GTX INC /DE/ Form S-3 August 04, 2005

As filed with the Securities and Exchange Commission on August 4, 2005

Registration No. 333-

UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

FORM S-3 REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

GTx. Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

62-1715807

(I.R.S. Employer Identification No.)

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

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

MITCHELL S. STEINER, M.D., F.A.C.S. CHIEF EXECUTIVE OFFICER

GTx, Inc.

3 N. Dunlap Street, 3rd Floor Van Vleet Building Memphis, TN 38163

(901) 523-9700

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copy to:

Suzanne Sawochka Hooper, Esq. Cooley Godward LLP Five Palo Alto Square 3000 El Camino Real Palo Alto, CA 94306-2155 (650) 843-5000

Approximate date of proposed sale to the public: From time to time after the effective date of this Registration Statement.

If the only securities being registered on this form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. o

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. b

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If delivery of the Prospectus is expected to be made pursuant to Rule 434, please check the following box, o CALCULATION OF REGISTRATION FEE

Title of Securities to be Registered(1) Common Stock, par value \$.001 per share

Proposed Maximum Aggregate Offering Price(2)

Amount of Registration Fee(3) \$100,000,000 \$11,770

- (1) There are being registered hereunder such indeterminate number of shares of common stock as shall have an aggregate initial offering price not to exceed \$100,000,000.
- (2) The proposed maximum aggregate offering price per share will be determined from time to time by the registrant in connection with the issuance by the registrant of the securities registered hereunder.
- (3) Calculated pursuant to Rule 457(o) under the

Securities Act.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment that specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

Information contained herein is subject to completion or amendment. A registration statement relating to these securities has been filed with the Securities and Exchange Commission. These securities may not be sold nor may offers to buy be accepted prior to the time the registration statement becomes effective. This prospectus shall not constitute an offer to sell or the solicitation of an offer to buy nor shall there be any sale of these securities in any State in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such State.

SUBJECT TO COMPLETION, DATED August 4, 2005 PROSPECTUS GTx, INC. \$100,000,000 Common Stock

From time to time, we may sell common stock in one or more offerings for an aggregate initial offering price of up to \$100,000,000.

We will provide the specific terms of any offering in one or more supplements to this prospectus. You should read this prospectus and any prospectus supplement, as well as any documents incorporated by reference in this prospectus and any prospectus supplement, carefully before you invest.

Our common stock is quoted on the Nasdaq National Market under the trading symbol GTXI. On August 3, 2005, the last reported sale price of our common stock on the Nasdaq National Market was \$11.50 per share.

THIS PROSPECTUS MAY NOT BE USED TO OFFER OR SELL ANY SECURITIES UNLESS ACCOMPANIED BY A PROSPECTUS SUPPLEMENT.

If any underwriters are involved in the sale of any securities with respect to which this prospectus is being delivered, the names of such underwriters and any applicable commissions or discounts will be set forth in a prospectus supplement. The net proceeds we expect to receive from such sale will also be set forth in a prospectus supplement.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR DETERMINED IF THIS PROSPECTUS IS TRUTHFUL OR COMPLETE. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

INVESTING IN OUR SECURITIES INVOLVES A HIGH DEGREE OF RISK. SEE THE SECTION ENTITLED RISK FACTORS ON PAGE 2 OF THIS PROSPECTUS.

The date of this prospectus is ______, 2005

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GTX. INC.

GTx, Inc. is a biopharmaceutical company dedicated to the discovery, development and commercialization of therapeutics for serious men s health conditions. Our drug discovery and development programs are focused on small molecules that selectively modulate the effects of estrogens and androgens.

We have four clinical programs. We are developing Acapodene (toremifene citrate) in two clinical programs in men: (1) a pivotal Phase III clinical trial for the prevention 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. In our third clinical program, we and our partner, Ortho Biotech Products, L.P., a subsidiary of Johnson & Johnson, are developing andarine, a selective androgen receptor modulator, or SARM, for cancer cachexia. We are working with Ortho Biotech to progress andarine into a Phase II clinical trial. In our fourth clinical program, we are developing our second SARM, ostarine, for andropause and other chronic wasting conditions related to aging, including frailty and sarcopenia. We also have the exclusive right to market Fareston (toremifene citrate 60 mg) tablets, which have been approved by the U.S. Food and Drug Administration for the treatment of metastatic breast cancer, in the United States. The active pharmaceutical ingredient in Fareston is the same as in Acapodene, but at a different dose.

