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): October 11, 2005

GTx, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

Delaware (State or Other Jurisdiction of Incorporation)

000-50549 (Commission File Number) **62-1715807** (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:

- 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)
- 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

Item 8.01. Other Events.
Item 9.01. Financial Statements and Exhibits.
SIGNATURES
EXHIBIT INDEX

EXHIBIT 1.1 EXHIBIT 5.1

EXHIBIT 99.1

Table of Contents

Item 8.01. Other Events.

On October 11, 2005, GTx, Inc. (the "Company") entered into an underwriting agreement and a related pricing agreement (collectively, the "Underwriting Agreement") with Lazard Capital Markets LLC and SG Cowen & Co., LLC, as underwriters (collectively, the "Underwriters"), relating to the public offering, issuance and sale of 5,500,000 shares of the Company's common stock, \$0.001 par value per share. The price to the public is \$7.80 per share, and the Underwriters have agreed to purchase the shares from the Company pursuant to the Underwriting Agreement at a price of \$7.332 per share. Under the terms of the Underwriting Agreement, the Company has granted the Underwriters an option, exercisable for 30 days after the offering, to purchase up to an additional 825,000 shares of common stock to the extent that the Underwriters sell more than 5,500,000 shares. The offering is being made pursuant to the Company's effective shelf registration statement on Form S-3 (Registration No. 333-127175) previously filed with the Securities and Exchange Commission. The Underwriting Agreement is filed as Exhibit 1.1 to this report and is incorporated herein by reference. The description of the material terms of the Underwriting Agreement is qualified in its entirety by reference to such exhibit.

On October 11, 2005, the Company also issued a press release announcing the pricing of the public offering. A copy of the press release is filed as Exhibit 99.1 to this report and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(c) Exhibits.

| Exhibit No. | Description |
|-------------|---|
| 1.1 | Underwriting Agreement and related Pricing Agreement, each dated October 11, 2005. |
| 5.1 | Opinion of Cooley Godward LLP. |
| 23.1 | Consent of Cooley Godward LLP (contained in Exhibit 5.1). |
| 99.1 | Press Release, dated October 11, 2005, entitled "GTx Prices Public Offering of Common Stock." |
| | |

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.

Dated: October 12, 2005

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

Table of Contents

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| GTx, Inc. |
|-------------------------------|
| Common Stock |
| (par value \$0.001 per share) |

Underwriting Agreement

October 11, 2005

Lazard Capital Markets LLC 30 Rockefeller Plaza New York, New York 10020

SG Cowen & Co., LLC 1221 Avenue of the Americas New York, New York 10020

Ladies and Gentlemen:

From time to time GTx, Inc., a Delaware corporation (the "Company"), proposes to enter into one or more Pricing Agreements (each a "Pricing Agreement") in the form of Annex I hereto, with such additions and deletions as the parties thereto may determine, and, subject to the terms and conditions stated herein and therein, to issue and sell to the firms named in Schedule I to the applicable Pricing Agreement (such firms constituting the "Underwriters" with respect to such Pricing Agreement and the shares specified therein) certain shares of its common stock, par value \$0.001 per share (the "Shares"), specified in Schedule II to such Pricing Agreement (with respect to such Pricing Agreement, the "Firm Shares"). If specified in such Pricing Agreement, the Company may grant to the Underwriters the right to purchase at their election an additional number of shares, specified in such Pricing Agreement as provided in Section 3 hereof (the "Optional Shares"). The Firm Shares and the Optional Shares, if any, which the Underwriters elect to purchase pursuant to Section 3 hereof are herein collectively called the "Designated Shares".

The terms and rights of any particular issuance of Designated Shares shall be as specified in the Pricing Agreement relating thereto.

1. Particular sales of Designated Shares may be made from time to time to the Underwriters of such Shares, for whom the firms designated as representatives of the Underwriters of such Shares in the Pricing Agreement relating thereto will act as representatives (the "Representatives"). The term "Representatives" also refers to a single firm acting as sole representative of the Underwriters and to Underwriters who act without any firm being designated as their representative. This Underwriting Agreement shall not be construed as an obligation of the Company to sell any of the Shares or as an obligation of any of the Underwriters to purchase any of the Shares. The obligation of the Company to issue and sell any of the Shares and the obligation of any of the Underwriters to purchase any of the Shares shall be evidenced by the Pricing Agreement with respect to the Designated Shares specified

therein. Each Pricing Agreement shall specify the aggregate number of the Firm Shares, the maximum number of Optional Shares, if any, the initial public offering price of such Firm Shares and Optional Shares or the manner of determining such price, the purchase price to the Underwriters of such Designated Shares, the names of the Underwriters of such Designated Shares, the names of the Representatives of such Underwriters, the number of such Designated Shares to be purchased by each Underwriter and the commission, if any, payable to the Underwriters with respect thereto and shall set forth the date, time and manner of delivery of such Firm and Optional Shares, if any, and payment therefor. The Pricing Agreement shall also specify (to the extent not set forth in the registration statement and prospectus with respect thereto) the terms of such Designated Shares. A Pricing Agreement shall be in the form of an executed writing (which may be in counterparts), and may be evidenced by an exchange of telegraphic communications or any other rapid transmission device designed to produce a written record of communications transmitted. The obligations of the Underwriters under this Agreement and each Pricing Agreement shall be several and not joint.

2. The Company represents and warrants to, and agrees with, each of the Underwriters that:

(a) A registration statement on Form S-3 (File No. 33-127175) (the "Initial Registration Statement") in respect of the Shares has been filed with the Securities and Exchange Commission (the "Commission"); the Initial Registration Statement and any post-effective amendment thereto, each in the form heretofore delivered or to be delivered to the Representatives and, excluding exhibits to the Initial Registration Statement, but including all documents incorporated by reference in the prospectus included therein, to the Representatives for each of the other Underwriters have been declared effective by the Commission in such form; other than a registration statement, if any, increasing the size of the offering (a "Rule 462(b) Registration Statement"), filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended (the "Act"), which became effective upon filing, no other document with respect to the Initial Registration Statement or document incorporated by reference therein has heretofore been filed, or transmitted for filing, with the Commission (other than amendments to such incorporated documents filed with the Commission and prospectuses filed pursuant to Rule 424(b) of the rules and regulations of the Commission under the Act, each in the form heretofore delivered to the Representatives); and no stop order suspending the effectiveness of the Initial Registration Statement, any post-effective amendment thereto or the Rule 462(b) Registration Statement, if any, has been issued and no proceeding for that purpose has been initiated or threatened by the Commission (any preliminary prospectus included in the Initial Registration Statement or filed with the Commission pursuant to Rule 424(a) under the Act, is hereinafter called a "Preliminary Prospectus": the various parts of the Initial Registration Statement and the Rule 462(b) Registration Statement, if any, including all exhibits thereto and the documents incorporated by reference in the prospectus contained in the Initial Registration Statement at the time such part of the Initial Registration Statement became effective, each as amended at the time such part of the Initial Registration Statement became effective, are hereinafter collectively called the "Registration Statement"; the prospectus relating to the Shares, in the form in which it has most recently been filed, or transmitted for filing, with the Commission on or prior to the date of this Agreement, is hereinafter called the "Prospectus"; any reference herein to any Preliminary Prospectus or the Prospectus shall be deemed to refer to and

include the documents incorporated by reference therein pursuant to the applicable form under the Act, as of the date of such Preliminary Prospectus or Prospectus, as the case may be; any reference to any amendment or supplement to any Preliminary Prospectus or the Prospectus shall be deemed to refer to and include any documents filed after the date of such Preliminary Prospectus or Prospectus, as the case may be, under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and incorporated by reference in such Preliminary Prospectus or Prospectus, as the case may be; any reference to any amendment to the Initial Registration Statement shall be deemed to refer to and include any annual report of the Company filed pursuant to Section 13(a) or 15(d) of the Exchange Act after the effective date of the Registration Statement that is incorporated by reference in the Registration Statement; and any reference to the Prospectus as amended or supplemented in relation to the applicable Designated Shares in the form in which it is filed with the Commission pursuant to Rule 424(b) under the Act in accordance with Section 5(a) hereof, including any documents incorporated by reference therein as of the date of such filing);

- (b) The documents incorporated by reference in the Prospectus, when they became effective or were filed with the Commission, as the case may be, conformed in all material respects to the requirements of the Act or the Exchange Act, as applicable, and the rules and regulations of the Commission thereunder, and none of such documents contained an untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary to make the statements therein not misleading; and any further documents so filed and incorporated by reference in the Prospectus or any further amendment or supplement thereto, when such documents become effective or are filed with the Commission, as the case may be, will conform in all material respects to the requirements of the Act or the Exchange Act, as applicable, and the rules and regulations of the Commission thereunder and will not contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading; provided, however, that this representation and warranty shall not apply to any statements or omissions made in reliance upon and in conformity with information furnished in writing to the Company by an Underwriter of Designated Shares through the Representatives expressly for use in the Prospectus as amended or supplemented relating to such Shares;
- (c) The Registration Statement and the Prospectus conform, and any further amendments or supplements to the Registration Statement or the Prospectus will conform, in all material respects to the requirements of the Act and the rules and regulations of the Commission thereunder and do not and will not, as of the applicable effective date as to the Registration Statement and any amendment thereto and as of the applicable filing date as to the Prospectus and any amendment or supplement thereto, contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading; provided, however, that this representation and warranty shall not apply to any statements or omissions made in reliance upon and in conformity with information furnished in writing to the Company by an Underwriter of Designated Shares through the Representatives expressly for use in the Prospectus as amended or supplemented relating to such Shares;

- (d) The Company has not sustained since the date of the latest audited financial statements included or incorporated by reference in the Prospectus any material loss or interference with its business from fire, explosion, flood or other calamity, whether or not covered by insurance, or from any labor dispute or court or governmental action, order or decree; and, since the respective dates as of which information is given in the Registration Statement and the Prospectus, there has not been any change in the capital stock (other than as a result of the grant of stock options to purchase an aggregate of not more than 100,000 shares of common stock pursuant to the Company's current stock option plans and the cancellation or exercise of stock options described in the Registration Statement and Prospectus), short-term debt or long-term debt of the Company or any material adverse change, or any development involving a prospective material adverse change, in or affecting the general affairs, management, financial position, stockholders' equity or results of operations of the Company ("Material Adverse Effect"), otherwise than as set forth or contemplated in the Prospectus;
- (e) The Company does not own any real property; the Company has good and marketable title to all tangible personal property owned by it, in each case free and clear of all liens, encumbrances and defects except such as are described in the Prospectus or such as do not materially affect the value of such property and do not interfere with the use made of such property by the Company; and any real property and buildings held under lease by the Company are held by it under valid, subsisting and enforceable leases with such exceptions as would not result in a Material Adverse Effect;
- (f) The Company has been duly incorporated and is validly existing as a corporation in good standing under the laws of the State of Delaware, with power and corporate authority to own its properties and conduct its business as described in the Prospectus, and has been duly qualified as a foreign corporation for the transaction of business and is in good standing under the laws of each other jurisdiction in which it owns or leases properties or conducts any business so as to require such qualification, except where the failure to be so qualified would not result in a Material Adverse Effect;
- (g) The Company does not control directly or indirectly or have any direct or indirect equity participation or similar interest in any corporation, partnership, limited liability company, joint venture, trust or other business association or entity;
- (h) The Company has an authorized capitalization as set forth in the Prospectus, and all of the issued shares of capital stock of the Company have been duly and validly authorized and issued and are fully paid and non-assessable;
- (i) The Shares have been duly and validly authorized, and, when the Firm Shares are issued and delivered pursuant to this Agreement and the Pricing Agreement with respect to such Designated Shares and, in the case of any Optional Shares, pursuant to Additional Shares Options (as defined in Section 3 hereof) with respect to such Shares, such Designated Shares will be duly and validly issued and fully paid and non-assessable; the Shares conform to the description thereof contained in the Registration Statement and the Designated Shares will conform to the description thereof contained in the Prospectus as amended or supplemented with respect to such Designated Shares;

- (j) The issue and sale of the Shares by the Company and the compliance by the Company with all of the provisions of this Agreement, any Pricing Agreement and each Additional Shares Option, if any, and the consummation of the transactions contemplated herein and therein will not conflict with or result in a breach or violation of any of the terms or provisions of, or constitute a default under, any indenture, mortgage, deed of trust, loan agreement or other agreement or instrument to which the Company is a party or by which the Company is bound or to which any of the property or assets of the Company is subject, other than any conflict, breach or violation that would not have a Material Adverse Effect, nor will such action result in any violation of the provisions of the Certificate of Incorporation or By-laws of the Company or any statute or any order, rule or regulation of any court or governmental agency or body having jurisdiction over the Company or any of its properties; and no consent, approval, authorization, order, registration or qualification of or with any such court or governmental agency or body is required for the issue and sale of the Shares or the consummation by the Company of the transactions contemplated by this Agreement or any Pricing Agreement or any Additional Shares Option, except such as have been, or will have been prior to each Time of Delivery (as defined in Section 4 hereof), obtained under the Act and such consents, approvals, authorizations, registrations or qualifications as may be required under state securities or Blue Sky laws in connection with the purchase and distribution of the Shares by the Underwriters;
- (k) The Company is not (i) in violation of its Certificate of Incorporation or By-laws or (ii) in default in the performance or observance of any material obligation, agreement, covenant or condition contained in any indenture, mortgage, deed of trust, loan agreement, lease or other agreement or instrument to which it is a party or by which it or any of its properties may be bound, except in the case of clause (ii), any default that would not have a Material Adverse Effect;
- (I) The statements set forth in the Prospectus under the caption "Description of Capital Stock", insofar as they purport to constitute a summary of the terms of the Shares, and the statements set forth in the Prospectus under the caption "Plan of Distribution", the statements incorporated by reference into the Prospectus from the Company's Annual Report on Form 10-K for the year ended December 31, 2004 filled with the Commission, as amended, under the captions "Business Licenses and Collaborative Relationships, Manufacturing, Intellectual Property, and Government Regulation," and the statements set forth in the Prospectus as amended or supplemented under the captions "Prospectus Supplement Summary Acapodene, Andarine for the Treatment of Cancer Weight Loss, Fareston and Orion Agreement," "Risk Factors Risks Related to Our Dependence on Third Parties – If third parties do not manufacture our product candidates in sufficient quantities and at an acceptable cost, clinical development and commercialization of our product candidates would be delayed, and – We are dependent on our collaborative arrangement with Ortho Biotech to develop and commercialize andarine, and we may be dependent upon additional collaborative arrangements to complete the development and commercialization of some of our other product candidates. These collaborative arrangements may place the development of our product candidates outside our control, may require us to relinquish important rights or may otherwise be on terms unfavorable to us, Risks Related to Our Intellectual Property Our license agreement with Orion excludes the use of toremifene in humans to treat breast cancer outside the United

