As filed with the Securities and Exchange Commission on January 15, 2004

Registration No. 333-109700

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Amendment No. 3

To

Form S-1

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

GTx, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**2834**	**62-1715807**
(State or other jurisdiction of incorporation or organization)	*(Primary Standard Industrial Classification Code Number)*	*(I.R.S. Employer Identification No.)*

GTx, Inc.

3 N. Dunlap Street, 3rd Floor
Van Vleet Building
Memphis, TN 38163
(901) 523-9700
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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

Chief Executive Officer
GTx, Inc.
3 N. Dunlap Street, 3rd Floor
Van Vleet Building
Memphis, TN 38163
(901) 523-9700
(Name, address, including zip code, and telephone number, including area code, of agent for service)

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Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. o

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

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

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

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box. o

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CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities Registered	Amount to be Registered(1)	Proposed Maximum Offering Price per Share(2)	Proposed Maximum Aggregate Offering Price(1)(2)	Amount of Registration Fee(3)
Common Stock, $0.001 par value per share	6,210,000	$15.00	$93,150,000.00	$7,535.84

(1) Includes shares that the underwriters have the option to purchase solely to cover over-allotments, if any.

(2) Estimated pursuant to Rule 457 under the Securities Act of 1933, as amended, solely for the purpose of computing the amount of the registration fee.

(3) Includes $6,977.63 previously paid.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the SEC, acting pursuant to Section 8(a), may determine.

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The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject to Completion. Dated January 15, 2004.

5,400,000 Shares

Common Stock

This is an initial public offering of shares of common stock of GTx, Inc. All of the 5,400,000 shares of common stock are being sold by the company.

Prior to this offering, there has been no public market for the common stock. It is currently estimated that the initial public offering price per share will be between $13.00 and $15.00. Application has been made for the quotation of the common stock on the Nasdaq National Market under the symbol "GTXI".

See "Risk Factors" on page 7 to read about factors you should consider before buying shares of the common stock.

Neither the Securities and Exchange Commission nor any other regulatory body has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

	Per Share	Total
Initial public offering price	$	$
Underwriting discount	$	$
Proceeds, before expenses, to GTx	$	$

To the extent that the underwriters sell more than 5,400,000 shares of common stock, the underwriters have the option to purchase up to an additional 810,000 shares from GTx at the initial public offering price less the underwriting discount.

The underwriters expect to deliver the shares against payment in New York, New York on , 2004.

Goldman, Sachs & Co.

SG Cowen

Lazard

Prospectus dated , 2004.

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PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus which we consider important to investors. You should read the entire prospectus carefully before making an investment in our common stock.

Our Business

GTx is a biopharmaceutical company dedicated to the discovery, development and commercialization of therapeutics primarily related to the treatment of serious men's health conditions. Our drug discovery and development programs are focused on small molecules that selectively modulate the effects of estrogens and androgens two essential classes of hormones. We currently have two product candidates that are in human clinical trials. We are developing Acapodene, our most advanced product candidate, through clinical trials for two separate indications: (1) a Phase IIb clinical trial for the reduction in the incidence of prostate cancer in men with precancerous prostate lesions and (2) a pivotal Phase III clinical trial for the treatment of serious side effects of advanced prostate cancer therapy. Phase IIb clinical trials typically evaluate efficacy and safety and determine the optimal dosing regimen. Pivotal Phase III clinical trials typically further evaluate efficacy and safety in an expanded patient population. We are initially developing our second product candidate, Andarine, for the treatment of potentially life-threatening muscle wasting weight loss from various types of cancer. Andarine is the most advanced of our internally discovered portfolio of compounds designed to modulate the effects of hormones.

We plan to build a specialized sales and marketing capability to market our product candidates directly to the relatively small and concentrated community of urologists and medical oncologists in the United States and to seek collaborators to commercialize our product candidates outside the United States and to broader target physician markets.

Acapodene for the Reduction in the Incidence of Prostate Cancer in Men with Precancerous Prostate Lesions

Prostate cancer is one of the most commonly diagnosed cancers in men and the second leading cause of cancer-related deaths in the United States. We believe that treating the precancerous lesions of prostate cancer known as high grade PIN may be an effective approach to this disease. In the United States, there are over 115,000 new cases of precancerous prostate lesions diagnosed each year, and an estimated 9.4 million men unknowingly harbor this condition. As there is currently no therapy for the treatment of this condition, we believe this represents a significant unmet medical need.

