GTX INC /DE/ Form 8-K September 14, 2005

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): September 14, 2005

GTx, Inc.

(Exact name of registrant as specified in its charter)

Delaware005-7958862-1715807(State or other jurisdiction of incorporation or organization)(Commission (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)

TABLE OF CONTENTS

ITEM 8.01 Other Events.

ITEM 9.01 Financial Statements and Exhibits.

SIGNATURE

EX-99.1 PRESS RELEASE 09/14/05

Table of Contents

ITEM 8.01 Other Events.

On September 14, 2005, GTx, Inc. announced that the Company has received a response letter from the Division of Oncology Drug Products of the United States Food and Drug Administration related to GTx s Special Protocol Assessment (SPA) on the design of its pivotal Phase III clinical trial of ACAPODENE® for the prevention of prostate cancer in high risk men. 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 September 14, 2005

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: September 14, 2005 By: /s/ Henry P. Doggrell

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