States and may limit our ability to market Acapodene for human uses of toremifene outside the United States, —— If some or all of our, or our licensors', patents expire or are invalidated or are found to be unenforceable, or if some or all of our patent applications do not yield issued patents or yield patents with narrow claims, or if we are estopped from asserting that the claims of an issued patent cover a product of a third party, we may be subject to competition from third parties with products with the same active pharmaceutical ingredients as our product candidates, and —— Off-label sale or use of toremifene products could decrease our sales of Acapodene and could lead to pricing pressure if such products become available at competitive prices and in dosages that are appropriate for the indications for which we are developing Acapodene, — Risks Related to Commercialization —— If we are unable to obtain adequate coverage and reimbursement from third-party payors for products we sell at acceptable prices, our revenues and prospects for profitability will suffer, — Risks Related to Our Common Stock —— Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management, and —— A significant portion of our total outstanding shares are restricted from immediate resale but may be sold into the market in the near future. This could cause the market price of our common stock to drop significantly, even if our business is doing well" underwriting", insofar as they purport to describe the provisions of the laws and documents referred to therein, are accurate, complete and fair;

- (m) There are no legal or governmental proceedings pending to which the Company is a party or of which any property of the Company is the subject, which, if determined adversely to the Company, would individually or in the aggregate have a Material Adverse Effect; and, to the Company's knowledge, no such proceedings are threatened or contemplated by governmental authorities or threatened by others;
- (n) The Company is not and, after giving effect to the offering and sale of the Shares, will not be an "investment company", as such term is defined in the Investment Company Act of 1940, as amended (the "Investment Company Act") and the rules and regulations of the Commission promulgated thereunder;
- (o) The Company does not do business with the government of Cuba nor, to the Company's knowledge, with any person or affiliate located in Cuba within the meaning of Section 517.075, Florida Statutes;
- (p) Ernst & Young LLP, who have certified certain financial statements of the Company, are independent public accountants as required by the Act and the rules and regulations of the Commission promulgated thereunder;
- (q) The financial statements of the Company (together with the related notes thereto) included or incorporated by reference in the Registration Statement and the Prospectus as amended and supplemented (i) fairly present the financial condition and results of the operations and cash flows of the Company as of the respective dates indicated and for the respective periods specified, (ii) complied as to form in all material respects with applicable accounting requirements and the published rules and regulations of the Commission with respect thereto (including, without limitation, Regulation S-X) and (ii) have been prepared in accordance with generally accepted accounting principles in the United States applied on a consistent basis during the

periods and at the dates involved (except as may be indicated in the notes thereto); the summary and selected financial data included or incorporated by reference in the Prospectus as amended or supplemented fairly present the information shown therein and have been compiled on a consistent basis with that of the audited financial information incorporated by reference in the Registration Statement and the Prospectus; the as adjusted financial information included in the Prospectus as amended or supplemented with respect to Designated Shares fairly presents the as adjusted financial position of the Company after giving effect to the sale of such Designated Shares at the date thereof and has been prepared in accordance with the Commission's rules and guidelines with respect to pro forma financial information; and the assumptions used in the preparation thereof are reasonable and the adjustments used therein are appropriate to give effect to the transactions and circumstances referred to therein;

- (r) The Company maintains a system of internal control over financial reporting (as such term is defined in Rule 13a-15(f) of the Exchange Act) that complies with the requirements of the Exchange Act and has been designed by the Company's principal executive officer and principal financial officer, or under their supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles; the Company's internal control over financial reporting is effective and the Company is not aware of any material weaknesses in its internal control over financial reporting; there has been no fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting; since the date of the latest audited financial statements included or incorporated by reference in the Prospectus, there has been no change in the Company's internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting;
- (s) The Company maintains disclosure controls and procedures (as such term is defined in Rule 13a-15(e) of the Exchange Act) that comply with the requirements of the Exchange Act; such disclosure controls and procedures have been designed to ensure that material information relating to the Company and its subsidiaries is made known to the Company's principal executive officer and principal financial officer by others within those entities; such disclosure controls and procedures are effective;
- (t) The Company is in compliance in all material respects with all applicable provisions of the Sarbanes-Oxley Act of 2002 and the rules and regulations promulgated by the Commission thereunder;
- (u) The Company owns or has valid, binding and enforceable licenses or other rights to use the patents and patent applications, copyrights, trademarks, trade names, service marks, service names, and know-how (including trade secrets and other unpatented proprietary intellectual property rights) that is necessary or used in any material respect to conduct its business in the manner in which it is described as being conducted and in the manner in which it is contemplated to be conducted as set forth in the Prospectus as amended or supplemented with respect to Company's product candidates identified in the table on pages S-1 and S-2 of the Prospectus Supplement dated October 11, 2005 (the "Product Candidates") (such rights are referred to herein

collectively as the "Company Intellectual Property"); the Company owns or possesses licenses or other rights to the patents and patent applications set forth on the schedule provided to the Representatives on behalf of the Underwriters on the date hereof (the "Patent Schedule") (the patents and patent applications set forth on the Patent Schedule that disclose or claim the Product Candidates are referred to herein collectively as the "Company Patents") that is necessary or used in the conduct of its business in the manner in which it is described as being conducted and in the manner in which it is contemplated to be conducted as set forth in the Prospectus as amended or supplemented; with respect to Product Candidates, the Company has exclusive rights to develop, market and commercialize as disclosed in the Prospectus as amended or supplemented; none of the issued patents within the Company Patents is unenforceable or invalid and to the Company's knowledge, none of the patent applications within Company Patents if issued would be unenforceable or invalid; nor is any material fact known by the Company with respect to such Company Patents that would preclude the issuance of patents with respect to such applications or would render such patents invalid or unenforceable; the Company is not obligated to pay a royalty, grant a license, or provide other consideration to any third party in connection with the Product Candidates other than as disclosed in the Prospectus as amended or supplemented; the Company has not received any notice of infringement or conflict with (and the Company is not aware of any infringement or conflict with) the rights of others with respect to the Product Candidates disclosed and claimed in the Company Patents or in connection with its business as currently conducted or as currently contemplated to be conducted as described in the Prospectus as amended or supplemented; there are no pending, nor has there been any notice of any, threatened, actions, suits, proceedings, claims or allegations by others that the Company is or will be infringing any patent, trade secret, trademark, service mark, copyright or other proprietary intellectual property rights through the manufacture, use or sale of any Product Candidates; the manufacture, use or sale of the products, including Product Candidates, described in the Prospectus as amended or supplemented as being under development and other activities of the Company referred to in the Prospectus as amended or supplemented does not, and to the Company's knowledge, will not, infringe or conflict with any patent of any third party in a manner which could reasonably be expected to have a Material Adverse Effect; to the Company's knowledge, the patents and patent applications within Company Patents cover the Product Candidates and are patentable; the Company has not been notified of any inventorship challenges or any interference proceeding having been declared or provoked with respect to the Company Patents, nor is any material fact known by the Company which fact is reasonably likely to result in any inventorship challenge or interference proceeding with respect to such patents and patent applications; to the Company's knowledge no third party has infringed or misappropriated, and no third party is currently infringing or misappropriating the Company Intellectual Property; except as described in the Prospectus as amended or supplemented and for any rights of the United States government pursuant to 35 U.S.C. § 200 et seq. relating to a Product Candidate other than Acapodene, no third party, including any academic institution or any other government entity, possesses rights to the Company Patents which, if exercised, could enable such party to develop products competitive to a Product Candidate or could reasonably be expected to have a Material Adverse Effect; the Company is not in material breach of, and has complied in all material respects with all terms of, any license agreement to which it is a party that covers technology

necessary to conduct or used in the conduct of the Company's business in the manner in which it is described as being conducted and in the manner in which it is contemplated to be conducted as set forth in the Prospectus as amended or supplemented; there are no contracts or other documents material to the Company's patents, trade secrets, trademarks, service marks, copyrights or other proprietary information or materials included in the Company Intellectual Property other than those described in the Prospectus as amended or supplemented; no Company employee is obligated under any contract (including licenses, covenants or commitments of any nature) or other agreement, or subject to any judgment, decree or order of any court or administrative agency, that would interfere with the use of such employee's best efforts to promote the interest of the Company or that would conflict with the Company's business; none of the execution and delivery of this Agreement or any Pricing Agreement, the carrying on of the Company's business by the employees of the Company, and the conduct of the Company's business as proposed, will conflict with or result in a breach of terms, conditions, or provisions of, or constitute a default under, any contract, covenant or instrument under which any such employee is now obligated; and it is not and will not be necessary to use any inventions, trade secrets or proprietary information of any of its consultants, or its employees (or persons it currently intends to hire) made prior to their employment by the Company, except for technology that is licensed to or owned by the Company;

(v) The Company has complied with the required duty of candor and good faith in dealing with the United States Patent and Trademark Office (the "PTO") with respect to the Company Patents, and to the Company's knowledge, all individuals to whom the duty of candor and good faith applies with respect to the Company Patents have complied with such duty, including the duty to disclose to the PTO all information believed to be material to the patentability of the Company Patents and pending U.S. patent applications within Company Patents; the Company, the University of Tennessee Research Foundation ("UTRF") and Orion are identified in the records of the PTO as the holder of record of the U.S. patents and patent applications of the Company Patents as set forth in the Patent Schedule; the Company, UTRF and Orion are similarly listed in the records of corresponding foreign agencies with respect to the foreign counterparts of the Company Patents; except for the rights of UTRF, Orion and The Ohio State University ("OSU") that are described in the Prospectus as amended or supplemented, the rights of the OSU solely to receive payments from UTRF with respect to certain patent applications and related patents and to utilize certain of the Company Patents for academic, non-commercial purposes, the rights of the United States government pursuant to 35 U.S.C. § 200 et seg. relating to a Product Candidate other than Acapodene and the nonexclusive rights that the Company granted to third party contractors to perform activities on the Company's behalf to develop Product Candidates (such as conducting clinical trials, research or manufacturing activities and which is set forth on Schedule 2(v)), no other entity or individual has any right, title or interest in the Company Patents; there are no legal or governmental proceedings pending relating to Company Patents other than PTO or World Intellectual Property Organization ("WIPO") (or patent offices in other jurisdictions) review of pending applications for patents, and, other than PTO or WIPO (or patent offices in other jurisdictions) review of pending applications for patents, to the Company's knowledge, no such proceedings are threatened or contemplated by governmental authorities or

others, and the Company is not aware of any fact that is likely to result in any such proceeding; and the Company is diligently prosecuting, and shall continue to diligently prosecute, claims in the patent applications within the Company Patents which claim products described in the Prospectus as being under development;

- (w) The Company possesses all registrations, approvals, certificates, authorizations and permits issued by the appropriate federal, state, local or foreign regulatory authorities necessary to conduct its business as described in the Prospectus as amended or supplemented, including without limitation, all such registrations, approvals, certificates, authorizations and permits required by the United States Food and Drug Administration (the "FDA") or any other federal, state, local or foreign agencies or bodies engaged in the regulation of pharmaceuticals or biohazardous substances or materials, except where the failure to possess such registrations, approvals, certificates, authorizations and permits, singly or in the aggregate, would not have a Material Adverse Effect; and the Company has not received any notice of proceedings relating to, and there are no facts or circumstances, including without limitation facts or circumstances relating to the withdrawal, revocation, suspension, modification or termination of any registration, approval, certificate, authorization or permit held by others, known to the Company that could lead to, the withdrawal, revocation, suspension, modification or termination of any such registration, approval, certificate, authorization or permit, which, singly or in the aggregate, if the subject of an unfavorable decision, ruling or finding, could result in a Material Adverse Effect;
- (x) The Company and, to the Company's knowledge, others who perform services on the Company's behalf have been and are in compliance with all applicable federal, state, local and foreign laws, rules, regulations, standards, orders and decrees governing their respective businesses, including without limitation, all regulations promulgated by the FDA or any other federal, state, local or foreign agencies or bodies engaged in the regulation of pharmaceuticals or biohazardous substances or materials, except where noncompliance would not, singly or in the aggregate, have a Material Adverse Effect; and the Company has not received any notice citing action or inaction by the Company or others who perform services on the Company's behalf that would constitute non-compliance with any applicable federal, state, local or foreign laws, rules, regulations or standards;
- (y) The tests and preclinical and clinical studies conducted by or on behalf of the Company that are described in the Registration Statement and the Prospectus as amended or supplemented were and, if still pending, are being, conducted in all material respects in accordance with experimental protocols, procedures and controls generally used by qualified experts in the preclinical and clinical study of new drugs, and laws and regulations; the descriptions of the tests and preclinical and clinical studies, and results thereof, conducted by or on behalf of the Company contained in the Registration Statement and the Prospectus as amended or supplemented are accurate in all material respects; the Company has not received any written notice or correspondence from the FDA or any foreign, state or local governmental body exercising comparable authority or any Institutional Review Board or comparable authority requiring the termination, suspension, material modification or clinical hold of any tests or preclinical or clinical studies conducted by or on behalf of the Company, which termination, suspension, material modification or clinical hold would reasonably be expected to have a Material

Adverse Effect; and the Company has not received any written notices or correspondence from others concerning the termination, suspension, material modification or clinical hold of any tests or preclinical or clinical studies conducted by others on any active ingredient contained in the existing products of the Company or the products described in the Prospectus as amended or supplemented as being under development, which termination, suspension, material modification or clinical hold would reasonably be expected to have a Material Adverse Effect;