We were originally incorporated under the name Genotherapeutics, Inc. in Tennessee in September 1997. We changed our name to GTx, Inc. in 2001, and we reincorporated in Delaware in 2003. Our principal executive office is located at 3 N. Dunlap Street, Van Vleet Building, Memphis, Tennessee, and our telephone number is (901) 523-9700. Our website address is www.gtxinc.com. The information contained in our website is not a part of this prospectus or any prospectus supplement.

Service marks, trademarks and trade names referred to in this prospectus are the property of their respective owners.

ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission using a shelf registration process. Under this shelf registration process, we may sell common stock in one or more offerings, up to a total dollar amount of \$100,000,000. This prospectus provides you with a general description of the securities we may offer. Each time we sell common stock, we will provide a prospectus supplement that will contain more specific information about the terms of that offering. We may also add, update or change in the prospectus supplement any of the information contained in this prospectus. However, no prospectus supplement will fundamentally change the terms that are set forth in this prospectus or offer a security that is not registered and described in this prospectus at the time of its effectiveness. This prospectus, together with applicable prospectus supplements, includes all material information relating to this offering. If there is any inconsistency between the information in this prospectus and the information in the accompanying prospectus supplement, you should rely on the information in the prospectus supplement. Please carefully read both this prospectus and any prospectus supplement together with the additional information described below under Where You Can Find More Information.

You should rely only on the information we have provided or incorporated by reference in this prospectus or any prospectus supplement. We have not authorized anyone to provide you with different information. No dealer, salesperson or other person is authorized to give any information or to represent anything not contained in this prospectus or any prospectus supplement. You must not rely on any unauthorized information or representation. This prospectus is an offer to sell only the securities offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. You should assume that the information in this prospectus or any prospectus supplement is accurate only as of the date on the front of the document and that any information we have incorporated by reference is accurate only as of the date of the document incorporated by reference, regardless of the time of delivery of this prospectus or any sale of a security.

Unless otherwise mentioned or unless the context requires otherwise, all references in this prospectus to GTx, we, our or similar references mean GTx, Inc.

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RISK FACTORS

Investment in our securities involves a high degree of risk. You should consider carefully the risk factors in any prospectus supplement and in our filings with the Securities and Exchange Commission, as well as other information in this prospectus and any prospectus supplement and the documents incorporated by reference herein or therein, before purchasing any of our securities. Each of the risk factors could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our securities.

FORWARD-LOOKING INFORMATION

This prospectus, any prospectus supplement and the documents that we incorporate by reference contain statements indicating expectations about future performance and other forward-looking statements that involve risks and uncertainties. We usually use words such as may, will, should, expect, future. intend. potential or continue or the negative of these terms or similar expressions to identify forward-lookin statements. These statements appear throughout this prospectus, any prospectus supplement and the documents that we incorporate by reference and are statements regarding our current intent, belief or expectation, primarily with respect to our operations and related industry developments. Examples of these statements include, but are not limited to, statements regarding the following: our current and anticipated clinical trials; the progress of our research and development programs; our corporate collaborations, including potential future licensing fees and milestone and royalty payments; our research and development expenses; protection of our intellectual property; sufficiency of our cash resources; and our operations and legal risks. You should not place undue reliance on these forward-looking statements. Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons. Important factors that could cause or contribute to such differences include, but are not limited to, those discussed in any prospectus supplement or in the documents we incorporate by reference in this prospectus, particularly in the section entitled Additional Factors That Might Affect Future Results contained in our filings made with the Securities and Exchange Commission from time to time. Any forward-looking statement speaks only as of the date on which it is made, and we undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

USE OF PROCEEDS

Except as described in any prospectus supplement, we intend to use the net proceeds from the sale of our common stock for research and development and general corporate purposes. We may also use a portion of the net proceeds to acquire or invest in businesses, products and technologies that are complementary to our own. Pending these uses, the net proceeds will be invested in investment-grade, interest-bearing securities.