A planned interim analysis of the first 120 patients in our Phase IIb clinical trial showed that treatment with Acapodene resulted in a 26% to 57% reduction in the incidence of prostate cancer compared to the placebo group 12 months after the diagnosis of precancerous prostate lesions. While these interim results do not necessarily predict favorable results from this trial or any future trial, we believe that the results of this interim analysis suggest that Acapodene may be effective in reducing the incidence of prostate cancer in men with precancerous prostate lesions. The last of the 515 enrolled patients is scheduled to complete this trial in May 2004, with final results expected in the third quarter of 2004. We believe that this Phase IIb clinical trial of Acapodene together with a single pivotal Phase III clinical trial will be sufficient to support an application with the FDA for marketing approval of Acapodene for this indication.

Acapodene for the Treatment of Side Effects of Advanced Prostate Cancer Therapy

The standard medical treatment for men who have advanced, recurrent or metastatic prostate cancer is androgen deprivation therapy, which reduces blood levels of testosterone, the growth factor for prostate cancer. In the United States, more than 675,000 men are currently being treated by this therapy, with over 120,000 new patients started on this therapy each year. Advanced prostate cancer therapy has serious side effects, including: severe bone loss, or osteoporosis, leading to skeletal fractures; hot flashes; and breast pain and enlargement. We are developing Acapodene as a treatment for these side effects. Because there are no drugs approved by the FDA for the treatment of these side effects, we believe that there could be a substantial market for Acapodene for this indication.

We have completed two six-month Phase II clinical trials of Acapodene for the treatment of osteoporosis and hot flashes in men receiving advanced prostate cancer therapy. Phase II clinical trials are typically conducted in a limited population to evaluate dosage, safety and, preliminarily, efficacy for a specific indication. The first Phase II clinical trial evaluated the use of Acapodene shortly after initiation of therapy, and the second Phase II clinical trial evaluated Acapodene in patients who had been receiving therapy for more than 12 months. The analysis of the second trial showed that Acapodene at the highest tested dose produced an increase in bone mineral density, an indicator of bone strength, and a reduction in the frequency of hot flashes. Our pivotal Phase III clinical trial for this indication, which we commenced in November 2003, is principally based on the results of the second Phase II clinical trial. The Phase III trial will evaluate the effect of Acapodene on the incidence of skeletal fractures as well as on bone loss and the incidence of hot flashes and breast pain and enlargement. The increase in bone mineral density and reduction in the frequency of hot flashes observed in the second Phase II clinical trial are not necessarily indicative of the results that will be demonstrated in our pivotal Phase III trial.

Andarine for the Treatment of Muscle Wasting Weight Loss from Cancer

We believe that Andarine has the potential to treat a variety of men's health conditions, including testosterone deficiency in aging men and related diseases, including osteoporosis and muscle wasting. Our strategy is to develop Andarine initially for the treatment of muscle wasting weight loss from various types of cancer, which is known as cancer cachexia. We selected this indication because it represents a potentially large market and, we believe, has a relatively well-defined clinical and regulatory process. There are approximately 1.3 million patients diagnosed with cancer each year in the United States. Muscle wasting weight loss afflicts approximately one-third of newly-diagnosed cancer patients. There are no drugs that have been approved by the FDA for the treatment of muscle wasting weight loss from cancer.

We have completed three Phase I clinical trials of Andarine in which Andarine was well-tolerated by all participants with no serious adverse events. Phase I clinical trials are designed to confirm safety and tolerance. In one of these Phase I clinical trials, we measured increased levels of a growth factor in the blood of some men who received Andarine, which suggests that Andarine may promote growth activity and thus may be an effective treatment for muscle wasting weight loss from cancer. However, these early observations are not necessarily indicative of the results that will be demonstrated in future clinical trials. We plan to commence a placebo-controlled, dose-finding Phase II clinical trial of Andarine for the treatment of muscle wasting weight loss from non-small cell lung cancer in the first half of 2004.

Pipeline

We have multiple product candidates that we are evaluating in preclinical and toxicology studies to support the possible commencement of clinical trials. We are developing our current preclinical product candidates for the treatment of major indications in men's health, including:

- Prostarine for the treatment of a benign prostate enlargement that results in obstruction of the urinary tract;
- Ostarine for the treatment of osteoporosis and testosterone deficiency in aging men; and
- Andromustine for the treatment of prostate cancer that is not responsive to androgen deprivation therapy.

We believe that our drug discovery capabilities position us well to design and develop nonsteroidal small molecule drugs that modulate the effects of hormones.