- (z) The Company has all consents, authorizations, approvals, orders, certificates and permits of and from, and has made all declarations and filings with, all foreign, federal, state, local and other governmental authorities, all self-regulatory organizations and all courts and other tribunals necessary to own, lease, license and use its properties and assets and to conduct its business in the manner in which it is described in the Prospectus as amended or supplemented, except for such consents, authorizations, approvals, orders, certificates, permits, declarations and filings the failure of which to have, maintain or make would not have a Material Adverse Effect; the Company has not received any notice of proceedings relating to the revocation or modification of any such consent, authorization, approval, order, certificate or permit; and the Company is in compliance with all applicable foreign, federal, state and local laws and regulations, except for any noncompliance that, singly or in the aggregate, would not have a Material Adverse Effect;
- (aa) There are no contracts, agreements or understandings between the Company and any person granting such person the right to require the Company to file a registration statement under the Act with respect to any securities of the Company or to include any securities of the Company with the Shares registered pursuant to the Registration Statement, except as otherwise disclosed in the Prospectus as amended or supplemented or as have been waived in writing by such person in connection with the offering of the Shares contemplated hereby;
- (ab) The Company (i) is in compliance with any and all applicable foreign, federal, state and local laws, regulations and common law standards of conduct relating to the protection of human health and safety, the environment or hazardous or toxic substances, chemicals, wastes, pollutants and contaminants ("Environmental Laws"), (ii) has received all permits, licenses or other approvals required of them under applicable Environmental Laws to conduct its businesses as described in the Prospectus as amended or supplemented, (iii) is in compliance with all terms and conditions of any such permit, license or approval, (iv) is not subject to any liability under any Environmental Law for the release or disposal of any substance regulated pursuant to any Environmental Law, (v) has not received any claim, notice or demand indicating that it may be in violation of, or subject to liability or costs under, any Environmental Law and (vi) is not subject to any order, decree, injunction or agreement with any governmental authority or any third party concerning obligations or liabilities relating to any Environmental Law, except where such noncompliance with Environmental Laws, failure to receive required permits, licenses or other approvals or failure to comply with the terms and conditions of such permits, licenses or approvals or liabilities, claims, orders or agreement would not, singly or in the aggregate, have a Material Adverse Effect;
- (ac) The Company is not involved in any labor dispute nor, to the Company's knowledge, is any such dispute threatened; and the Company is not aware that (i) any

executive, key employee, key consultant or significant group of employees or consultants of the Company plans to terminate his or her employment or consulting arrangement with the Company or (ii) any such executive, key employee or key consultant is subject to any noncompete, nondisclosure, confidentiality, employment, consulting or similar agreement that would be violated by the present or proposed business activities of the Company;

- (ad) The Company is insured by insurers of recognized financial responsibility against such losses and risks and in such amounts as are prudent and customary in the business in which the Company is engaged; except as disclosed in a letter from the Company to the Representatives of even date herewith, the Company has not been refused any insurance coverage sought or applied for; and the Company does not have any reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business at a cost that would not have a Material Adverse Effect;
- (ae) Each material contract, agreement and license filed as an exhibit to the Registration Statement to which the Company is bound is legal, valid, binding, enforceable in accordance with its terms and in full force and effect against the Company and, to the Company's knowledge, each other party thereto; neither the Company nor, to the Company's knowledge, any other party, is in material breach or default with respect to any such contract, agreement and license, and, to the Company's knowledge, no event has occurred which with notice or lapse of time would constitute a material breach or default, or permit termination, modification, or acceleration, under any such contract, agreement or license; and to the Company's knowledge, no party has repudiated any material provision of any such contract, agreement or license; and
- (af) The statistical and market-related data included in the Registration Statement and the Prospectus as amended or supplemented are based on or derived from sources which the Company reasonably and in good faith believes are reliable and accurate, and such data agree with the sources from which they are derived.
- 3. Upon the execution of the Pricing Agreement applicable to any Designated Shares and authorization by the Representatives of the release of the Firm Shares, the several Underwriters propose to offer the Firm Shares for sale upon the terms and conditions set forth in the Prospectus as amended or supplemented.

The Company may specify in the Pricing Agreement applicable to any Designated Shares that the Company thereby grants to the Underwriters the right (an "Additional Shares Option") to purchase at their election up to the number of Optional Shares set forth in such Pricing Agreement, on the terms set forth in the Prospectus as amended or supplemented (provided that the purchase price per Optional Share shall be reduced by an amount per share equal to any dividends or distributions declared by the Company and payable on the Firm Shares but not payable on the Optional Shares), for the sole purpose of covering sales of shares by the Underwriters in excess of the number of Firm Shares. Any such election to purchase Optional Shares may be exercised by written notice from the Representatives to the Company, given within a period specified in the Pricing Agreement, setting forth the aggregate number of Optional Shares to be purchased and the date on which such Optional Shares are to be delivered, as determined by the Representatives but in no event earlier than the First Time

of Delivery (as defined in Section 4 hereof) or, unless the Representatives and the Company otherwise agree in writing, earlier than or later than the respective number of business days after the date of such notice set forth in such Pricing Agreement.

The number of Optional Shares to be added to the number of Firm Shares to be purchased by each Underwriter as set forth in Schedule I to the Pricing Agreement applicable to such Designated Shares shall be, in each case, the number of Optional Shares which the Company has been advised by the Representatives have been attributed to such Underwriter; provided that, if the Company has not been so advised, the number of Optional Shares to be so added shall be, in each case, that proportion of Optional Shares which the number of Firm Shares to be purchased by such Underwriter under such Pricing Agreement bears to the aggregate number of Firm Shares (rounded as the Representatives may determine to the nearest 100 shares). The total number of Designated Shares to be purchased by all the Underwriters pursuant to such Pricing Agreement shall be the aggregate number of Firm Shares set forth in Schedule I to such Pricing Agreement plus the aggregate number of Optional Shares which the Underwriters elect to purchase.

- 4. Certificates for the Firm Shares and the Optional Shares to be purchased by each Underwriter pursuant to the Pricing Agreement relating thereto, in the form specified in such Pricing Agreement and in such authorized denominations and registered in such names as the Representatives may request upon at least forty-eight hours' prior notice to the Company, shall be delivered by or on behalf of the Company to the Representatives for the account of each Underwriter, against payment by such Underwriter or on its behalf of the purchase price therefor by wire transfer of Federal (same-day) funds to the account specified by the Company to the Representatives at least forty-eight hours in advance as specified in such Pricing Agreement, (i) with respect to the Firm Shares, all in the manner and at the place and time and date specified in such Pricing Agreement or at such other place and time and date as the Representatives and the Company may agree upon in writing, such time and date being herein called the "First Time of Delivery" and (ii) with respect to the Optional Shares, if any, in the manner and at the time and date specified by the Representatives in the written notice given by the Representatives of the Underwriters' election to purchase such Optional Shares, or at such other time and date as the Representatives and the Company may agree upon in writing, such time and date, if not the First Time of Delivery, herein called the "Second Time of Delivery". Each such time and date for delivery is herein called a "Time of Delivery".
 - 5. The Company agrees with each of the Underwriters of any Designated Shares:
 - (a) To prepare the Prospectus as amended and supplemented in relation to the applicable Designated Shares in a form approved by the Representatives and to file such Prospectus pursuant to Rule 424(b) under the Act not later than the Commission's close of business on the second business day following the execution and delivery of the Pricing Agreement relating to the applicable Designated Shares or, if applicable, such earlier time as may be required by Rule 424(b); to make no further amendment or any supplement to the Registration Statement or Prospectus as amended or supplemented after the date of the Pricing Agreement relating to such Shares and prior to any Time of Delivery for such Shares which shall be disapproved by the Representatives for such Shares promptly after reasonable notice thereof; to advise the Representatives promptly of any such amendment or supplement after any Time of Delivery for such Shares and furnish the Representatives with copies thereof; to file promptly all reports and any definitive proxy or information statements required to be

filed by the Company with the Commission pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act for so long as the delivery of a prospectus is required in connection with the offering or sale of such Shares, and during such same period to advise the Representatives, promptly after it receives notice thereof, of the time when any amendment to the Registration Statement has been filed or becomes effective or any supplement to the Prospectus or any amended Prospectus has been filed with the Commission, of the issuance by the Commission of any stop order or of any order preventing or suspending the use of any prospectus relating to the Shares, of the suspension of the qualification of such Shares for offering or sale in any jurisdiction, of the initiation or threatening of any proceeding for any such purpose, or of any request by the Commission for the amending or supplementing of the Registration Statement or Prospectus or for additional information; and, in the event of the issuance of any such stop order or of any such order preventing or suspending the use of any prospectus relating to the Shares or suspending any such qualification, promptly to use its best efforts to obtain the withdrawal of such order:

- (b) Promptly from time to time to take such action as the Representatives may reasonably request to qualify such Shares for offering and sale under the securities laws of such jurisdictions as the Representatives may request and to comply with such laws so as to permit the continuance of sales and dealings therein in such jurisdictions for as long as may be necessary to complete the distribution of such Shares, provided that in connection therewith the Company shall not be required to qualify as a foreign corporation or to file a general consent to service of process in any jurisdiction;
- (c) Prior to 10:00 A.M., New York City time, on the New York Business Day next succeeding the date of this Agreement and from time to time, to furnish the Underwriters with written and electronic copies of the Prospectus as amended or supplemented in New York City in such quantities as the Representatives may reasonably request, and, if the delivery of a prospectus is required at any time in connection with the offering or sale of the Shares and if at such time any event shall have occurred as a result of which the Prospectus as then amended or supplemented would include an untrue statement of a material fact or omit to state any material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made when such Prospectus is delivered, not misleading, or, if for any other reason it shall be necessary during such same period to amend or supplement the Prospectus or to file under the Exchange Act any document incorporated by reference in the Prospectus in order to comply with the Act or the Exchange Act, to notify the Representatives and upon their request to file such document and to prepare and furnish without charge to each Underwriter and to any dealer in securities as many written and electronic copies as the Representatives may from time to time reasonably request of an amended Prospectus or a supplement to the Prospectus which will correct such statement or omission or effect such compliance;
- (d) To make generally available to its security holders as soon as practicable, but in any event not later than eighteen months after the effective date of the Registration Statement (as defined in Rule 158(c) under the Act), an earnings statement of the Company (which need not be audited) complying with Section 11(a) of the Act and the rules and regulations of the Commission thereunder (including, at the option of the Company, Rule 158);

- (e) During the period beginning from the date hereof and continuing to and including the date 90 days after the date of the Pricing Agreement (the initial "Lock-Up Period"), not to offer, sell, contract to sell or otherwise dispose of, except as provided hereunder any securities of the Company that are substantially similar to the Designated Shares, including but not limited to any securities that are convertible into or exchangeable for, or that represent the right to receive, common stock or any such substantially similar securities (other than pursuant to employee stock option, non-employee director stock option and director deferred compensation plans existing on, or upon the conversion or exchange of convertible or exchangeable securities outstanding as of, the date of this Agreement), without the prior written consent of the Representatives; provided, however, that if (1) during the last 17 days of the initial Lock-Up Period, the Company releases earnings results or announces material news or a material event or (2) prior to the expiration of the initial Lock-Up Period, the Company announces that it will release earnings results during the 15-day period following the last day of the initial Lock-Up Period, then in each case the Lock-Up Period will be automatically extended until the expiration of the 18-day period beginning on the date of release of the earnings results or the announcement of the material news or material event, as applicable, unless the Representatives waive, in writing, such extension; the Company will provide the Representatives and any co-managers and each stockholder subject to the Lock-Up Period pursuant to the lockup letters described in subsection 5(f) with notice of any such announcement that gives rise to an extension of the Lock-up Period;
- (f) During the initial Lock-Up Period, not to file any registration statement under the Act for the sale of securities for the account of any stockholder, and during the Lock-Up Period, not to file any registration statement under the Act for the sale of securities for its own account:
- (g) To cause each of the Company's directors, executive officers and their affiliated entities to execute and deliver to you a lock-up agreement in substantially the form of Annex III attached hereto (a "Lock-up Agreement");
- (h) If the Company elects to rely upon Rule 462(b), the Company shall file a Rule 462(b) Registration Statement with the Commission in compliance with Rule 462(b) by 10:00 P.M., Washington, D.C. time, on the date of this Agreement, and the Company shall at the time of filing either pay the Commission the filing fee for the Rule 462(b) Registration Statement or give irrevocable instructions for the payment of such fee pursuant to Rule 111(b) under the Act;
- (i) To use the net proceeds received by it from the sale of the Shares pursuant to this Agreement in the manner specified in the Prospectus as amended or supplemented under the caption "Use of Proceeds";
 - (j) To use its best efforts to list for quotation the Shares on NASDAQ National Market System; and
- (k) Upon request of any Underwriter, to furnish, or cause to be furnished, to such Underwriter an electronic version of the Company's trademarks, servicemarks and corporate logo for use on the website, if any, operated by such Underwriter for the purpose of facilitating the on-line offering of the Shares (the "License"); provided,

however, that the License shall be used solely for the purpose described above, is granted without any fee and may not be assigned or transferred.

- 6. The Company covenants and agrees with the several Underwriters that the Company will pay or cause to be paid the following: (i) the fees, disbursements and expenses of the Company's counsel and accountants in connection with the registration of the Shares under the Act and all other expenses in connection with the preparation, printing and filing of the Registration Statement, any Preliminary Prospectus and the Prospectus and amendments and supplements thereto and the mailing and delivering of copies thereof to the Underwriters and dealers; (ii) the cost of printing or producing any Agreement among Underwriters, this Agreement, any Pricing Agreement, any Blue Sky Memorandum, closing documents (including compilations thereof) and any other documents in connection with the offering, purchase, sale and delivery of the Shares; (iii) all expenses in connection with the qualification of the Shares for offering and sale under state securities laws as provided in Section 5(b) hereof, including the reasonable fees and disbursements of counsel for the Underwriters in connection with such qualification and in connection with the Blue Sky survey(s); (iv) any filing fees incident to, and the fees and disbursements of counsel for the Underwriters in connection with, any required reviews by the National Association of Securities Dealers, Inc. ("NASD") of the terms of the sale of the Shares; (v) the cost of preparing certificates for the Shares; (vi) the cost and charges of any transfer agent or registrar or dividend disbursing agent; and (vii) all other costs and expenses incident to the performance of its obligations hereunder and under any Additional Shares Options which are not otherwise specifically provided for in this Section. It is understood, however, that, except as provided in this Section, and Sections 8 and 11 hereof, the Underwriters will pay all of their own costs and expenses, including the fees of their counsel, transfer taxes on resale of any of the Shares by them, and any advertising expenses connected wi
- 7. The obligations of the Underwriters of any Designated Shares under the Pricing Agreement relating to such Designated Shares shall be subject, in the discretion of the Representatives, to the condition that all representations and warranties and other statements of the Company in or incorporated by reference in the Pricing Agreement relating to such Designated Shares are, at and as of each Time of Delivery for such Designated Shares, true and correct, the condition that the Company shall have performed all of its obligations hereunder theretofore to be performed, and the following additional conditions:
 - (a) The Prospectus as amended or supplemented in relation to such Designated Shares shall have been filed with the Commission pursuant to Rule 424(b) within the applicable time period prescribed for such filing by the rules and regulations under the Act and in accordance with Section 5(a) hereof; if the Company has elected to rely upon Rule 462(b), the Rule 462(b) Registration Statement shall have become effective by 10:00 P.M., Washington, D.C. time, on the date of this Agreement; no stop order suspending the effectiveness of the Registration Statement or any part thereof shall have been issued and no proceeding for that purpose shall have been initiated or threatened by the Commission; and all requests for additional information on the part of the Commission shall have been complied with to the Representatives' reasonable satisfaction;
 - (b) Wilmer Cutler Pickering Hale and Dorr LLP, counsel for the Underwriters, shall have furnished to the Representatives such written opinion or opinions, dated each Time of Delivery for such Designated Shares, with respect to the matters as the