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DESCRIPTION OF CAPITAL STOCK

Our authorized capital stock consists of 60,000,000 shares of common stock, \$0.001 par value per share, and 5,000,000 shares of preferred stock, \$0.001 par value per share. As of July 25, 2005, there were 24,664,716 shares of our common stock outstanding and no shares of preferred stock outstanding.

Common Stock

The holders of common stock are entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders and do not have cumulative voting rights. The affirmative vote of the holders of a majority of the shares of common stock entitled to vote on a matter is required to approve the matter (except when a different vote is required by law, Nasdaq rules, our certificate if incorporation or our bylaws), and directors are elected by plurality vote. Subject to preferences that may be applicable to any outstanding shares of preferred stock, the holders of common stock are entitled to receive ratably such dividends as may be declared by the board of directors out of legally available funds. Upon our liquidation, dissolution or winding up, holders of our common stock are entitled to share ratably in all assets remaining after payment of liabilities and the liquidation preferences of any outstanding shares of preferred stock. Holders of common stock have no preemptive rights and no right to convert their common stock into any other securities. There are no redemption or sinking fund provisions applicable to our common stock. All outstanding shares of our common stock are, and all shares of common stock that may be issued under this prospectus will be, fully paid and non-assessable.

The foregoing summary description of our common stock is based on the provisions of our certificate of incorporation and bylaws and the applicable provisions of the Delaware General Corporation Law. This information may not be complete in all respects and is qualified entirely by reference to the provisions of our certificate of incorporation, bylaws and the Delaware General Corporation Law. For information on how to obtain copies of our certificate of incorporation and bylaws, see Where You Can Find More Information.

The rights of the holders of our common stock are subject to, and may be adversely affected by, the rights of holders of shares of any preferred stock that we may designate and issue in the future.

Preferred Stock

Pursuant to our certificate of incorporation, our board of directors has the authority, without further action by the stockholders (unless such stockholder action is required by applicable law or Nasdaq rules), to issue up to 5,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon, and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding. Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of us and may adversely affect the market price of the common stock and the voting and other rights of the holders of common stock. We have no present plans to issue preferred stock.

Registration Rights

As of the date of this prospectus, holders of approximately 11,141,057 shares of our common stock are entitled to rights with respect to the registration of those shares of common stock under the Securities Act of 1933. If we propose to register any of our securities under the Securities Act, either for our own account or for the account of others, the holders of these shares are entitled to notice of the registration and are entitled to include, at our expense, their shares of common stock in the registration and any related underwriting, provided, among other conditions, that the underwriters may limit the number of shares to be included in the registration. In addition, the holders of certain of these shares may require us, at our expense and subject to certain limitations, to file a registration statement under the Securities Act with respect to their shares of our common stock. These holders have waived these registration rights in connection with the offerings that might be made under this registration statement.

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Anti-Takeover Effects of Provisions of Delaware Law and Our Charter Documents

Delaware Takeover Statute. We are subject to the provisions of Section 203 of the Delaware General Corporation Law. In general, the statute prohibits a publicly-held Delaware corporation such as us from engaging in a business combination with an interested stockholder for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. For purposes of Section 203, a business combination includes a merger, asset or stock sale or other transaction resulting in a financial benefit to the interested stockholder, and an interested stockholder is a person who, together with affiliates and associates, owns, or within three years prior, did own, 15% or more of our voting stock. Section 203 of the Delaware General Corporation Law will generally have an anti-takeover effect for transactions not approved in advance by our board of directors, including discouraging attempts that might result in a premium over the market price for the shares of common stock held by our stockholders.

Charter Documents. Our certificate of incorporation and bylaws provide that our board of directors be divided into three classes of directors, with each class serving a staggered three-year term. The classification system of electing directors may tend to discourage a third party from making a tender offer or otherwise attempting to obtain control of us and may maintain the composition of our current board of directors, as the classification of the board of directors generally increases the difficulty of replacing a majority of directors. In addition, our certificate of incorporation and bylaws:

provide that any action required or permitted to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and may not be effected by any consent in writing;

establish advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon at a stockholder meeting;

provide that the authorized number of directors may be changed only by resolution of the board of directors; and

provide that special meetings of our stockholders may be called only by the chairman of our board of directors, our chief executive officer or our board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors.