Early Stage Company

All of our product candidates are undergoing clinical trials or are in early stages of development, and failure is common and can occur at any stage of development To date, we have not obtained regulatory approval for the commercial sale of any products, and we have not received any revenues from the commercial sale of products. Industry sources report that the preparation and submission of new drug applications, or NDAs, which are required for regulatory approval, generally take six months to one year to complete after completion of a pivotal clinical trial. Industry sources also report that approximately 75% of all NDAs are approved by the FDA, and the FDA reports that most NDAs are approved within 12 to 24 months of submission, although it may take longer if additional information is required by the FDA or for other reasons. The Pharmaceutical Research and Manufacturers of America reports that only one out of five product candidates that enter clinical trials will ultimately be approved by the FDA for commercial sale. We do not expect any of our product candidates, if successfully developed, to receive regulatory approval for commercial sale for at least several years. Any products that we sell may not become commercially successful.

For the nine months ended September 30, 2003, our net loss was $9.6 million, and as of that date, we had a deficit accumulated during the development stage of $144.9 million, of which $110.6 million related to non-cash dividends and adjustments to the preferred stock redemption value.

Company Information

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

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

The Offering

Common stock offered by GTx	5,400,000 shares
Common stock to be outstanding after the offering	24,592,762 shares
Proposed Nasdaq National Market symbol	GTXI
Use of proceeds	We expect to use the net proceeds from this offering to fund our clinical trials and other research and development activities and for general corporate purposes.

The number of shares of common stock to be outstanding after this offering is based on the number of shares outstanding as of December 31, 2003 and excludes:

- 828,750 shares of common stock issuable upon exercise of options issued under our current stock option plans, at a weighted average exercise price of $6.18 pe share;
- 453,050 shares of common stock reserved for future issuance under our current stock option plans and 1,700,000 shares of common stock reserved for future issuance under our 2004 Equity Incentive Plan and 2004 Non-Employee Directors' Stock Option Plan, which will become effective upon the completion of this offering; and
- shares of common stock issuable upon conversion of outstanding preferred stock in satisfaction of dividends that will accrue on our preferred stock between January 1, 2004 and the closing of this offering.

Except as otherwise noted, all information in this prospectus:

- assumes no exercise of the underwriters' over-allotment option;
- gives effect to the conversion into common stock of all outstanding shares of preferred stock and dividends accrued thereon through December 31, 2003; and
- gives effect to an 8.5-for-1 stock split of our common stock, which was effected on January 14, 2004.

Summary Financial Information

You should read the summary financial information below in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the financial statements, notes thereto and other financial information included elsewhere in this prospectus. We derived the information presented for the nine-month periods ended September 30, 2002 and September 30, 2003 from unaudited financial statements which include, in the opinion of management, all adjustments, consisting only of normal recurring accruals, necessary to present fairly the information for such periods. The results for the nine-month period ended September 30, 2003 are not necessarily indicative of the results to be expected for the full fiscal year.

We computed pro forma net loss per share for the year ended December 31, 2002 and the nine months ended September 30, 2003 by using the weighted average number of shares of common stock outstanding, including the pro forma effects of the automatic conversion of our preferred stock and dividends accrued thereon into shares of common stock effective upon the closing of the offering as if such conversion occurred on January 1, 2002 and January 1, 2003 or at the date of the original issuance, if later. The calculation of pro forma net loss per share attributable to common stockholders excludes incremental common stock issuable upon exercise of options, as its effect would be antidilutive.

	Year Ended December 31,			Nine Months Ended September 30,	
	2000	2001	2002	2002	2003
				(unaudited)	
	(in thousands, except share and per share data)				
Statement of Operations Data:					
Operating expenses:					
Research and development	$ 2,679	$ 5,744	$ 9,285	$ 6,408	$ 7,123
General and administrative	1,203	2,187	2,405	1,830	2,339
Depreciation	80	215	332	240	264
Total operating expenses	3,962	8,146	12,022	8,478	9,726
Interest income	150	83	156	105	79
Net loss	(3,812)	(8,063)	(11,866)	(8,373)	(9,647)
Accrued preferred stock dividends	(297)	(790)	(2,147)	(1,466)	(2,300)
Adjustment to preferred stock redemption value	(21,077)	(57)	(7,220)	(7,147)	(76,666)
Net loss attributable to common stockholders	$ (25,186)	$ (8,910)	$ (21,233)	$ (16,986)	$ (88,613)
Net loss per share attributable to common stockholders, basic and diluted:	$ (3.26)	$ (1.15)	$ (2.75)	$ (2.20)	$ (11.46)
Weighted average shares used in computing net loss per share attributable to common stockholders, basic and diluted:	7,735,000	7,735,000	7,735,000	7,735,000	7,735,000
Pro forma net loss per share attributable to common stockholders — basic and diluted			$ (0.80)		$ (0.59)
Shares used in computing pro forma net loss per share attributable to common stockholders — basic and diluted			14,811,786		16,455,728