Representatives may reasonably request, and such counsel shall have received such papers and information as they may reasonably request to enable them to pass upon such matters;

- (c) Bass, Berry & Sims PLC, counsel for the Company, shall have furnished to the Representatives their written opinions (a draft of each such opinion is attached as Annex II(a) hereto), dated each Time of Delivery for such Designated Shares, respectively, in form and substance satisfactory to the Representatives, to the effect that:
 - (i) To such counsel's knowledge and other than as set forth in the Prospectus, there are no legal or governmental proceedings pending to which the Company is a party or of which any property of the Company is the subject which, if determined adversely to the Company, would individually or in the aggregate have a material adverse effect on the current or future financial position, stockholders' equity or results of operations of the Company; and, to such counsel's knowledge, no such proceedings are threatened or contemplated by governmental authorities or threatened by others;
 - (ii) The issued and outstanding shares of capital stock of the Company have been duly authorized and validly issued and are fully paid and non-assessable;
 - (iii) The issue and sale of the Designated Shares being delivered at such Time of Delivery and the compliance by the Company with all of the provisions of this Agreement and the Pricing Agreement with respect to the Designated Shares and the consummation of the transactions herein and therein contemplated have not conflicted with or resulted in a breach or violation of any of the terms or provisions of, or constituted a default under, and will not conflict with or result in a breach or violation of any of the terms or provisions of, or constitute a default under, the Certificate of Incorporation or By-laws of the Company or any agreement or other instrument filed by the Company as an Exhibit to the Registration Statement or to any of the documents incorporated by reference in the Prospectus as amended or supplemented, nor will such action result in any violation of the provisions of any statute or any order, rule or regulation of any court or governmental agency or body having jurisdiction over the Company or any of its properties;
 - (iv) No consent, approval, authorization, order, registration or qualification of or with any such court or governmental agency or body is required for the issue and sale of the Designated Shares being delivered at such Time of Delivery or the consummation by the Company of the transactions contemplated by this Agreement or such Pricing Agreement, except such as have been obtained under the Act and such consents, approvals, authorizations, registrations or qualifications as may be required under state securities or Blue Sky laws in connection with the purchase and distribution of the Designated Shares by the Underwriters;
 - (v) To such counsel's knowledge, the Company is not in violation of its Certificate of Incorporation or By-laws or, to such counsel's knowledge, in default in the performance or observance of any material obligation, agreement,

covenant or condition contained in any agreement or other instrument filed by the Company as an Exhibit to the Registration Statement or to any of the documents incorporated by reference in the Prospectus as amended or supplemented:

- (vi) The statements set forth in the Prospectus under the caption "Plan of Distribution" and in the Prospectus as amended or supplemented under the caption "Underwriting", insofar as they purport to summarize the terms of this Agreement or the Pricing Agreement, fairly present, in all material respects, such terms;
- (vii) The documents incorporated by reference in the Prospectus as amended or supplemented (other than the financial statements, related schedules and other financial and accounting data contained or referred to therein, as to which such counsel need express no opinion), when they became effective or were filed with the Commission, as the case may be, complied as to form in all material respects with the requirements of the Act or the Exchange Act, as applicable, and the rules and regulations of the Commission thereunder:
- (viii) The Registration Statement and the Prospectus as amended or supplemented, and any further amendments and supplements thereto made by the Company prior to such Time of Delivery (other than the financial statements and related schedules and other financial data derived therefrom, as to which such counsel need express no opinion), comply as to form in all material respects with the requirements of the Act and the rules and regulations thereunder; and, to such counsel's knowledge, there are no contracts or other documents of a character required to be filed as exhibits to the Registration Statement or required to be incorporated by reference into the Prospectus as amended or supplemented or required to be described in the Registration Statement or the Prospectus as amended or supplemented which are not filed or incorporated by reference or described as required; and such counsel does not know of any amendment to the Registration Statement required to be filed; and

In addition, such counsel shall state that, in connection with the preparation of the Registration Statement and the Prospectus as amended or supplemented, it has participated in conferences with officers of the Company, representatives of the Company's independent public accountants and representatives of the Representatives and their counsel during which the contents of the Registration Statement and the Prospectus as amended or supplemented were discussed. Such counsel has not independently verified, is not passing upon and assumes no responsibility for the accuracy, completeness or fairness of the Registration Statement or Prospectus, as amended or supplemented (except as and to the extent specified in paragraph (vi) of this Section 7(c)). On the basis of the foregoing, no facts have come to such counsel's attention that causes such counsel to believe that (A) as of its effective date, the Registration Statement or any further amendment thereto made by the Company prior to such Time of Delivery (except for the financial statements and related schedules and other financial data derived therefrom, as to which such counsel expresses no belief) contained an untrue statement of a material fact or omitted to state a material fact

required to be stated therein or necessary to make the statements therein not misleading, (B) as of its date, the Prospectus as amended or supplemented or any further amendment or supplement thereto made by the Company prior to such Time of Delivery (except for the financial statements and related schedules and other financial data derived therefrom, as to which such counsel expresses no belief) contained an untrue statement of a material fact or omitted to state a material fact necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading, or (C) as of such Time of Delivery, either the Registration Statement or the Prospectus as amended or supplemented or any further amendment or supplement thereto made by the Company prior to such Time of Delivery (other than the financial statements and related schedules and other financial data derived therefrom, as to which such counsel need express no opinion) contains an untrue statement of a material fact or omits to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.

- (d) Cooley Godward LLP, counsel for the Company, shall have furnished to the Representatives their written opinion (a draft of such opinion is attached as Annex II(b) hereto), dated each Time of Delivery for such Designated Shares, respectively, in form and substance satisfactory to the Representatives, to the effect that:
 - (i) The Company has been duly incorporated and is validly existing as a corporation in good standing under the laws of the State of Delaware, with requisite corporate power to own or lease, as the case may be, its properties and conduct its business as described in the Prospectus as amended or supplemented, and is duly qualified to do business as a foreign corporation and is in good standing under the laws of the State of Tennessee;
 - (ii) The Company has an authorized capitalization as set forth in the Prospectus as amended or supplemented;
 - (iii) The Designated Shares have been duly authorized and, when issued to and paid for by the Underwriters pursuant to this Agreement and the applicable Pricing Agreement, will be validly issued, fully paid and non-assessable; and the Designated Shares conform in all material respects to the description thereof contained in the Prospectus as amended or supplemented;
 - (iv) To such counsel's knowledge, there is no action, suit or proceeding by or before any court or other governmental agency, authority or body or any arbitrator pending against the Company or to which any of the properties of the Company is the subject of a character required to be disclosed in the Registration Statement or Prospectus that is not disclosed in the Registration Statement or Prospectus as required by the Act and the rules and regulations promulgated by the Commission thereunder;
 - (v) This Agreement and the Pricing Agreement with respect to the Designated Shares have been duly authorized by all necessary corporate action on the part of the Company and have been executed and delivered by the Company;

- (vi) The execution and delivery by the Company of this Agreement and the Pricing Agreement with respect to the Designated Shares, the issue and sale of the Designated Shares being delivered at such Time of Delivery, the compliance by the Company with all of the provisions of this Agreement and the Pricing Agreement with respect to the Designated Shares, and the consummation by the Company of the transactions herein and therein contemplated with respect to the Designated Shares will not (i) result in a breach or violation of the Certificate of Incorporation or By laws of the Company, (ii) result in a breach or violation of, or constitute a default under, the terms of any indenture, mortgage, deed of trust, loan agreement or other agreement or instrument filed as an exhibit to the Company's reports or other documents filed with the Commission pursuant to the Exchange Act or (iii) result in a breach or violation of any statute, law, rule or regulation, which in such counsel's experience is typically applicable to transactions of the nature contemplated by this Agreement and the Pricing Agreement and is applicable to the Company, or any order, writ, judgment, injunction, decree or award that has been entered against the Company or any of its properties and of which such counsel is aware, in the case of clause (ii), the breach or violation of, or default under, would have a Material Adverse Effect or would impair the validity of the issuance and sale of the Designated Shares or the validity or enforceability of this Agreement or the Pricing Agreement with respect to the Designated Shares, other than the rules and regulations of the NASD (as to which such counsel need express no opinion);
- (vii) No consent, approval, authorization or filing with or order of any court or governmental agency or body in the United States having jurisdiction over the Company is required for the issue and sale of the Designated Shares being delivered at such Time of Delivery or the consummation by the Company of the transactions contemplated by this Agreement or such Pricing Agreement, except such as have been obtained under the Act and such as may be required under state securities or "blue sky" laws of any jurisdiction or the bylaws, rules and regulations of the NASD (as to which such counsel need express no opinion) in connection with the purchase and distribution of the Designated Shares by the Underwriters;
- (viii) The statements set forth in the Prospectus under the caption "Description of Capital Stock", insofar as they purport to summarize the terms of the Shares, fairly present, to the extent required by the Act and the rules and regulations promulgated by the Commission thereunder, in all material respects such matters;
- (ix) The Company is not an "investment company", as such term is defined in the Investment Company Act, and the rules and regulations promulgated by the Commission thereunder;
- (x) The documents incorporated by reference in the Prospectus as amended or supplemented (other than the financial statements, related schedules and other financial and accounting data contained or referred to therein, as to which such counsel need express no opinion), when they became effective or were filed with the Commission, as the case may be, complied as to form in all

material respects with the requirements of the Act or the Exchange Act, as applicable, and the rules and regulations of the Commission thereunder:

(xi) The Registration Statement and the Prospectus as amended or supplemented, and any further amendments and supplements thereto made by the Company prior to such Time of Delivery (other than the financial statements, related schedules and other financial and accounting data contained or referred to therein, as to which such counsel need express no opinion), comply as to form in all material respects with the requirements of the Act and the rules and regulations thereunder; and to such counsel's knowledge, there is no indenture, contract, lease, mortgage, deed of trust, note agreement, loan or other agreement, instrument or document of a character required to be filed as an exhibit to the Registration Statement which is not filed as required by the Act and the rules and regulations promulgated by the Commission thereunder; and

In addition, such counsel shall state that, in connection with the preparation of the Registration Statement and the Prospectus as amended or supplemented, it has participated in conferences with officers and representatives of the Company and with its certified public accountants, as well as with representatives of the Representatives and counsel to the Representatives. At such conferences, the contents of the Registration Statement and the Prospectus and related matters were discussed. Such counsel has not independently verified, and accordingly, except as and to the extent specified in paragraphs (ii) and (viii) of this Section 7(d), is not confirming and assumes no responsibility for the accuracy, completeness or fairness of the statements contained in the Registration Statement or Prospectus as amended or supplemented. On the basis of the foregoing, no facts have come to such counsel's attention that have caused it to believe that (A) as of its effective date, the Registration Statement or any further amendment thereto made by the Company prior to such Time of Delivery (including the documents incorporated by reference therein) contained an untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary to make the statements therein not misleading; (B) as of its date, the Prospectus as amended or supplemented or any further amendment or supplement thereto made by the Company prior to such Time of Delivery (including the documents incorporated by reference therein) contained an untrue statement of a material fact or omitted to state a material fact necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading, or (C) as of such Time of Delivery, either the Registration Statement or the Prospectus as amended or supplemented or any further amendment or supplement thereto made by the Company prior to such Time of Delivery (including the documents incorporated by reference therein) contains an untrue statement of a material fact or omits to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading; provided that, in the case of clauses (A), (B) and (C), such counsel need express no opinion with respect to the financial statements, related schedules and other financial and

accounting data contained or incorporated by reference in the Registration Statement or the Prospectus as amended or supplemented.

- (e) Pearl Cohen Zedek Latzer, LLP, special patent counsel for the Company, shall have furnished to the Representatives their written opinions (a draft of each such opinion is attached as Annex II(c) hereto), dated each Time of Delivery for such Designated Shares, respectively, in form and substance satisfactory to the Representatives, to the effect that:
 - (i) The Company owns or is the exclusive licensee of the patents and patent applications that disclose and claim the Product Candidates, which patents and patent applications are set forth in the Patent Schedule (the "Company Patents"); no liens or other encumbrances have been recorded in the PTO against the Company Patents; no liens or encumbrances against the Company Patents have been recorded; no other entity has rights or interest in the Company Patents except as set forth in the Prospectus as amended or supplemented;
 - (ii) The Company does not lack any rights or licenses to practice any Company Patents;
 - (iii) The Company is diligently prosecuting claims in the patent applications included in the Company Patents and such claims cover the Product Candidates described in the Prospectus as amended or supplemented as being under development; for each U.S. patent application included in the Company Patents, all information known by such counsel, to date, and for each U.S. patent included in the Company Patents, all information known to such counsel as of the date of issuance of such patent, to be "material to patentability" as defined in 37 C.F.R. Section 1.56(b), has been disclosed, or will be disclosed, if required pursuant to 37 C.F.R. Section 1.97, to the PTO; such counsel and, to such counsel's knowledge, the Company, have complied and will comply with the required duty of candor and good faith in dealing with the PTO with respect to the Company Patents, including the duty to disclose to the PTO all information believed to be material to the patentability of the Company's pending U.S. patent applications included in the Company Patents, and none of the pending patent applications included in the Company Patents claiming any of the Product Candidates is currently under final rejection:
 - (iv) None of the Company Patents are invalid and none of the Company Patents are unenforceable. The Company Patents disclose subject matter encompassing the Product Candidates and claim patentable subject matter under the U.S. patent laws encompassing the Product Candidates; in particular, the Company Patents contain valid or patentable claims to the Product Candidates or to the use for which the Product Candidates are being developed as set forth in the Prospectus as amended or supplemented, there is no reason to believe that any of the patent applications pending in the United States included in the Company Patents that cover a Product Candidate and has not yet issued into a patent to cover a Product Candidate will not result in an issued patent, and there is no reason to believe that any patents issued in respect of any such patent applications will not be valid or enforceable, or will not afford the Company the patent protection described by the claims therein;
 - (v) Neither such counsel nor, to such counsel's knowledge, the Company has been advised by the PTO that there are any issued patents or pending

applications that would interfere with any of the Company Patents claiming any of the Product Candidates; neither such counsel nor, to such counsel's knowledge, the Company, is aware of any facts, issued patents or pending applications that could form the basis of a declaration or provocation of an interference with any Company Patents; and there are no third party patents that would dominate the claims of any of the Company Patents; no interference has been threatened, declared or provoked with respect to any of the Company Patents;