The Delaware corporate law statute provides generally that the affirmative vote of a majority of the shares entitled to vote is required to amend a corporation s bylaws, unless a corporation s certificate of incorporation requires a greater percentage or also confers the power upon the corporation s directors. Our bylaws may be amended or repealed by:

the affirmative vote of a majority of our directors then in office; or

the affirmative vote of the holders of at least 66-2/3% of the voting power of all then-outstanding shares of our capital stock entitled to vote generally in the election of directors.

The provisions described in the preceding paragraph that are included in our certificate of incorporation may only be amended or repealed by the affirmative vote of a majority of our directors and the affirmative vote of the holders of at least 66-2/3% of the voting power of all then-outstanding shares of our capital stock entitled to vote generally in the election of directors.

These and other provisions contained in our certificate of incorporation and bylaws could delay or discourage some types of transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares over then current prices, and may limit the ability of stockholders to remove current management or approve transactions that stockholders may deem to be in their best interests and, therefore, could adversely affect the price of our common stock.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare. Its address is 150 Royall Street, Canton, MA 02021.

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PLAN OF DISTRIBUTION

We may sell the common stock through underwriters or dealers, through agents, or directly to one or more purchasers. One or more prospectus supplements will describe the terms of the offering of the common stock, including:

the name or names of any agents or underwriters;

the purchase price of the common stock and the proceeds we will receive from the sale;

any over-allotment options under which underwriters may purchase additional shares of common stock from us;

any agency fees or underwriting discounts and other items constituting agents or underwriters compensation;

any discounts or concessions allowed or reallowed or paid to dealers; and

any securities exchange or market on which the common stock may be listed.

Only underwriters named in the prospectus supplement are underwriters of the common stock offered by the prospectus supplement.

If underwriters are used in the sale, they will acquire the common stock for their own account and may resell the common stock from time to time in one or more transactions, including negotiated transactions, at a fixed public offering price or at varying prices determined at the time of sale. The obligations of the underwriters to purchase the common stock will be subject to the conditions set forth in the applicable underwriting agreement. We may offer the common stock to the public through underwriting syndicates represented by managing underwriters or by underwriters without a syndicate. Subject to certain conditions, the underwriters will be obligated to purchase all the common stock offered by the prospectus supplement if they are to purchase any of such offered shares. Any public offering price and any discounts or concessions allowed or reallowed or paid to dealers may change from time to time. We may use underwriters with whom we have a material relationship. We will describe in the prospectus supplement naming the underwriter, the nature of any such relationship.

We may sell the common stock directly or through agents we designate from time to time. We will name any agent involved in the offering and sale of the common stock and we will describe any commissions we will pay the agent in the prospectus supplement. Unless the prospectus supplement states otherwise, our agent will act on a best-efforts basis for the period of its appointment.

We may authorize agents or underwriters to solicit offers by certain types of institutional investors to purchase the common stock from us at the public offering price set forth in the prospectus supplement pursuant to delayed delivery contracts providing for payment and delivery on a specified date in the future. We will describe the conditions to these contracts and the commissions we must pay for solicitation of these contracts in the prospectus supplement.

We may provide agents and underwriters with indemnification against certain civil liabilities, including liabilities under the Securities Act, or contribution with respect to payments that the agents or underwriters may make with respect to such liabilities. Agents and underwriters may engage in transactions with, or perform services for, us in the ordinary course of business.

Any underwriter may engage in overallotment, stabilizing transactions, short covering transactions and penalty bids in accordance with Regulation M under the Securities Exchange Act of 1934. Overallotment involves sales in excess of the offering size, which create a short position. Stabilizing transactions permit bids to purchase the underlying shares of common stock so long as the stabilizing bids do not exceed a specified maximum price. Short covering transactions involve exercise by underwriters of an over-allotment option or purchases of the common

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stock in the open market after the distribution is completed to cover short positions. Penalty bids permit the underwriters to reclaim a selling concession from a dealer when the shares of common stock originally sold by the dealer are purchased in a short covering transaction. Those activities may cause the price of the common stock to be higher than it would otherwise be. If commenced, the underwriters may discontinue any of the activities at any time.