The following table presents a summary of our balance sheet as of September 30, 2003:

- on an actual basis; and
- on an as adjusted basis to reflect the conversion into common stock of all outstanding shares of preferred stock and dividends accrued thereon through September 30, 2003 and the sale in this offering of 5,400,000 shares of common stock at an assumed initial public offering price of $14.00 per share, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

	As of September 30, 2003	
	Actual	As Adjusted
	(in thousands)	
Balance Sheet Data:		
Cash and cash equivalents	$ 19,788	$ 87,796
Working capital	18,280	86,289
Total assets	21,107	89,115
Cumulative redeemable convertible preferred stock	162,978	—
Deficit accumulated during development stage	(144,891)	(145,159)
Total stockholders' (deficit) equity	(143,838)	87,149

RISK FACTORS

Risks Related to Our Financial Results and Need for Additional Financing

We have incurred losses since inception and anticipate that we will incur continued losses for the foreseeable future.

We are a development stage company with a limited operating history. As of September 30, 2003, we had a deficit accumulated during the development stage of $144.9 million, of which $110.6 million related to non-cash dividends and adjustments to the preferred stock redemption value. We have incurred losses in each year since our inception in 1997. Net losses were $11.9 million in 2002, $8.1 million in 2001 and $3.8 million in 2000. For the nine months ended September 30, 2003, net losses were $9.6 million. We expect to continue to incur significant and increasing operating losses for the foreseeable future. These losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

Because of the numerous risks and uncertainties associated with developing small molecule drugs, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Currently, we have no products approved for commercial sale, and, to date, we have not generated any product revenue. We have financed our operations and internal growth almost exclusively through private placements of preferred stock. We have devoted substantially all of our efforts to research and development, including clinical trials.

We expect our research and development expenses to increase in connection with the conduct of clinical trials. In addition, subject to regulatory approval of any of our product candidates, we expect to incur sales and marketing and increased manufacturing expenses.

We will need substantial additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts.

We will need to raise additional capital to:

- fund our operations and clinical trials;
- continue our research and development; and
- commercialize our product candidates, if any such product candidates receive regulatory approval for commercial sale.

We believe that the net proceeds from this offering, our existing cash resources and interest on these funds will be sufficient to meet our projected operating requirements through the end of 2005. Our future funding requirements will depend on many factors, including:

- the scope, rate of progress and cost of our clinical trials and other research and development activities;
- future clinical trial results;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the cost and timing of regulatory approvals;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- the cost of establishing clinical and commercial supplies of our product candidates and any products that we may develop;
- the effect of competing technological and market developments;

- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and

- the extent to which we acquire or invest in businesses, products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

Until we can generate a sufficient amount of product revenue, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements, as well as through interest income earned on cash balances.

If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Debt financing, if available, may involve restrictive covenants. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it will be necessary to relinquish some rights to our technologies or our product candidates, or grant licenses on terms that are not favorable to us.

Risks Related to Development of Product Candidates

We will not be able to commercialize our product candidates if our preclinical studies do not produce successful results or our clinical trials do not demonstrate safety and efficacy in humans.

Preclinical and clinical testing is expensive, can take many years and has an uncertain outcome. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and interim results of a clinical trial do not necessarily predict final results. We may experience numerous unforeseen events during, or as a result of, preclinical testing and the clinical trial process that could delay or prevent our ability to commercialize our product candidates, including:

- regulators or institutional review boards may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;

- our preclinical or clinical trials may produce negative or inconclusive results, which may require us to conduct additional preclinical or clinical testing or to abandon projects that we expect to be promising;

- registration or enrollment in our clinical trials may be slower than we currently anticipate, resulting in significant delays;

- we might have to suspend or terminate our clinical trials if the participating patients are being exposed to unacceptable health risks;

- regulators or institutional review boards may suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements; and

- the effects of our product candidates may not be the desired effects or may include undesirable side effects.

If any of these events were to occur and, as a result, we have significant delays in or termination of clinical trials, our costs would increase and our ability to generate revenue could be impaired, which would adversely impact our financial results.

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.