- (vi) There are no legal or governmental proceedings pending involving the Company Patents, other than PTO (or patent offices in other jurisdictions) or WIPO review of pending patent applications included in the Company Patents; except for PTO (or patent offices in other jurisdictions) or WIPO review of pending patent applications included in the Company Patents, the Company has not received any other notice of a threatened or contemplated legal proceeding by governmental authorities or others challenging the validity or scope of the Company Patents; none of the patents included in the Company Patents is the subject of a reexamination or reissue proceeding in the PTO; and none of the Company Patents are or have been opposed in any foreign patent office or court;
- (vii) The Company and/or its licensors are identified in the records of the PTO as the holders of record of the U.S. patents and patent applications included in the Company Patents; the Company and/or its licensors are similarly identified in the records of corresponding foreign agencies with respect to the foreign counterparts of the foregoing included in the Company Patents; and to such counsel's knowledge, no other entity or individual (other than the Company, UTRF and/or OSU and/or, with respect to Company Patents that disclose or claim a Product Candidate other than Acapodene, the United States Government pursuant to 35 U.S.C. §200 et seq) has any right, title or interest in the Company Patents; and, with respect to Company Patents disclosing or claiming inventions made using funds in whole or in part from a federal agency, the Company and/or its licensors pursuant to 37 C.F.R. §1.51 have set forth the name of the U.S. Government agency and contract number;
- (viii) The Company or its Licensors, have not received, and to such counsel's knowledge, the Company or its licensors, have not been threatened with, any claims of third parties to any inventorship, ownership interest or lien with respect to any of the Company Patents;
- (ix) The Company does not infringe any currently issued U.S. patents by the Company's manufacture, use, sale, offer for sale or importation of any of the Product Candidates; the Company has not received any notice of any pending or threatened action, suit, proceeding or claim by others that the Company is infringing any patent rights or other intellectual property rights of third parties by the Company's manufacture, use, sale, offer for sale or importation of any of the Product Candidates; and neither the manufacture, use or sale of any product of any third party is infringing any of the Company Patents;
- (x) The statements set forth or incorporated by reference in the Prospectus as amended or supplemented under the captions "Risk Factors Risks Related to Our Intellectual Property" and the statements set forth in the Company's Amendment No. 3 to Annual Report on Form 10-K/A incorporated by

reference in the Prospectus as amended or supplement under the caption "Business – Intellectual Property", insofar as they purport to describe the filing, prosecution and ownership of the Company Patents are accurate, complete and fair; and

- (xi) Such counsel have reviewed those portions of the Registration Statement and Prospectus as amended or supplemented, and any further amendments and supplements thereto made by the Company prior to such Time of Delivery that concern the Company Patents and, such counsel have no reason to believe that (A) as of its effective date, the Registration Statement or any further amendment thereto made by the Company prior to such Time of Delivery (except for the financial statements and related schedules and other financial data derived therefrom, as to which such counsel expresses no belief) contained an untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary to make the statements therein not misleading, (B) as of its date, the Prospectus as amended or supplemented or any further amendment or supplement thereto made by the Company prior to such Time of Delivery (except for the financial statements and related schedules and other financial data derived therefrom, as to which such counsel expresses no belief) contained an untrue statement of a material fact or omitted to state a material fact necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading, or (C) as of such Time of Delivery, either the Registration Statement or the Prospectus as amended or supplemented or any further amendment or supplement thereto made by the Company prior to such Time of Delivery (other than the financial statements and related schedules and any other financial data derived therefrom, as to which such counsel need express no opinion) contains an untrue statement of a material fact or omits to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.
- (f) Hogan & Hartson L.L.P., special regulatory counsel for the Company, shall have furnished to the Representatives Hogan & Hartson's written opinions (a draft of each such opinion is attached as Annex II(d) hereto), dated each Time of Delivery for such Designated Shares, respectively, in form and substance satisfactory to the Representatives, to the effect that:
 - (i) The statements incorporated by reference into the Prospectus from Amendment No. 3 to the Company's Annual Report on Form 10-K/A for the year ended December 31, 2004 under the captions "Business Government Regulation – New Drug Development and Approval Process, – Preclinical and Clinical Testing, – Product Formulation and Manufacture, – New Drug Application Process, – Marketing Approval and Post-Marketing Obligations, and – Drug Price Competition and Patent Term Restoration Act of 1984" and the statements in the Prospectus as amended or supplemented under the captions "Risk Factors Risks Related to Our Dependence on Third Parties – Use of third-party manufacturers may increase the risk that we will not have adequate supplies of our product candidates, Risks Related to Our Intellectual Property If some or all of our, or our licensors', patents expire or are invalidated or are found to be unenforceable, or if some or all of our patent applications do not yield issued patents or yield patents with narrow claims, or if we are estopped from asserting that the claims of an issued patent cover a product of a third party, we

may be subject to competition from third parties with products with the same active pharmaceutical ingredients as our product candidates, and — Off-label sale or use of toremifene products could decrease our sales of Acapodene and could lead to pricing pressure if such products become available at competitive prices and in dosages that are appropriate for the indications for which we are developing Acapodene, and — Risks Related to Regulatory Approval of Our Product Candidates — If we are not able to obtain required regulatory approvals, we will not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired" (collectively, the "FDA Regulatory Sections"), insofar as such statements purport to summarize applicable provisions of the Federal Food, Drug, and Cosmetic Act, as amended (the "FDC Act"), and the regulations promulgated thereunder, including without limitation statements relating to Special Protocol Assessments, are accurate summaries in all material respects of the provisions purported to be summarized therein; and

- (ii) To such counsel's knowledge, based on the business of the Company as described in the Prospectus as amended or supplemented, there is no provision of the FDC Act and the regulations promulgated thereunder that would be material to an investor in the Shares that is not summarized in the FDA Regulatory Sections.
- (g) On the date of the Pricing Agreement for such Designated Shares and at each Time of Delivery for such Designated Shares, the independent accountants of the Company who have certified the financial statements of the Company included or incorporated by reference in the Registration Statement shall have furnished to the Representatives a letter, dated the date of the Pricing Agreement for such Designated Shares, and a letter dated such Time of Delivery, respectively, to the effect set forth in Annex II hereto (a draft of the form of letter to be delivered on the date of the Pricing Agreement for such Designated Shares is attached as Annex I(a) hereto and a draft of the form of letter to be delivered at the Time of Delivery for such Designated Shares is attached as Annex I(b) hereto), and with respect to such letter dated such Time of Delivery, as to such other matters as the Representatives may reasonably request and in form and substance satisfactory to the Representatives;
- (h) (i) The Company shall not have sustained since the date of the latest audited financial statements included or incorporated by reference in the Prospectus as amended prior to the date of the Pricing Agreement relating to the Designated Shares any loss or interference with its business from fire, explosion, flood or other calamity, whether or not covered by insurance, or from any labor dispute or court or governmental action, order or decree, otherwise than as set forth or contemplated in the Prospectus as amended prior to the date of the Pricing Agreement relating to the Designated Shares, and (ii) since the respective dates as of which information is given in the Prospectus as amended prior to the date of the Pricing Agreement relating to the Designated Shares there shall not have been any change in the capital stock (other than as a result of the grant of stock options to purchase an aggregate of not more than 100,000 shares of common stock pursuant to the Company's current stock option plans the cancellation or exercise of stock options described in the Registration Statement and Prospectus), short-term debt or long-term debt of the Company or any change, or any development involving a prospective change, in or affecting the general affairs,

management, financial position, stockholders' equity or results of operations of the Company and its subsidiaries, otherwise than as set forth or contemplated in the Prospectus as amended prior to the date of the Pricing Agreement relating to the Designated Shares, the effect of which, in any such case described in clause (i) or (ii), is in the judgment of the Representatives so material and adverse as to make it impracticable or inadvisable to proceed with the public offering or the delivery of the Designated Shares on the terms and in the manner contemplated in the Prospectus as amended relating to the Designated Shares;

- (i) On or after the date of the Pricing Agreement relating to the Designated Shares (i) no downgrading shall have occurred in the rating accorded the Company's debt securities or preferred stock by any "nationally recognized statistical rating organization", as that term is defined by the Commission for purposes of Rule 436(g)(2) under the Act, and (ii) no such organization shall have publicly announced that it has under surveillance or review, with possible negative implications, its rating of any of the Company's debt securities or preferred stock;
- (j) On or after the date of the Pricing Agreement relating to the Designated Shares there shall not have occurred any of the following: (i) a suspension or material limitation in trading in securities generally on the New York Stock Exchange or on NASDAQ; (ii) a suspension or material limitation in trading in the Company's securities on NASDAQ; (iii) a general moratorium on commercial banking activities declared by either Federal authorities or authorities of the State of New York or Commonwealth of Massachusetts or a material disruption in commercial banking or securities settlement or clearance services in the United States; (iv) the outbreak or escalation of hostilities involving the United States or the declaration by the United States of a national emergency or war or (v) the occurrence of any other calamity or crisis or any change in financial, political or economic conditions in the United States or elsewhere; if the effect of any such event specified in clause (iv) or (v) in the judgment of the Representatives makes it impracticable or inadvisable to proceed with the public offering or the delivery of the Firm Shares or Optional Shares or both on the terms and in the manner contemplated in the Prospectus as first amended or supplemented relating to the Designated Shares;
 - (k) The Designated Shares at each Time of Delivery shall have been duly listed for quotation on NASDAQ National Market System;
- (I) The Company shall have obtained and delivered to the Underwriters executed copies of the Lock-up Agreements from each of the Company's directors, executive officers and their affiliated entities;
- (m) The Company shall have complied with the provisions of Section 5(c) hereof with respect to the furnishing of prospectuses on the New York Business Day next succeeding the date of the Pricing Agreement relating to such Designated Shares; and
- (n) The Company shall have furnished or caused to be furnished to the Representatives at each Time of Delivery for the Designated Shares certificates of officers of the Company satisfactory to the Representatives as to the accuracy of the representations and warranties of the Company herein at and as of such Time of Delivery, as to the performance by the Company of all of its obligations hereunder to be performed at or prior to such Time of Delivery, as to the matters set forth in subsections

- (a) and (h) of this Section and as to such other matters as the Representatives may reasonably request.
- 8. (a) The Company will indemnify and hold harmless each Underwriter against any losses, claims, damages or liabilities, joint or several, to which such Underwriter may become subject, under the Act or otherwise, insofar as such losses, claims, damages or liabilities (or actions in respect thereof) arise out of or are based upon an untrue statement or alleged untrue statement of a material fact contained in any Preliminary Prospectus, any preliminary prospectus supplement, the Registration Statement, the Prospectus as amended or supplemented and any other prospectus relating to the Shares, or any amendment or supplement thereto, or arise out of or are based upon the omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, and will reimburse each Underwriter for any legal or other expenses reasonably incurred by such Underwriter in connection with investigating or defending any such action or claim as such expenses are incurred; provided, however, that the Company shall not be liable in any such case to the extent that any such loss, claim, damage or liability arises out of or is based upon an untrue statement or alleged untrue statement or omission or alleged omission made in any Preliminary Prospectus, any preliminary prospectus supplement, the Registration Statement, the Prospectus as amended or supplemented and any other prospectus relating to the Shares, or any such amendment or supplement in reliance upon and in conformity with written information furnished to the Company by any Underwriter of Designated Shares through the Representatives expressly for use in the Prospectus as amended or supplemented relating to such Shares.
- (b) Each Underwriter will indemnify and hold harmless the Company against any losses, claims, damages or liabilities to which the Company may become subject, under the Act or otherwise, insofar as such losses, claims, damages or liabilities (or actions in respect thereof) arise out of or are based upon an untrue statement or alleged untrue statement of a material fact contained in any Preliminary Prospectus, any preliminary prospectus supplement, the Registration Statement, the Prospectus as amended or supplemented and any other prospectus relating to the Shares, or any amendment or supplement thereto, or arise out of or are based upon the omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, in each case to the extent, but only to the extent, that such untrue statement or alleged untrue statement or omission or alleged omission was made in any Preliminary Prospectus, any preliminary prospectus supplement, the Registration Statement, the Prospectus as amended or supplemented and any other prospectus relating to the Shares, or any such amendment or supplement in reliance upon and in conformity with written information furnished to the Company by such Underwriter through the Representatives expressly for use therein; and will reimburse the Company for any legal or other expenses reasonably incurred by the Company in connection with investigating or defending any such action or claim as such expenses are incurred.
- (c) Promptly after receipt by an indemnified party under subsection (a) or (b) above of notice of the commencement of any action, such indemnified party shall, if a claim in respect thereof is to be made against the indemnifying party under such subsection, notify the indemnifying party in writing of the commencement thereof; but the omission so to notify the indemnifying party shall not relieve it from any liability which it may have to any indemnified party otherwise than under such subsection. In case any such action shall be brought against

any indemnified party and it shall notify the indemnifying party of the commencement thereof, the indemnifying party shall be entitled to participate therein and, to the extent that it shall wish, jointly with any other indemnifying party similarly notified, to assume the defense thereof, with counsel satisfactory to such indemnified party (who shall not, except with the consent of the indemnified party, be counsel to the indemnifying party), and, after notice from the indemnifying party to such indemnified party of its election so to assume the defense thereof, the indemnifying party shall not be liable to such indemnified party under such subsection for any legal expenses of other counsel or any other expenses, in each case subsequently incurred by such indemnified party, in connection with the defense thereof other than reasonable costs of investigation. No indemnifying party shall, without the written consent of the indemnified party, effect the settlement or compromise of, or consent to the entry of any judgment with respect to, any pending or threatened action or claim in respect of which indemnification or contribution may be sought hereunder (whether or not the indemnified party is an actual or potential party to such action or claim) unless such settlement, compromise or judgment (i) includes an unconditional release of the indemnified party from all liability arising out of such action or claim and (ii) does not include any statement as to or an admission of fault, culpability or a failure to act, by or on behalf of any indemnified party.