Our common stock is quoted on the Nasdaq National Market. One or more underwriters may make a market in our common stock, but the underwriters will not be obligated to do so and may discontinue market making at any time without notice. We cannot give any assurance as to liquidity of the trading market for our common stock.

Any underwriters who are qualified market makers on the Nasdaq National Market may engage in passive market making transactions in the securities on the Nasdaq National Market in accordance with Rule 103 of Regulation M under the Securities Exchange Act of 1934, during the five business days prior to the pricing of the offering, before the commencement of offers or sales of the securities. Passive market makers must comply with applicable volume and price limitations and must be identified as passive market makers. In general, a passive market maker must display its bid at a price not in excess of the highest independent bid for such security; if all independent bids are lowered below the passive market maker s bid, however, the passive market maker s bid must then be lowered when certain purchase limits are exceeded.

In compliance with guidelines of the National Association of Securities Dealers, or NASD, the maximum consideration or discount to be received by any NASD member or independent broker dealer may not exceed 8% of the aggregate amount of the securities offered pursuant to this prospectus and any applicable prospectus supplement.

LEGAL MATTERS

The validity of the securities being offered hereby will be passed upon by Cooley Godward LLP, Palo Alto, California.

EXPERTS

Ernst & Young LLP, independent registered public accounting firm, has audited our financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2004, as set forth in their report, which is incorporated by reference in this prospectus and elsewhere in the registration statement. Our financial statements are incorporated by reference in reliance on Ernst & Young LLP s report, given on their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We are a reporting company and file annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission. We have filed with the Securities and Exchange Commission a registration statement on Form S-3 under the Securities Act with respect to the common stock we are offering under this prospectus. This prospectus does not contain all of the information set forth in the registration statement and the exhibits to the registration statement. For further information with respect to us and the common stock we are offering under this prospectus, we refer you to the registration statement and the exhibits filed as a part of the registration statement. You may read and copy the registration statement, as well as our reports, proxy statements and other information, at the Securities and Exchange Commission s public reference room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You can request copies of these documents by writing to the Securities and Exchange Commission and paying a fee for the copying cost. Please call the Securities and Exchange Commission at 1-800-SEC-0330 for more information about the operation of the public reference room. Our Securities and Exchange Commission filings are also available at the Securities and Exchange Commission s website at http://www.sec.gov.

The Securities and Exchange Commission allows us to incorporate by reference information that we file with it, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is an important part of this prospectus. Information in this prospectus supersedes information incorporated by reference that we filed with the Securities and Exchange Commission prior to the date of this prospectus, while information that we file later with the Securities and Exchange Commission will

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automatically update and supersede this information. We incorporate by reference into this registration statement and prospectus the documents listed below and any future filings we will make with the Securities and Exchange Commission under Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended, after the date of the initial registration statement but prior to effectiveness of the registration statement and after the date of this prospectus but prior to the termination of the offering of the securities covered by this prospectus, except in each case for information contained in any such filing where we indicate that such information is being furnished and is not to be considered filed under the Securities Exchange Act of 1934, as amended.

The following documents filed with the Securities and Exchange Commission are incorporated by reference in this prospectus:

our Annual Report on Form 10-K, as amended, for the year ended December 31, 2004, filed with the Securities and Exchange Commission on March 24, 2005;

our Quarterly Report on Form 10-Q, as amended, for the quarter ended March 31, 2005, filed with the Securities and Exchange Commission on April 29, 2005;

our Current Report on Form 8-K filed with the Securities and Exchange Commission on February 1, 2005;

our Current Report on Form 8-K filed with the Securities and Exchange Commission on February 2, 2005;

our Current Report on Form 8-K/A filed with the Securities and Exchange Commission on March 7, 2005;

our Current Report on Form 8-K filed with the Securities and Exchange Commission on June 2, 2005;

our Quarterly Report on Form 10-Q for the quarter ended June 30, 2005, filed with the Securities and Exchange Commission on July 27, 2005; and

the description of our common stock contained in our registration statement on Form 8-A filed with the Securities and Exchange Commission on January 13, 2004, including all amendments and reports filed for the purpose of updating such information.