We do not currently own or operate manufacturing facilities and rely and expect to continue to rely on third parties for the production of clinical and commercial quantities of our product candidates. Our current and anticipated future dependence upon others for the manufacture of our product candidates may adversely affect our future profit margins and our ability to develop product candidates and commercialize any product candidates on a timely and competitive basis.

We have agreed to purchase from Orion Corporation our worldwide requirements of Acapodene in finished tablet form at specified transfer prices under a license and supply agreement. We rely on Orion as a single source supplier for Acapodene. In the event that Orion terminates the agreement under specified circumstances, we would not be able to manufacture Acapodene until Orion's patents with respect to the composition of matter of toremifene, the active pharmaceutical ingredient in Acapodene, expire. This could delay the development of and impair our ability to commercialize this product candidate. In addition, Orion may terminate its obligation to supply us with toremifene under specified circumstances. Under some of these circumstances, we will have the right to manufacture Acapodene, but we would be required to make arrangements with a qualified alternative supplier to do so.

In addition, we currently rely on ChemSyn Laboratories, a department of EaglePicher Technologies, LLC, as our single supplier of Andarine. We do not have a contract with ChemSyn for the supply of Andarine for full-scale commercialization.

We may not be able to maintain or renew our existing or any other third-party manufacturing arrangements on acceptable terms, if at all. If we are unable to continue relationships with Orion for Acapodene and ChemSyn for Andarine, or to do so at an acceptable cost, or if these suppliers fail to meet our requirements for these product candidates for any reason, we would be required to obtain alternate suppliers, which we may not be permitted to do for Acapodene under our license agreement with Orion in some circumstances. Any inability to obtain alternate suppliers, including an inability to obtain approval of an alternate supplier from the Food and Drug Administration, or FDA, would delay or prevent the clinical development and commercialization of these product candidates.

Use of third-party manufacturers may increase the risk that we will not have adequate supplies of our product candidates.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates or products ourselves, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party because of factors beyond our control; and
- the possible termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us.

If we are not able to obtain adequate supplies of our product candidates, it will be more difficult for us to develop our product candidates and compete effectively. Our product candidates and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. For example, the active pharmaceutical ingredient in Acapodene is also the active pharmaceutical ingredient in Fareston. Orion also manufactures Fareston for Shire Pharmaceuticals Group, which markets it in the United States for the treatment of advanced breast cancer in post-menopausal women.

Our present or future manufacturing partners may not be able to comply with FDA mandated current Good Manufacturing Practice regulations, other FDA regulatory requirements or similar regulatory requirements outside the United States. Failure of our third-party manufacturers or us to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates.

If third parties on whom we rely do not perform as contractually required or expected, we may not be able to obtain regulatory approval for or commercialize our product candidates.

We do not have the ability to independently conduct clinical trials for our product candidates, and we must rely on third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct our clinical trials. In addition, we rely on third parties to assist with our preclinical development of product candidates. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our preclinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates.

We expect to be dependent upon collaborative arrangements to complete the development and commercialization of some of our 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.

We may not be successful in entering into collaborative arrangements with third parties. If we fail to enter into additional collaborative arrangements on favorable terms, it could delay or impair our ability to develop and commercialize our product candidates and could increase our costs of development and commercialization. Dependence on collaborative arrangements will subject us to a number of risks, including:

- we may not be able to control the amount and timing of resources that our collaborators may devote to the product candidates;
- our collaborators may experience financial difficulties;
- we may be required to relinquish important rights such as marketing and distribution rights;
- should a collaborator fail to develop or commercialize one of our compounds or product candidates, we may not receive any future milestone payments and will not receive any royalties for this compound or product candidate;
- business combinations or significant changes in a collaborator's business strategy may also adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement;
- a collaborator could independently move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors; and
- the collaborative arrangements are often terminated or allowed to expire, which would delay the development and may increase the cost of developing our product candidates.

Risks Related to Our Intellectual Property

Our license agreement with Orion Corporation is limited to specific fields of use of toremifene and will limit our ability to market Acapodene.

Our license from Orion is limited to the use of toremifene for the prevention and treatment of prostate cancer and the prevention and treatment of osteoporosis, hot flashes and breast pain and enlargement as side effects of advanced prostate cancer therapy. The license is exclusive in North America and Japan in these fields. Orion has licensed Shire Pharmaceuticals Group in the United States and other parties elsewhere in the world to market, sell and distribute toremifene for the treatment of advanced breast cancer and could license other parties to market, sell and distribute toremifene for other indications in the United States and elsewhere.