(d) If the indemnification provided for in this Section 8 is unavailable to or insufficient to hold harmless an indemnified party under subsection (a) or (b) above in respect of any losses, claims, damages or liabilities (or actions in respect thereof) referred to therein, then each indemnifying party shall contribute to the amount paid or payable by such indemnified party as a result of such losses, claims, damages or liabilities (or actions in respect thereof) in such proportion as is appropriate to reflect the relative benefits received by the Company on the one hand and the Underwriters of the Designated Shares on the other from the offering of the Designated Shares to which such loss, claim, damage or liability (or action in respect thereof) relates. If, however, the allocation provided by the immediately preceding sentence is not permitted by applicable law or if the indemnified party failed to give the notice required under subsection (c) above, then each indemnifying party shall contribute to such amount paid or payable by such indemnified party in such proportion as is appropriate to reflect not only such relative benefits but also the relative fault of the Company on the one hand and the Underwriters of the Designated Shares on the other in connection with the statements or omissions which resulted in such losses, claims, damages or liabilities (or actions in respect thereof), as well as any other relevant equitable considerations. The relative benefits received by the Company on the one hand and such Underwriters on the other shall be deemed to be in the same proportion as the total net proceeds from such offering (before deducting expenses) received by the Company bear to the total underwriting discounts and commissions received by such Underwriters. The relative fault shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or the omission or alleged omission to state a material fact relates to information supplied by the Company on the one hand or such Underwriters on the other and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission. The Company and the Underwriters agree that it would not be just and equitable if contributions pursuant to this subsection (d) were determined by pro rata allocation (even if the Underwriters were treated as one entity for such purpose) or by any other method of allocation which does not take account of the equitable considerations referred to above in this subsection (d). The amount paid or payable by an indemnified party as a result of the losses, claims, damages or liabilities (or actions in respect thereof) referred to above in this subsection (d) shall be deemed

to include any legal or other expenses reasonably incurred by such indemnified party in connection with investigating or defending any such action or claim. Notwithstanding the provisions of this subsection (d), no Underwriter shall be required to contribute any amount in excess of the amount by which the total price at which the applicable Designated Shares underwritten by it and distributed to the public were offered to the public exceeds the amount of any damages which such Underwriter has otherwise been required to pay by reason of such untrue or alleged untrue statement or omission or alleged omission. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. The obligations of the Underwriters of Designated Shares in this subsection (d) to contribute are several in proportion to their respective underwriting obligations with respect to such Shares and not joint.

- (e) The obligations of the Company under this Section 8 shall be in addition to any liability which the Company may otherwise have and shall extend, upon the same terms and conditions, to each person, if any, who controls any Underwriter within the meaning of the Act; and the obligations of the Underwriters under this Section 8 shall be in addition to any liability which the respective Underwriters may otherwise have and shall extend, upon the same terms and conditions, to each officer and director of the Company and to each person, if any, who controls the Company within the meaning of the Act.
- 9. (a) If any Underwriter shall default in its obligation to purchase the Firm Shares or Optional Shares which it has agreed to purchase under the Pricing Agreement relating to such Shares, the Representatives may in their discretion arrange for themselves or another party or other parties to purchase such Shares on the terms contained herein and in the Pricing Agreement. If within thirty-six hours after such default by any Underwriter the Representatives do not arrange for the purchase of such Firm Shares or Optional Shares, as the case may be, then the Company shall be entitled to a further period of thirty-six hours within which to procure another party or other parties satisfactory to the Representatives to purchase such Shares on such terms. In the event that, within the respective prescribed period, the Representatives notify the Company that they have so arranged for the purchase of such Shares, or the Company notifies the Representatives that it has so arranged for the purchase of such Shares, the Representatives or the Company shall have the right to postpone a Time of Delivery for such Shares for a period of not more than seven days, in order to effect whatever changes may thereby be made necessary in the Registration Statement or the Prospectus as amended or supplemented, or in any other documents or arrangements, and the Company agrees to file promptly any amendments or supplements to the Registration Statement or the Prospectus which in the opinion of the Representatives may thereby be made necessary. The term "Underwriter" as used in this Agreement shall include any person substituted under this Section with like effect as if such person had originally been a party to the Pricing Agreement with respect to such Designated Shares.
- (b) If, after giving effect to any arrangements for the purchase of the Firm Shares or Optional Shares, as the case may be, of a defaulting Underwriter or Underwriters by the Representatives and the Company as provided in subsection (a) above, the aggregate number of such Shares which remains unpurchased does not exceed one-eleventh of the aggregate number of the Firm Shares or Optional Shares, as the case may be, to be purchased at the respective Time of Delivery, then the Company shall have the right to require each non-defaulting Underwriter to purchase the number of Firm Shares or Optional Shares, as the

case may be, which such Underwriter agreed to purchase under the Pricing Agreement relating to such Designated Shares and, in addition, to require each non-defaulting Underwriter to purchase its pro rata share (based on the number of Firm Shares or Optional Shares, as the case may be, which such Underwriter agreed to purchase under such Pricing Agreement) of the Firm Shares or Optional Shares, as the case may be, of such defaulting Underwriter or Underwriters for which such arrangements have not been made; but nothing herein shall relieve a defaulting Underwriter from liability for its default.

- (c) If, after giving effect to any arrangements for the purchase of the Firm Shares or Optional Shares, as the case may be, of a defaulting Underwriter or Underwriters by the Representatives and the Company as provided in subsection (a) above, the aggregate number of Firm Shares or Optional Shares, as the case may be, which remains unpurchased exceeds one-eleventh of the aggregate number of the Firm Shares or Optional Shares, as the case may be, to be purchased at the respective Time of Delivery, as referred to in subsection (b) above, or if the Company shall not exercise the right described in subsection (b) above to require non-defaulting Underwriters to purchase Firm Shares or Optional Shares, as the case may be, of a defaulting Underwriter or Underwriters, then the Pricing Agreement relating to such Firm Shares or the Additional Shares Option relating to such Optional Shares, as the case may be, shall thereupon terminate, without liability on the part of any non-defaulting Underwriter or the Company, except for the expenses to be borne by the Company and the Underwriters as provided in Section 6 hereof and the indemnity and contribution agreements in Section 8 hereof; but nothing herein shall relieve a defaulting Underwriter from liability for its default.
- 10. The respective indemnities, agreements, representations, warranties and other statements of the Company and the several Underwriters, as set forth in this Agreement or made by or on behalf of them, respectively, pursuant to this Agreement, shall remain in full force and effect, regardless of any investigation (or any statement as to the results thereof) made by or on behalf of any Underwriter or any controlling person of any Underwriter, or the Company, or any officer or director or controlling person of the Company, and shall survive delivery of and payment for the Shares.
- 11. If any Pricing Agreement or Additional Shares Option shall be terminated pursuant to Section 9 hereof, the Company shall not then be under any liability to any Underwriter with respect to the Firm Shares or Optional Shares with respect to which such Pricing Agreement shall have been terminated except as provided in Sections 6 and 8 hereof; but, if for any other reason, Designated Shares are not delivered by or on behalf of the Company as provided herein, the Company will reimburse the Underwriters through the Representatives for all out-of-pocket expenses approved in writing by the Representatives, including fees and disbursements of counsel, reasonably incurred by the Underwriters in making preparations for the purchase, sale and delivery of such Designated Shares, but the Company shall then be under no further liability to any Underwriter with respect to such Designated Shares except as provided in Sections 6 and 8 hereof.
- 12. In all dealings hereunder, the Representatives of the Underwriters of Designated Shares shall act on behalf of each of such Underwriters, and the parties hereto shall be entitled to act and rely upon any statement, request, notice or agreement on behalf of any Underwriter made or given by such Representatives jointly or by such of the Representatives, if any, as may be designated for such purpose in the Pricing Agreement.

All statements, requests, notices and agreements hereunder shall be in writing, and if to the Underwriters shall be delivered or sent by mail, telex or facsimile transmission to the address of the Representatives as set forth in the Pricing Agreement; if to the Company shall be delivered or sent by mail, telex or facsimile transmission to the address of the Company set forth in the Registration Statement, Attention: Secretary; and if to a signatory of a Lock-up Agreement shall be delivered to the address of such signatory as set forth in such Lock-up Agreement; provided, however, that any notice to an Underwriter pursuant to Section 8(c) hereof shall be delivered or sent by mail, telex or facsimile transmission to such Underwriter at its address set forth in its Underwriters' Questionnaire, or telex constituting such Questionnaire, which address will be supplied to the Company by the Representatives upon request; provided, further, that notices under subsection 5(e) shall be in writing, and if to the Underwriters shall be delivered or sent by mail, telex or facsimile transmission to you as the representatives at Lazard Capital Markets LLC, 30 Rockefeller Plaza, New York, New York 10020, Attention: David McMillan, Jr. and SG Cowen & Co., LLC, 1221 Avenue of the Americas, New York, New York 10020, Attention: General Counsel. Any such statements, requests, notices or agreements shall take effect upon receipt thereof

- 13. This Agreement and each Pricing Agreement shall be binding upon, and inure solely to the benefit of, the Underwriters, the Company and, to the extent provided in Sections 8 and 10 hereof, the officers and directors of the Company and each person who controls the Company or any Underwriter, and their respective heirs, executors, administrators, successors and assigns, and no other person shall acquire or have any right under or by virtue of this Agreement or any such Pricing Agreement. No purchaser of any of the Shares from any Underwriter shall be deemed a successor or assign by reason merely of such purchase.
- 14. Time shall be of the essence of each Pricing Agreement. As used herein, the term "business day" shall mean any day when the Commission's office in Washington, D.C. is open for business.

15. This Agreement and each Pricing Agreement shall be governed by and construed in accordance with the laws of the State of New York.

- 16. This Agreement and each Pricing Agreement may be executed by any one or more of the parties hereto and thereto in any number of counterparts, each of which shall be deemed to be an original, but all such respective counterparts shall together constitute one and the same instrument.
- 17. Notwithstanding anything herein to the contrary, the Company is authorized to disclose to any persons U.S. federal and state tax treatment and tax structure of the potential transaction and all materials of any kind (including tax opinions and other tax analyses) provided to the Company relating to that treatment and structure, without the Underwriters imposing any limitation of any kind. However, any information relating to the tax treatment and tax structure shall remain confidential (and the foregoing sentence shall not apply) to the extent necessary to enable any person to comply with securities laws. For this purpose, "tax structure" is limited to any facts that may be relevant to that treatment.
- 18. The Company acknowledges and agrees that (i) the purchase and sale of Designated Shares pursuant to this Agreement and the Pricing Agreement relating to such Designated Shares is an arm's-length commercial transaction between the Company, on the one hand, and the Underwriter or several Underwriters specified in Schedule II to such Pricing Agreement, on the other, (ii) in connection therewith and with the process leading to such

transaction each such Underwriter is acting solely as a principal and not the agent or fiduciary of the Company, (iii) no Underwriter has assumed an advisory or fiduciary responsibility in favor of the Company with respect to the offering contemplated hereby or thereby or the process leading thereto (irrespective of whether such Underwriter has advised or is currently advising the Company on other matters) or any other obligation to the Company except the obligations expressly set forth in this Agreement and any Pricing Agreement and (iv) the Company has consulted its own legal and financial advisors to the extent it deemed appropriate. The Company agrees that it will not claim that the Underwriters of Designated Shares, or any of them, has rendered advisory services of any nature or respect, or owes a fiduciary or similar duty to the Company, in connection with such transaction or the process leading thereto.

This Agreement supersedes all prior agreements and understandings (whether written or oral) between the Company and the Underwriters, or any of them, with respect to the subject matter hereof.

The Company and each of the Underwriters hereby irrevocably waives, to the fullest extent permitted by applicable law, any and all right to trial by jury in any legal proceeding arising out of or relating to this Agreement or any Pricing Agreement or the transactions contemplated hereby or thereby.

[Remainder of page intentionally blank]

If the foregoing is in accordance with your understanding, please sign and return to us six counterparts hereof.

Very truly yours,

GTx, Inc.

By: /s/ Mitchell S. Steiner

Name: Mitchell S. Steiner

Title: Chief Executive Officer, Vice Chairman and

Director

Accepted as of the date hereof:

Lazard Capital Markets LLC

By: /s/ David G. McMillan, Jr.

David G. McMillan, Jr. Managing Director

SG Cowen & Co., LLC

By: /s/ Bill Buchanan

Bill Buchanan Managing Director

33

Pricing Agreement

Lazard Capital Markets LLC 30 Rockefeller Plaza New York, New York 10020 SG Cowen & Co., LLC

SG Cowen & Co., LLC 1221 Avenue of the Americas New York, New York 10020

Ladies and Gentlemen:

GTx, Inc., a Delaware corporation (the "Company"), proposes, subject to the terms and conditions stated herein and in the Underwriting _, 2005 (the "Underwriting Agreement"), between the Company on the one hand and Lazard Capital Markets LLC and Agreement, dated SG Cowen & Co., LLC, on the other hand, to issue and sell to the Underwriters named in Schedule I hereto (the "Underwriters") the Shares specified in Schedule II hereto (the "Designated Shares" consisting of Firm Shares and any Optional Shares the Underwriters may elect to purchase). Each of the provisions of the Underwriting Agreement is incorporated herein by reference in its entirety, and shall be deemed to be a part of this Agreement to the same extent as if such provisions had been set forth in full herein; and each of the representations and warranties set forth therein shall be deemed to have been made at and as of the date of this Pricing Agreement, except that each representation and warranty which refers to the Prospectus in Section 2 of the Underwriting Agreement shall be deemed to be a representation or warranty as of the date of the Underwriting Agreement in relation to the Prospectus (as therein defined), and also a representation and warranty as of the date of this Pricing Agreement in relation to the Prospectus as amended or supplemented relating to the Designated Shares which are the subject of this Pricing Agreement. Each reference to the Representatives herein and in the provisions of the Underwriting Agreement so incorporated by reference shall be deemed to refer to you. Unless otherwise defined herein, terms defined in the Underwriting Agreement are used herein as therein defined. The Representatives designated to act on behalf of the Representatives and on behalf of each of the Underwriters of the Designated Shares pursuant to Section 12 of the Underwriting Agreement and the address of the Representatives referred to in such Section 12 are set forth in Schedule II hereto.

An amendment to the Registration Statement, or a supplement to the Prospectus, as the case may be, relating to the Designated Shares, in the form heretofore delivered to you is now proposed to be filed with the Commission.

Subject to the terms and conditions set forth herein and in the Underwriting Agreement incorporated herein by reference, (a) the Company agrees to issue and sell to each of the Underwriters, and each of the Underwriters agrees, severally and not jointly, to purchase from the Company, at the time and place and at the purchase price to the Underwriters set forth in Schedule II hereto, the number of Firm Shares set forth opposite the name of such Underwriter in Schedule I hereto and, (b) in the event and to the extent that the Underwriters shall exercise

the election to purchase Optional Shares, as provided below, the Company agrees to issue and sell to each of the Underwriters, and each of the Underwriters agrees, severally and not jointly, to purchase from the Company at the purchase price to the Underwriters set forth in Schedule II hereto that portion of the number of Optional Shares as to which such election shall have been exercised.