We will furnish without charge to you, upon written or oral request, a copy of any or all of the documents incorporated by reference, including exhibits to these documents. You should direct any requests for documents to GTx, Inc., Attention: Corporate Secretary, 3 N. Dunlap Street, Van Vleet Building, Memphis, TN 38163. Our phone number is (901) 523-9700.

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PART II INFORMATION NOT REQUIRED IN THE PROSPECTUS

Item 14. Other Expenses of Issuance and Distribution

The following table sets forth the estimated costs and expenses, other than the underwriting discounts and commissions, payable by the registrant in connection with the offering of the securities being registered. All the amounts shown are estimates, except for the registration fee.

Securities and Exchange Commission registration fee	\$ 11,770
Accounting fees and expenses	100,000
Legal fees and expenses	150,000
Printing, transfer agent and miscellaneous expenses	75,000

Total \$336.770

Item 15. Indemnification of Officers and Directors

Our certificate of incorporation contains provisions permitted under Delaware law relating to the liability of directors. These provisions eliminate a director s personal liability for monetary damages resulting from a breach of fiduciary duty, except in circumstances involving wrongful acts, such as:

any breach of the director s duty of loyalty to us or our stockholders;

any act or omission not in good faith or that involves intentional misconduct or a knowing violation of the law;

any act related to unlawful stock repurchases, redemptions or other distribution or payments of dividends; or

any transaction from which the director derived an improper personal benefit.

These provisions do not limit or eliminate our rights or any stockholder s rights to seek non-monetary relief, such as an injunction or rescission, in the event of a breach of director s fiduciary duty. These provisions will not alter a director s liability under federal securities laws.

As permitted by Section 145 of the Delaware General Corporation Law, our bylaws require us to indemnify our directors and executive officers to the fullest extent not prohibited by the Delaware law. We may expand the extent of such indemnification by individual contracts with our directors and executive officers. Further, we may decline to indemnify any director or executive officer in connection with any proceeding initiated by such person or any proceeding by such person against us or our directors, officers, employees or other agents, unless such indemnification is expressly required to be made by law or the proceeding was authorized by our board of directors.

We have entered into indemnity agreements with each of our current directors and our executive officers to give such directors and officers additional contractual assurances regarding the scope of the indemnification set forth in our certificate of incorporation and bylaws and to provide additional procedural protections. At present, there is no pending litigation or proceeding involving any of our directors, officers or employees for which indemnification is sought, nor are we aware of any threatened litigation that may result in claims for indemnification.

We have the power to indemnify our other officers, employees and other agents, as permitted by Delaware law, but we are not required to do so.

We have a directors and officers insurance and registrant reimbursement policy. The policy insures directors and officers against unindemnified losses arising from certain wrongful acts in their capacities as directors and officers and reimburses the registrant for those losses for which the registrant has lawfully indemnified the directors and officers. The policy contains various exclusions, none of which apply to this offering.

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The underwriting agreement that we might enter into (Exhibit 1.1) will provide for indemnification by any underwriters of GTx, our directors, our officers who sign the registration statement and our controlling persons for some liabilities, including liabilities arising under the Securities Act of 1933.

Item 16. Exhibits and Financial Statement Schedules

(a) Exhibits

Exhibit Number **Description of Document** 1.1 Form of Underwriting Agreement.(1) 4.1 Amended and Restated Certificate of Incorporation of the Company. 4.2 Amended and Restated Bylaws of the Company.(2) 4.3 Specimen Common Stock Certificate.(2) 5.1 Opinion of Cooley Godward LLP. 23.1 Consent of Ernst & Young LLP, independent registered public accounting firm. 23.2 Consent of Cooley Godward LLP (included in Exhibit 5.1). 24.1 Power of Attorney (included in the signature page).

- (1) To be filed by amendment or as an exhibit to a current report of the registrant on Form 8-K and incorporated herein by
- (2) Filed as an exhibit to the registrant s registration statement on Form S-1 or

amendments

reference.

thereto (File No. 333-109700), originally filed with the Securities

and Exchange

Commission on

October 15, 2003,

as amended, and

incorporated herein by reference.