Under the terms of our license agreement with Orion, Orion may require us to modify our final Acapodene development plans for specified major markets if such development plans could adversely affect toremifene outside the fields that Orion has licensed to us. Although we do not believe that our development plans adversely affect toremifene outside the licensed fields, any future modifications to our plans may limit our ability to maximize the commercial potential of Acapodene.

Furthermore, we and our affiliates are prohibited from selling a product that competes with toremifene in the licensed field in major countries located outside the European Union during the term of the agreement and in major countries in the European Union through October 2006. While we are not currently developing any product candidate that would compete with toremifene in the licensed field, this noncompetition provision may limit our ability to commercialize any other compounds in the licensed field even if we believe that other compounds have more commercial potential than Acapodene. The binding effect of this noncompetition provision on our affiliates, as well as Orion's right to terminate the agreement if we are acquired by a direct competitor of Orion with respect to toremifene, may make it more difficult for us to be acquired by some potential buyers even if we determine that a sale of the company would be in the best interests of our stockholders.

If some or all of our patents expire or are invalidated or are unenforceable, or if some or all of our patent applications do not yield issued patents or yield patents with narrow claims, we may be subject to competition from third parties with products with the same active pharmaceutical ingredients as our product candidates.

Our commercial success will depend in part on obtaining and maintaining patent and trade secret protection for our product candidates, the methods used to manufacture these product candidates and the methods for treating patients using these product candidates. We will be able to protect our product candidates and our technologies from unauthorized use by third parties only to the extent that valid and enforceable patents or trade secrets cover them.

Even if our product candidates and technologies are covered by valid and enforceable patents, the patents will provide protection only for a limited amount of time. For example, the patents that we have licensed from Orion covering the composition of matter of toremifene expire in the United States in 2009 and are likely to expire in countries outside the United States before we commercialize Acapodene. As a result, outside the United States and in the United States after 2009, we will need to rely primarily on the protection afforded by method of use patents that have issued or may issue in respect of our owned or licensed patent applications relating to the use of Acapodene for the relevant indications. To date, most of these pending method of use patent applications have not yielded issued patents.

Our and our collaborators' ability to obtain patents is highly uncertain because, to date, some legal principles remain unresolved and there has not been a consistent policy regarding the breadth or interpretation of claims allowed in patents in the United States, and the specific content of patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, scientific and factual issues. Furthermore, the

policies governing biotechnology patents outside the United States are even more uncertain. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection.

Even if patents are issued regarding our product candidates or methods of using them, those patents can be challenged by our competitors who can argue such patents are invalid. Patents also will not protect our product candidates if competitors devise ways of making these product candidates without legally infringing our patents. The Federal Food, Drug, and Cosmetic Act and FDA regulations and policies provide incentives to manufacturers to challenge patent validity or create modified, noninfringed versions of a drug in order to facilitate the approval of abbreviated new drug applications for generic substitutes. These same types of incentives encourage manufacturers to submit new drug applications that rely on literature and clinical data not prepared for or by the drug sponsor. See "Government Regulation" beginning on page 53 for additional information.

We also rely on trade secrets to protect our technology, especially where we do not believe that patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Enforcing a claim that a third party illegally obtained and is using our trade secrets is expensive and time-consuming, and the outcome is unpredictable. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. Failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

Off-label sale or use of generic toremifene products could decrease 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.

In all countries in which we hold or have licensed rights to patents or patent applications related to Acapodene, the composition of matter patents will expire before the method of use patents. Method of use patents may not protect Acapodene from the risk of off-label sale or use of the subject compounds. Physicians are permitted to prescribe legally available drugs for uses that are not described in the drug's labeling and that differ from those uses tested and approved by the FDA. Such off-label uses are common across medical specialties. Off-label sales would adversely affect our ability to generate revenue from the sale of Acapodene, if approved for commercial sale.

In the event that patents issue in respect of our pending method of use patent applications, after the expiration of the patent covering the composition of matter of toremifene in a particular country, competitors could market and sell generic versions of toremifene at doses and in formulations that are equivalent to Acapodene for uses other than the indications for Acapodene covered by these pending method of use patent applications, and physicians would be permitted to prescribe these generic versions of toremifene for indications that are protected by these method of use patents and pending patent applications. Moreover, because Orion has licensed and could further license other parties to market, sell and distribute toremifene for other indications in the United States and elsewhere, physicians could prescribe these products sold pursuant to another Orion license off-label. This further increases the risk of off-label competition developing for Acapodene for the indications for which we are developing this product candidate. In addition, if no patents issue in respect of our pending method of use patent applications related to the use of Acapodene, after the expiration of the patent covering the composition of matter of toremifene in a particular country, competitors could market and sell generic versions of toremifene at doses and in formulations equivalent to Acapodene for the indications covered by our pending method of use patent applications.