The Company hereby grants to each of the Underwriters the right to purchase at their election up to the number of Optional Shares set forth opposite the name of such Underwriter in Schedule I hereto on the terms referred to in the paragraph above for the sole purpose of covering sales of shares in excess of the number of Firm Shares. Any such election to purchase Optional Shares may be exercised by written notice from the Representatives to the Company given within a period of 30 calendar days after the date of this Pricing Agreement, setting forth the aggregate number of Optional Shares to be purchased and the date on which such Optional Shares are to be delivered, as determined by the Representatives, but in no event earlier than the First Time of Delivery or, unless the Representatives and the Company otherwise agree in writing, no earlier than two or later than ten business days after the date of such notice.

[Remainder of page intentionally blank]

If the foregoing is in accordance with your understanding, please sign and return to us six counterparts hereof, and upon acceptance hereof by you, on behalf of each of the Underwriters, this letter and such acceptance hereof, including the provisions of the Underwriting Agreement incorporated herein by reference, shall constitute a binding agreement between each of the Underwriters and the Company. It is understood that your acceptance of this letter on behalf of each of the Underwriters is or will be pursuant to the authority set forth in a form of Agreement among Underwriters, the form of which shall be submitted to the Company for examination, upon request, but without warranty on the part of the Representatives as to the authority of the signers thereof.

Very truly yours,

GTx, Inc.

| | Very truly yours, |
|---------------------------------|------------------------|
| | GTx, Inc. |
| | By: Name: Title: |
| Accepted as of the date hereof: | |
| Lazard Capital Markets LLC | |
| Ву: | |
| SG Cowen & Co., LLC | |
| Ву: | |
| | 3 |
| | |

SCHEDULE I

| | Maximum Number of Number of Firm Shares Optional Shares |
|-------------------------------|---|
| Underwriter | to be Which May be Purchased Purchased |
| Lazard Capital Markets LLC | <u>ruicilaseu</u> <u>ruicilaseu</u> |
| SG Cowen & Co., LLC | |
| [Names of other Underwriters] | |
| Total | |
| | _ |
| 4 | |

SCHEDULE II

Common Stock, par value \$.001 per share Number of Designated Shares:

Number of Firm Shares:

Title of Designated Shares:

Maximum Number of Optional Shares:

Initial Offering Price to Public:

\$..... per Share

Purchase Price by Underwriters:

\$..... per Share

Commission Payable to Underwriters:

\$...... per Share in Federal (same-day) funds

Form of Designated Shares:

Definitive form, to be made available for checking at least twenty-four hours prior to the Time of Delivery at the office of The Depository Trust Company or its designated custodian

Specified Funds for Payment of Purchase Price:

Federal (same-day) funds

Blackout provisions with respect to the Designated Shares:

As referred to in Section 5(e) of the Underwriting Agreement, the blackout period applicable to the Company shall continue for 90 days after the date of this Pricing Agreement (unless extended under the circumstances described in Section 5(e) of the Underwriting Agreement) and, at or before the signing of this Pricing Agreement, the Company shall cause to be delivered to the Underwriters a signed copy of a lock-up agreement from each of its directors, executive officers and their affiliated entities covering the blackout period. Such lock-up agreement for directors, executive officers and their affiliated entities shall be in the forms previously agreed between the Underwriters and the Company.

Time of Delivery:

...... a.m. (New York City time), 2005

Closing Location:

Wilmer Cutler Pickering Hale and Dorr LLP 60 State Street Boston, Massachusetts 02109

Names and Addresses of Representatives:

Designated Representatives:

Lazard Capital Markets LLC 30 Rockefeller Plaza New York, New York 10020

SG Cowen & Co., LLC 1221 Avenue of the Americas New York, New York 10020

Address for Notices, etc.:

Lazard Capital Markets LLC 30 Rockefeller Plaza New York, New York 10020 Attention: David McMillan, Jr.

SG Cowen & Co., LLC 1221 Avenue of the Americas New York, New York 10020 Attention: General Counsel

FORM OF COMFORT LETTER TO BE DELIVERED ON DATE OF PRICING AGREEMENT

FORM OF COMFORT LETTER TO BE DELIVERED ON DATE OF DELIVERY OF DESIGNATED SHARES

Pursuant to Section 7(g) of the Underwriting Agreement, the accountants shall furnish letters to the Underwriters to the effect that:

- (i) They are independent certified public accountants with respect to the Company within the meaning of the Act and the applicable published rules and regulations thereunder;
- (ii) In their opinion, the financial statements and any supplementary financial information and schedules (and, if applicable, financial forecasts and/or pro forma financial information) examined by them and included or incorporated by reference in the Registration Statement or the Prospectus comply as to form in all material respects with the applicable accounting requirements of the Act or the Exchange Act, as applicable, and the related published rules and regulations thereunder; and, if applicable, they have made a review in accordance with standards established by the American Institute of Certified Public Accountants of the consolidated interim financial statements, selected financial data, pro forma financial information, financial forecasts and/or condensed financial statements derived from audited financial statements of the Company for the periods specified in such letter, as indicated in their reports thereon, copies of which have been furnished to the representatives of the Underwriters (the "Representatives");
- (iii) They have made a review in accordance with standards established by the American Institute of Certified Public Accountants of the unaudited condensed statements of income, balance sheets and statements of cash flows included in the Prospectus and/or included in the Company's quarterly reports on Form 10-Q incorporated by reference into the Prospectus as indicated in their reports thereon copies of which have been separately furnished to the Representatives; and on the basis of specified procedures including inquiries of officials of the Company who have responsibility for financial and accounting matters regarding whether the unaudited condensed financial statements referred to in paragraph (vi)(A)(i) below comply as to form in all material respects with the applicable accounting requirements of the Act and the Exchange Act and the related published rules and regulations, nothing came to their attention that caused them to believe that the unaudited condensed financial statements do not comply as to form in all material respects with the applicable accounting requirements of the Act and the Exchange Act and the related published rules and regulations;
- (iv) The unaudited selected financial information with respect to the results of operations and financial position of the Company for the five most recent fiscal years included in the Prospectus and included or incorporated by reference in Item 6 of the Company's Annual Report on Form 10-K for the most recent fiscal year agrees with the corresponding amounts (after restatement where applicable) in the audited financial statements for such five fiscal years which were included or incorporated by reference in the Company's Annual Reports on Form 10-K for such fiscal years;
- (v) They have compared the information in the Prospectus under selected captions with the disclosure requirements of Regulation S-K and on the basis of limited procedures specified in such letter nothing came to their attention as a result of the foregoing procedures that caused them to believe that this information does not conform

in all material respects with the disclosure requirements of items 301, 302, 402 and 503(d), respectively, of Regulation S-K;

- (vi) On the basis of limited procedures, not constituting an examination in accordance with generally accepted auditing standards, consisting of a reading of the unaudited financial statements and other information referred to below, a reading of the latest available interim financial statements of the Company, inspection of the minute books of the Company since the date of the latest audited financial statements included or incorporated by reference in the Prospectus, inquiries of officials of the Company responsible for financial and accounting matters and such other inquiries and procedures as may be specified in such letter, nothing came to their attention that caused them to believe that:
 - (A) (i) the unaudited condensed statements of income, balance sheets and statements of cash flows included in the Prospectus and/or included or incorporated by reference in the Company's Quarterly Reports on Form 10-Q incorporated by reference in the Prospectus do not comply as to form in all material respects with the applicable accounting requirements of the Exchange Act and the related published rules and regulations, or (ii) any material modifications should be made to the unaudited condensed statements of income, balance sheets and statements of cash flows included in the Prospectus or included in the Company's Quarterly Reports on Form 10-Q incorporated by reference in the Prospectus, for them to be in conformity with generally accepted accounting principles;
 - (B) any other unaudited income statement data and balance sheet items included in the Prospectus do not agree with the corresponding items in the unaudited financial statements from which such data and items were derived, and any such unaudited data and items were not determined on a basis substantially consistent with the basis for the corresponding amounts in the audited financial statements included or incorporated by reference in the Company's Annual Report on Form 10-K for the most recent fiscal year;
 - (C) the unaudited financial statements which were not included in the Prospectus but from which were derived the unaudited condensed financial statements referred to in clause (A) and any unaudited income statement data and balance sheet items included in the Prospectus and referred to in clause (B) were not determined on a basis substantially consistent with the basis for the audited financial statements included or incorporated by reference in the Company's Annual Report on Form 10-K for the most recent fiscal year;
 - (D) any unaudited pro forma condensed financial statements included or incorporated by reference in the Prospectus do not comply as to form in all material respects with the applicable accounting requirements of the Act and the published rules and regulations thereunder or the pro forma adjustments have not been properly applied to the historical amounts in the compilation of those statements;
 - (E) as of a specified date not more than five days prior to the date of such letter, there have been any changes in the capital stock (other than

issuances of capital stock upon exercise of options and stock appreciation rights, upon earn-outs of performance shares and upon conversions of convertible securities, in each case which were outstanding on the date of the latest balance sheet included or incorporated by reference in the Prospectus) or any increase in the long-term debt of the Company and its subsidiaries, or any decreases in net current assets or stockholders' equity or other items specified by the Representatives, or any increases in any items specified by the Representatives, in each case as compared with amounts shown in the latest balance sheet included or incorporated by reference in the Prospectus, except in each case for changes, increases or decreases which the Prospectus discloses have occurred or may occur or which are described in such letter; and

(F) for the period from the date of the latest financial statements included or incorporated by reference in the Prospectus to the specified date referred to in clause (E) there were any decreases in net revenues or operating profit or the total or per share amounts of net income or other items specified by the Representatives, or any increases in any items specified by the Representatives, in each case as compared with the comparable period of the preceding year and with any other period of corresponding length specified by the Representatives, except in each case for increases or decreases which the Prospectus discloses have occurred or may occur or which are described in such letter; and

(vii) In addition to the examination referred to in their report(s) included or incorporated by reference in the Prospectus and the limited procedures, inspection of minute books, inquiries and other procedures referred to in paragraphs (iii) and (vi) above, they have carried out certain specified procedures, not constituting an examination in accordance with generally accepted auditing standards, with respect to certain amounts, percentages and financial information specified by the Representatives which are derived from the general accounting records of the Company, which appear in the Prospectus (excluding documents incorporated by reference), or in Part II of, or in exhibits and schedules to, the Registration Statement specified by the Representatives or in documents incorporated by reference in the Prospectus specified by the Representatives, and have compared certain of such amounts, percentages and financial information with the accounting records of the Company and have found them to be in agreement.

All references in this Annex II to the Prospectus shall be deemed to refer to the Prospectus (including the documents incorporated by reference therein) as defined in the Underwriting Agreement as of the date of the letter delivered on the date of the Pricing Agreement for purposes of such letter and to the Prospectus as amended or supplemented (including the documents incorporated by reference therein) in relation to the applicable Designated Shares for purposes of the letter delivered at the Time of Delivery for such Designated Shares.

FORM OF OPINION OF BASS, BERRY & SIMS PLC

FORM OF OPINION OF COOLEY GODWARD LLP

FORM OF OPINION OF HOGAN & HARTSON L.L.P.

LOCK-UP AGREEMENT

GTx, Inc.

Lock-Up Agreement

October 11, 2005

Lazard Capital Markets LLC 30 Rockefeller Plaza New York, NY 10020

SG Cowen & Co., LLC 1221 Avenue of the Americas New York, NY 10020

Re: GTx, Inc. — Lock-Up Agreement

Ladies and Gentlemen:

Reference is made to that certain Lock-up Agreement delivered by the undersigned on September 15, 2005 (the "Previous Agreement"). This Lock-up Agreement hereby amends and restates the Previous Agreement in its entirety.

The undersigned understands that you, as representatives (the "Representatives"), propose to enter into an Underwriting Agreement and Pricing Agreement on behalf of the several Underwriters to be named in Schedule I to such Pricing Agreement (collectively, the "Underwriters"), with GTx, Inc., a Delaware corporation (the "Company"), providing for a public offering of the Common Stock of the Company (the "Shares") pursuant to a Registration Statement on Form S-3 (the "Registration Statement") filed with the Securities and Exchange Commission (the "SEC").

In consideration of the agreement by the Underwriters to offer and sell the Shares, and of other good and valuable consideration the receipt and sufficiency of which is hereby acknowledged, the undersigned agrees that, during the period specified in the following paragraph (the "Lock-Up Period"), the undersigned will not offer, sell, contract to sell, pledge, grant any option to purchase, make any short sale or otherwise dispose of any shares of Common Stock of the Company, or any options or warrants to purchase any shares of Common Stock of the Company, or any securities convertible into, exchangeable for or that represent the right to receive shares of Common Stock of the Company, whether now owned or hereinafter acquired, owned directly by the undersigned (including holding as a custodian) or with respect to which the undersigned has beneficial ownership within the rules and regulations of the SEC (collectively the "Undersigned's Shares"). The foregoing restriction shall not prohibit the exercise by the undersigned of an option to purchase shares of Common Stock of the Company issued under the Company's stock incentive plans, provided that all of the shares of Common Stock of the Company issued upon such exercise shall constitute Undersigned's Shares and shall be subject to the foregoing restriction.

The foregoing restriction is expressly agreed to preclude the undersigned from engaging in any hedging or other transaction which is designed to or which reasonably could be expected to lead to or result in a sale or disposition of the Undersigned's Shares even if such Shares would be disposed of by someone other than the undersigned. Such prohibited hedging or other transactions would include without limitation any short sale or any purchase, sale or grant of any right (including without limitation any put or call option) with respect to any of the Undersigned's Shares or with respect to any security that includes, relates to, or derives any significant part of its value from such Shares.

The initial Lock-Up Period will commence on the date of the Previous Agreement and continue for 90 days after the public offering date set forth on the final prospectus supplement used to sell the Shares (the "Public Offering Date") pursuant to the Underwriting Agreement and Pricing Agreement; provided, however, that if (1) during the last 17 days of the initial Lock-Up Period, the Company releases earnings results or announces material news or a material event or (2) prior to the expiration of the initial Lock-Up Period, the Company announces that it will release earnings results during the 15-day period following the last day of the initial Lock-Up Period, then in each case the Lock-Up Period will be automatically extended until the expiration of the 18-day period beginning on the date of release of the earnings results or the announcement of the material news or material event, as applicable, unless the Representatives waive, in writing, such extension.