Item 17. Undertakings

The undersigned registrant hereby undertakes:

- (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:
 - (i) to include any prospectus required by section 10(a)(3) of the Securities Act of 1933;
- (ii) to reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Securities and Exchange Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective registration statement; and

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- (iii) to include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement. *provided, however,* that paragraphs (1)(i) and (1)(ii) do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in periodic reports filed with or furnished to the Securities and Exchange Commission by the registrant pursuant to section 13 or 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement.
- (2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of the securities at that time shall be deemed to be the initial bona fide offering thereof.
- (3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of this offering.
- (4) That, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant s annual report pursuant to section 13(a) or section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan s annual report pursuant to section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (5) That: (i) for purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in the form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act of 1933 shall be deemed to be part of the registration statement as of the time it was declared effective; and (ii) for the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act of 1933 and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by a director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act of 1933 and will be governed by the final adjudication of such issue.

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/s/ Andrew M. Clarkson

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Memphis, State of Tennessee, on August 4, 2005.

GTx, Inc.

By: /s/ Mitchell S. Steiner

Mitchell S. Steiner, M.D., F.A.C.S.

Chief Executive Officer

POWER OF ATTORNEY

Know All Persons By These Presents, that each person whose signature appears below constitutes and appoints Mitchell S. Steiner, Marc S. Hanover, Henry P. Doggrell and Mark E. Mosteller, and each of them, as true and lawful attorneys-in-fact and agents, with full powers of substitution and resubstitution, for them and in their name, place and stead, in any and all capacities, to sign any and all amendments (including pre-effective and post-effective amendments) to this registration statement and any additional registration statements filed pursuant to Rule 462, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission (the SEC), and generally to do all such things in their names and behalf in their capacities as officers and directors to enable GTx to comply with the provisions of the Securities Act of 1933 and all requirements of the SEC, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his or her substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed below by the following persons in the capacities and on the dates indicated.

Signatures	Title	Date
/s/ Mitchell S. Steiner	Chief Executive Officer,	August 4,
Mitchell S. Steiner	Vice-Chairman and Director (Principal Executive Officer)	2005
/s/ Mark E. Mosteller	Chief Financial Officer (Principal	August 4, 2005
Mark E. Mosteller	Financial and Accounting Officer)	2003
/s/ J.R. Hyde, III	Chairman of the Board of Directors	August 4,
J.R. Hyde, III		2005
/s/ Marc S. Hanover	Chief Operating Officer and Director	August 4, 2005
Marc S. Hanover		2003

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Director

Andrew M. Clarkson		August 4, 2005
/s/ J. Kenneth Glass	Director	August 4, 2005
J. Kenneth Glass		2003
/s/ Robert Karr	Director	August 4, 2005
Robert Karr		2003
/s/ Rosemary Mazanet	Director	August 4, 2005
Rosemary Mazanet, M.D., Ph.D.		2003
/s/ John H. Pontius	Director	August 4, 2005
John H. Pontius		2003
/s/ Timothy R. G. Sear	Director	August 4,
Timothy R. G. Sear		2005
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INDEX TO EXHIBITS

Exhibit Number	Description of Document
1.1	Form of Underwriting Agreement.(1)
4.1	Amended and Restated Certificate of Incorporation of the Company.
4.2	Amended and Restated Bylaws of the Company.(2)
4.3	Specimen Common Stock Certificate.(2)
5.1	Opinion of Cooley Godward LLP.
23.1	Consent of Ernst & Young LLP, independent registered public accounting firm.
23.2	Consent of Cooley Godward LLP (included in Exhibit 5.1).
24.1	Power of Attorney (included in the signature page).

- (1) To be filed by amendment or as an exhibit to a current report of the registrant on Form 8-K and incorporated herein by reference.
- (2) Filed as an exhibit to the registrant s registration statement on Form S-1 or amendments thereto (File No. 333-109700), originally filed with the Securities and Exchange Commission on October 15, 2003, as amended, and incorporated herein by

reference.