disease, chronic obstructive pulmonary disease and other diseases. However, testosterone and other anabolic steroids may cause serious unwanted side effects, including stimulating prostate cancer growth in men and masculinization in women. Ostarine is a novel non-steroidal agent designed to have anabolic activity like testosterone without unwanted side effects on the prostate and skin and in a once daily oral dose. In December 2006, we announced that ostarine met its primary endpoint in a Phase II proof of concept, double-blind, randomized, placebo-controlled clinical trial in 60 elderly men and 60 postmenopausal women. We initiated this proof of concept Phase II clinical trial of ostarine in May 2006 and completed enrollment in July 2006. The trial was designed to evaluate the activity of ostarine on building muscle and promoting bone as well as to assess safety in both elderly men and postmenopausal women. Without a prescribed diet or exercise regimen, all subjects treated with ostarine had a dose dependent increase in total lean body mass (muscle), the trial s primary endpoint, with the 3 mg cohort achieving an increase of 1.3 kg compared to baseline and 1.4 kg compared to placebo ($p<0.001$) after three months of treatment. Treatment with ostarine also resulted in a dose dependent improvement in functional performance, a secondary endpoint measured by a stair climb test, with the 3 mg cohort achieving a clinically significant improvement in both speed ($p=0.006$) and power ($p=0.005$) compared to baseline. Ostarine continued to demonstrate a favorable safety profile, with no serious adverse events reported. Ostarine also exhibited tissue selectivity with beneficial effects on lean body mass and performance and with no apparent change in measurements for serum PSA, sebum production, or serum LH compared to placebo. We recently conducted discussions with various divisions of the FDA to investigate the required regulatory pathways for several indications under consideration for ostarine s ongoing clinical development. With more clarity regarding the required regulatory pathway and with proof of concept Phase II clinical data, we have selected cancer cachexia as the initial acute indication for ostarine development. We plan to initiate a Phase IIb ostarine clinical trial for cancer cachexia by the summer of 2007. Although we had planned to commence a Phase II clinical trial of ostarine in burn patients, we do not currently intend to pursue the development of ostarine for the treatment of severe burn wounds and associated wasting and have terminated that clinical trial.

Also in December 2006, we reacquired our rights to develop and commercialize andarine and all backup compounds previously licensed to Ortho Biotech Products, L.P., a subsidiary of Johnson & Johnson, or Ortho Biotech, pursuant to a joint collaboration and license agreement we had entered into with Ortho Biotech in March 2004, which has been terminated.

We plan to build specialized sales and marketing capabilities to promote our product candidates to urologists and medical oncologists in the United States and to seek partners to commercialize our product candidates to broader markets in the United States and in the rest of the world. We currently market FARESTON® (toremifene citrate 60 mg) tablets, which have been approved by the FDA for the treatment of metastatic breast cancer in post-menopausal women in the United States. The active pharmaceutical ingredient in FARESTON® is the same as in ACAPODENE®, but at a different dose.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Number	Description
1.1	Placement Agent Agreement, dated as of December 13, 2006, by and between GTx, Inc. and Lazard Capital Markets LLC and Cowen and Company, LLC, as placement agents
5.1	Opinion of Cooley Godward Kronish LLP
10.1	Form of Subscription Agreement
23.1	Consent of Cooley Godward Kronish LLP (included as part of Exhibit 5.1)

Table of Contents

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

GTx, Inc.

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

Dated: December 13, 2006

Table of Contents

EXHIBIT INDEX

Number	Description
1.1	Placement Agent Agreement, dated as of December 13, 2006, by and between GTx, Inc. and Lazard Capital Markets LLC and Cowen and Company, LLC, as placement agents
5.1	Opinion of Cooley Godward Kronish LLP
10.1	Form of Subscription Agreement
23.1	Consent of Cooley Godward Kronish LLP (included as part of Exhibit 5.1)