If we infringe intellectual property rights of third parties, it may increase our costs or prevent us from being able to commercialize our product candidates.

There is a risk that we are infringing the proprietary rights of third parties because numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields that are the focus of our drug discovery and development efforts. Others might have been the first to make the inventions covered by each of our or our licensors' pending patent applications and issued patents and might have been the first to file patent applications for these inventions. In addition, because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that cover the production, manufacture, commercialization or use of our product candidates. In addition, the production, manufacture, commercialization or use of our product candidates may infringe existing patents of which we are not aware. Defending ourselves against third-party claims, including litigation in particular, would be costly and time consuming and would divert management's attention from our business, which could lead to delays in our development or commercialization efforts. If third parties are successful in their claims, we might have to pay substantial damages or take other actions that are adverse to our business.

As a result of intellectual property infringement claims, or to avoid potential claims, we might:

- be prohibited from selling or licensing any product that we may develop unless the patent holder licenses the patent to us, which it is not required to do;
- be required to pay substantial royalties or grant a cross license to our patents to another patent holder; or
- be required to redesign the formulation of a product candidate so it does not infringe, which may not be possible or could require substantial funds and time.

Risk 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.

Our product candidates and the activities associated with their development and commercialization are subject to comprehensive regulation by the FDA, and other regulatory agencies in the United States and by comparable authorities in other countries. Failure to obtain regulatory approval for a product candidate will prevent us from commercializing the product candidate. We have not received regulatory approval to market any of our product candidates in any jurisdiction and have only limited experience in preparing and filing the applications necessary to gain regulatory approvals. The process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon the type, complexity and novelty of the product candidates involved.

Changes in the regulatory approval policy during the development period, changes in or the enactment of additional regulations or statutes, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. Even if the FDA approves a product candidate, the approval may impose significant restrictions on the indicated uses, conditions for use, labeling, advertising, promotion, marketing and/or production of such product, and may impose ongoing requirements for post-approval studies, including additional research and development and clinical trials. The FDA also may impose various civil or criminal sanctions for failure to comply with regulatory requirements, including withdrawal of product approval.

Furthermore, the approval procedure and the time required to obtain approval varies among countries and can involve additional testing beyond that required by the FDA. Approval by one regulatory authority does not ensure approval by regulatory authorities in other jurisdictions.

The FDA has substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. For example, while we believe that our ongoing Phase IIb clinical trial of Acapodene for the reduction in the incidence of prostate cancer in men with high grade PIN will support a single pivotal Phase III clinical trial for this indication, the FDA may require more than one pivotal Phase III clinical trial in order to grant marketing approval of Acapodene for this indication which could delay the approval process. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate.

We do not expect to receive regulatory approval for the commercial sale of any of our product candidates for a number of years. The inability to obtain FDA approval or approval from comparable authorities in other countries would prevent us from commercializing our product candidates in the United States or other countries. See “Government Regulation” beginning on page 53 for additional information.

Risks Related to Commercialization

The commercial success of any products that we may develop will depend upon the degree of market acceptance among physicians, patients, health care payors and the medical community.

Any products that we may develop may not gain market acceptance among physicians, patients, health care payors and the medical community. If these products do not achieve an adequate level of acceptance, we may not generate material product revenues and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the prevalence and severity of any side effects;
- potential advantages over alternative treatments;
- the ability to offer our product candidates for sale at competitive prices;
- relative convenience and ease of administration;
- the strength of marketing and distribution support; and
- sufficient third-party coverage or reimbursement.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate product revenue.

We do not have a sales organization and have no experience as a company in the sales, marketing and distribution of pharmaceutical products. There are risks involved with establishing our own sales and marketing capabilities, as well as entering into arrangements with third parties to perform these services. For example, developing a sales force is expensive and time-consuming and could delay any product launch. In addition, to the extent that we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenues are likely to be lower than if we market and sell any products that we develop ourselves.

If we are unable to obtain adequate coverage and reimbursement from third-party payors for any products that we may develop or acceptable prices, our revenues and prospects for profitability will suffer.