The undersigned hereby acknowledges that the Company has agreed in the Underwriting Agreement to provide written notice of any event that would result in an extension of the Lock-Up Period pursuant to the previous paragraph to the undersigned (in accordance with Section 12 of the Underwriting Agreement) and agrees that any such notice properly delivered will be deemed to have been given to, and received by, the undersigned. The undersigned hereby further agrees that, prior to engaging in any transaction or taking any other action that is subject to the terms of this Lock-Up Agreement during the period from the date of this Lock-Up Agreement to and including the 34th day following the expiration of the initial Lock-Up Period, it will give notice thereof to the Company and will not consummate such transaction or take any such action unless it has received written confirmation from the Company that the Lock-Up Period (as such may have been extended pursuant to the previous paragraph) has expired.

Notwithstanding the foregoing, the undersigned may transfer the Undersigned's Shares (i) as a *bona fide* gift or gifts, provided that the donee or donees thereof agree to be bound in writing by the restrictions set forth herein, (ii) to any trust for the direct or indirect benefit of the undersigned or the immediate family of the undersigned, or to a corporation, partnership, limited partnership or limited liability company the stockholders, partners and members of which are the undersigned or the immediate family of the undersigned, provided that, in each case, the trustee of the trust or the applicable transferee, as the case may be, agrees to be bound in writing by the restrictions set forth herein, and provided further that any such transfer shall not involve a disposition for value, or (iii) with the prior written consent of the Representatives on behalf of the Underwriters. For purposes of this Lock-Up Agreement, "immediate family" shall mean any relationship by blood, marriage or adoption, not more remote than first cousin. In addition, notwithstanding the foregoing, if the undersigned is a corporation, the corporation may transfer the capital stock of the Company to any wholly-owned subsidiary of such corporation; <u>provided</u>, <u>however</u>, that in any such case, it shall be a condition to the transfer that the transferee execute

an agreement stating that the transferee is receiving and holding such capital stock subject to the provisions of this Agreement and there shall be no further transfer of such capital stock except in accordance with this Agreement, and provided further that any such transfer shall not involve a disposition for value. The undersigned now has, and, except as contemplated by clause (i), (ii) or (iii) above, for the duration of this Lock-Up Agreement will have, good and marketable title to the Undersigned's Shares, free and clear of all liens, encumbrances, and claims whatsoever. The undersigned also agrees and consents to the entry of stop transfer instructions with the Company's transfer agent and registrar against the transfer of the Undersigned's Shares except in compliance with the foregoing restrictions.

In addition, the undersigned hereby waives any rights the undersigned may have to require registration of any shares of Common Stock or any security convertible into or exercisable or exchangeable for Common Stock in connection with, arising out of or relating to the offering. The undersigned further agrees that, without the prior written consent of the Representatives on behalf of the Underwriters, it will not, during the Lock-Up Period make any demand for or exercise any right with respect to, the registration of any shares of Common Stock or any security convertible into or exercisable or exchangeable for Common Stock, and hereby waives any and all rights the undersigned may have to require the Company to include shares of Common Stock in the Registration Statement and to receive notice of the filing of such Registration Statement or the offering contemplated thereby.

The undersigned understands that the Company and the Underwriters are relying upon this Lock-Up Agreement in proceeding toward consummation of the offering. The undersigned further understands that this Lock-Up Agreement is irrevocable and shall be binding upon the undersigned's heirs, legal representatives, successors, and assigns.

[To be inserted in Lock-Up Agreement of participating insiders: The undersigned hereby represents that any Shares acquired by the undersigned in the offering shall be acquired for investment purposes and that the undersigned does not have a present intention to resell any such Shares.]

This Lock-Up Agreement shall be terminated and the undersigned shall be released from the undersigned's obligations hereunder if (i) the Company notifies you in writing on or prior to November 30, 2005 that it does not intend to proceed with the offering or (ii) the offering is not consummated by November 30, 2005.

| Very truly yours, |
|---------------------------|
| Exact Name of Shareholder |
| Authorized Signature |
| Title |
| Address: |
| |
| |
| |

Pricing Agreement

Lazard Capital Markets LLC 30 Rockefeller Plaza New York, New York 10020

SG Cowen & Co., LLC 1221 Avenue of the Americas New York, New York 10020

October 11, 2005

Ladies and Gentlemen:

GTx, Inc., a Delaware corporation (the "Company"), proposes, subject to the terms and conditions stated herein and in the Underwriting Agreement, dated October 11, 2005 (the "Underwriting Agreement"), between the Company on the one hand and Lazard Capital Markets LLC and SG Cowen & Co., LLC, on the other hand, to issue and sell to the Underwriters named in Schedule I hereto (the "Underwriters") the Shares specified in Schedule II hereto (the "Designated Shares" consisting of Firm Shares and any Optional Shares the Underwriters may elect to purchase). Each of the provisions of the Underwriting Agreement is incorporated herein by reference in its entirety, and shall be deemed to be a part of this Agreement to the same extent as if such provisions had been set forth in full herein; and each of the representations and warranties set forth therein shall be deemed to have been made at and as of the date of this Pricing Agreement, except that each representation and warranty which refers to the Prospectus in Section 2 of the Underwriting Agreement shall be deemed to be a representation or warranty as of the date of the Underwriting Agreement in relation to the Prospectus (as therein defined), and also a representation and warranty as of the date of this Pricing Agreement in relation to the Prospectus as amended or supplemented relating to the Designated Shares which are the subject of this Pricing Agreement. Each reference to the Representatives herein and in the provisions of the Underwriting Agreement so incorporated by reference shall be deemed to refer to you. Unless otherwise defined herein, terms defined in the Underwriting Agreement are used herein as therein defined. The Representatives designated to act on behalf of the Representatives and on behalf of each of the Underwriters of the Designated Shares pursuant to Section 12 of the Underwriting Agreement and the address of the Representatives referred to in such Section 12 are set forth in Schedule II hereto.

An amendment to the Registration Statement, or a supplement to the Prospectus, as the case may be, relating to the Designated Shares, in the form heretofore delivered to you is now proposed to be filed with the Commission.

Subject to the terms and conditions set forth herein and in the Underwriting Agreement incorporated herein by reference, (a) the Company agrees to issue and sell to each of the Underwriters, and each of the Underwriters agrees, severally and not jointly, to purchase from the Company, at the time and place and at the purchase price to the Underwriters set forth in Schedule II hereto, the number of Firm Shares set forth opposite the name of such Underwriter in Schedule I hereto and, (b) in the event and to the extent that the Underwriters shall exercise the election to purchase Optional Shares, as provided below, the Company agrees to issue and sell to each of the Underwriters, and each of the Underwriters agrees, severally and not jointly,

to purchase from the Company at the purchase price to the Underwriters set forth in Schedule II hereto that portion of the number of Optional Shares as to which such election shall have been exercised.

The Company hereby grants to each of the Underwriters the right to purchase at their election up to the number of Optional Shares set forth opposite the name of such Underwriter in Schedule I hereto on the terms referred to in the paragraph above for the sole purpose of covering sales of shares in excess of the number of Firm Shares. Any such election to purchase Optional Shares may be exercised by written notice from the Representatives to the Company given within a period of 30 calendar days after the date of this Pricing Agreement, setting forth the aggregate number of Optional Shares to be purchased and the date on which such Optional Shares are to be delivered, as determined by the Representatives, but in no event earlier than the First Time of Delivery or, unless the Representatives and the Company otherwise agree in writing, no earlier than two or later than ten business days after the date of such notice.

[Remainder of page intentionally blank]

If the foregoing is in accordance with your understanding, please sign and return to us six counterparts hereof, and upon acceptance hereof by you, on behalf of each of the Underwriters, this letter and such acceptance hereof, including the provisions of the Underwriting Agreement incorporated herein by reference, shall constitute a binding agreement between each of the Underwriters and the Company. It is understood that your acceptance of this letter on behalf of each of the Underwriters is or will be pursuant to the authority set forth in a form of Agreement among Underwriters, the form of which shall be submitted to the Company for examination, upon request, but without warranty on the part of the Representatives as to the authority of the signers thereof.

Very truly yours,

GTx, Inc.

By: /s/ Mitchell S. Steiner

Name: Mitchell S. Steiner

Title: Chief Executive Officer, Vice Chairman and Director

Accepted as of the date hereof:

Lazard Capital Markets LLC

By: /s/ David G. McMillan, Jr.

Name: David G. McMillan, Jr. Title: Managing Director

SG Cowen & Co., LLC

By: /s/ Bill Buchanan

Name: Bill Buchanan Title: Managing Director

SCHEDULE I

| Underwriter | Number of Firm Shares to be Purchased | Maximum Number of Optional Shares Which May be Purchased |
|----------------------------|---|---|
| Lazard Capital Markets LLC | 2,750,000 | 412,500 |
| SG Cowen & Co., LLC | 2,750,000 | 412,500 |
| Total | 5,500,000 | 825,000 |

SCHEDULE II

Title of Designated Shares:

Common Stock, par value \$.001 per share

Number of Designated Shares:

Number of Firm Shares: 5,500,000

Maximum Number of Optional Shares: 825,000

Initial Offering Price to Public:

\$7.800 per Share

Purchase Price by Underwriters:

\$7.332 per Share

Commission Payable to Underwriters:

\$0.468 per Share in Federal (same-day) funds

Form of Designated Shares:

Definitive form, to be made available for checking at least twenty-four hours prior to the Time of Delivery at the office of The Depository Trust Company or its designated custodian

Specified Funds for Payment of Purchase Price:

Federal (same-day) funds

Blackout provisions with respect to the Designated Shares:

As referred to in Section 5(e) of the Underwriting Agreement, the blackout period applicable to the Company shall continue for 90 days after the date of this Pricing Agreement (unless extended under the circumstances described in Section 5(e) of the Underwriting Agreement) and, at or before the signing of this Pricing Agreement, the Company shall cause to be delivered to the Underwriters a signed copy of a lock-up agreement from each of its directors, executive officers and their affiliated entities covering the blackout period. Such lock-up agreement for directors, executive officers and their affiliated entities shall be in the forms previously agreed between the Underwriters and the Company.

Time of Delivery:

10:00 a.m. (New York City time), October 17, 2005

Closing Location:

Wilmer Cutler Pickering Hale and Dorr LLP 60 State Street Boston, Massachusetts 02109

Names and Addresses of Representatives:

Designated Representatives:

Lazard Capital Markets LLC 30 Rockefeller Plaza New York, New York 10020

SG Cowen & Co., LLC 1221 Avenue of the Americas New York, New York 10020

Address for Notices, etc.:

Lazard Capital Markets LLC 30 Rockefeller Plaza New York, New York 10020 Attention: David McMillan, Jr.

SG Cowen & Co., LLC 1221 Avenue of the Americas New York, New York 10020 Attention: General Counsel

[LETTERHEAD OF COOLEY GODWARD LLP]

October 11, 2005 GTx, Inc. 3 N. Dunlap Street, 3rd Floor Van Vleet Building Memphis. TN 38163

Ladies and Gentlemen:

You have requested our opinion with respect to certain matters in connection with the sale by GTx, Inc., a Delaware corporation (the "Company"), of up to 6,325,000 shares of the Company's common stock, par value \$0.001 (the "Shares"), including 825,000 Shares for which the underwriters have been granted an over-allotment option, pursuant to a Registration Statement on Form S-3 and the related Prospectus and Prospectus Supplement filed with the Securities and Exchange Commission (the "Commission"). All of the Shares are to be sold by the Company as described in the Registration Statement and related Prospectus and Prospectus Supplement.

In connection with this opinion, we have examined and relied upon the Registration Statement and related Prospectus included therein, the Prospectus Supplement filed with the Commission pursuant to Rule 424 under the Securities Act of 1933, as amended, the Company's Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws, as currently in effect, and the originals or copies certified to our satisfaction of such other documents, records, certificates, memoranda and other instruments as we deem necessary or appropriate to enable us to render the opinion expressed below. We have assumed the genuineness and authenticity of all documents submitted to us as originals, the conformity to originals of all documents submitted to us as copies thereof and the due execution and delivery of all documents where due execution and delivery are a prerequisite to the effectiveness thereof.

On the basis of the foregoing, and in reliance thereon, we are of the opinion that the Shares, when sold in accordance with the Registration Statement and the related Prospectus and the Prospectus Supplement, will be validly issued, fully paid and nonassessable.

We consent to the reference to our firm under the caption "Validity of Common Stock" in the Prospectus Supplement and under the caption "Legal Matters" in the Prospectus included in the Registration Statement and to the filing of this opinion as an exhibit to the Registration Statement.

Very truly yours,

Cooley Godward LLP

By: //S/ Suzanne Sawochka Hooper
Suzanne Sawochka Hooper

GTx Prices Public Offering of Common Stock

Memphis, Tenn., October 11, 2005 — GTx, Inc. (Nasdaq: GTXI) today announced the pricing of an underwritten public offering of 5,500,000 shares of its common stock at a price to the public of \$7.80 per share. All of the shares are being offered by GTx pursuant to its effective shelf registration statement previously filed with the Securities and Exchange Commission.

Lazard Capital Markets LLC and SG Cowen & Co., LLC are acting as joint book-running managers of the offering. The Company has granted the underwriters a 30-day option to purchase up to an additional 825,000 shares of common stock from GTx to cover over-allotments, if any.

This press release does not constitute an offer to sell or a solicitation of an offer to buy nor will there be any sale of these securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

The shares of common stock may only be offered by means of a prospectus, including a prospectus supplement, forming part of the effective registration statement. Printed copies of the final prospectus supplement and accompanying base prospectus relating to the offering may be obtained, when available, from Lazard Capital Markets LLC, Prospectus Department, c/o ADP Financial Services, Integrated Distribution Services, 1155 Long Island Avenue, Edgewood, New York 11717, monica_castillo@adp.com, or SG Cowen & Co., LLC, Prospectus Department, 1221 Avenue of the Americas, 6th Floor, New York, New York 10020 (or through ADP by fax at (631) 254-7268). The final prospectus supplement and accompanying base prospectus relating to the offering will also be filed with the SEC, and will be available on the SEC's website at http://www.sec.gov.

About GTx

GTx 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, headquartered in Memphis, Tenn., currently has four clinical programs.

Forward-Looking Information is Subject to Risk and Uncertainty

This press release contains forward-looking statements, including, without limitation, statements related to the completion of the proposed sale of common stock. 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, and other important factors, which include, without limitation, risks and uncertainties related to satisfaction of closing conditions related to the public offering and other risks detailed from time to time in GTx's SEC filings, including its current report filed on Form 8-K with the SEC on September 16, 2005 and other filings with the SEC from time to time. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this press release. 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.