Many patients will not be capable of paying for any products that we may develop themselves and will rely on Medicare and Medicaid, private health insurers and other third-party payors to pay for their medical needs. If third-party payors do not provide coverage or reimbursement for any products that we may develop, our revenues and prospects for profitability will suffer. In December 2003, the President signed into law legislation creating a prescription drug benefit program for Medicare recipients. The prescription drug program established by the legislation may have the effect of reducing the prices that we are able to charge for products we develop and sell through these plans. This prescription drug legislation may also cause third-party payors other than the federal government, including the states under the Medicaid program, to discontinue coverage for products we develop or to lower the amount that they pay.

State Medicaid programs generally have outpatient prescription drug coverage, subject to state regulatory restrictions, for the population eligible for Medicaid. The availability of coverage or reimbursement for prescription drugs under private health insurance and managed care plans varies based on the type of contract or plan purchased.

A primary trend in the United States health care industry is toward cost containment. In addition, in some foreign countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take six to 12 months or longer after the receipt of regulatory marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost effectiveness of our product candidates or products to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in our commercialization. Third-party payors are challenging the prices charged for medical products and services, and many third-party payors limit reimbursement for newly-approved health care products. In particular, third-party payors may limit the indications for which they will reimburse patients who use any products that we may develop. Cost-control initiatives could decrease the price we might establish for products that we may develop, which would result in lower product revenues to us.

Another development that may affect the pricing of drugs is proposed Congressional action regarding drug reimportation into the United States. The Medicare Prescription Drug Plan legislation gives additional discretion to the Secretary of Health and Human Services to allow drug reimportation from foreign countries into the United States under some circumstances, including countries where the drugs are sold at a lower price than in the United States. Proponents of drug reimportation may attempt to pass legislation which would directly allow reimportation under certain circumstances. If legislation or regulations were passed allowing the reimportation of drugs, they could decrease the price we receive for any products that we may develop, negatively affecting our revenues and prospects for profitability.

If product liability lawsuits are brought against us, we will incur substantial liabilities and may be required to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. If we cannot successfully defend ourselves against claims that our product candidates caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;

- injury to our reputation;

- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue; and
- the inability to commercialize any products that we may develop.

We have product liability insurance that covers our clinical trials up to a $5 million annual aggregate limit. We intend to expand our insurance coverage to include the sale of commercial products if marketing approval is obtained for any products that we may develop. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost and we may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise.

If our competitors are better able to develop and market products that are more effective than any products that we may develop, our commercial opportunity will be reduced or eliminated.

We face competition from established pharmaceutical and biotechnology companies, as well as from academic institutions, government agencies and private and public research institutions. Our commercial opportunity will be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer side effects or are less expensive than any products that we may develop. In addition, significant delays in the development of our product candidates could allow our competitors to bring products to market before us and impair our ability to commercialize our product candidates.

Various products are currently marketed or sold and used off-label for some of the diseases and conditions that we are targeting, and a number of companies are or may be developing new treatments. The occurrence of such off-label uses could significantly reduce our ability to market and sell any products that we may develop. For example, although there are no products that have been approved by the FDA to treat multiple side effects of advanced prostate cancer therapy, we are aware of a number of drugs marketed by Eli Lilly, Merck, Aventis, Proctor & Gamble, Wyeth Pharmaceuticals, Boehringer and Bristol Myers Squibb that are prescribed off-label to treat single side effects of this therapy and that external beam radiation is used to treat breast pain and enlargement. Similarly, while there are no drugs that have been approved by the FDA for the treatment of muscle wasting weight loss from cancer, there are drugs marketed by Steris Laboratories and Savient Pharmaceuticals that are being prescribed off-label for the treatment of some types of muscle wasting weight loss from cancer. In addition, there may be product candidates of which we are not aware at an earlier stage of development that may compete with our product candidates. If any are successfully developed and approved, they could compete directly with our product candidates. This could result in reduced sales and pricing pressure on our product candidates, if approved, which in turn would reduce our ability to generate revenue and have a negative impact on our results of operations.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies and technology licenses complementary to our programs or advantageous to our business.

Risks Related to Employees and Growth

If we fail to attract and keep senior management and key scientific personnel, we may be unable to successfully develop or commercialize our product candidates.

Our success depends on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel and on our ability to develop and maintain important relationships with leading academic institutions, clinicians and scientists. If we are not able to attract and keep senior management and key scientific personnel, particularly Dr. Mitchell S. Steiner, we may not be able to successfully develop or commercialize our product candidates. All of our employees are at-will employees and can terminate their employment at any time. We do not carry "key person" insurance covering members of senior management, other than $15 million of insurance covering Dr. Steiner.

We will need to hire additional employees in order to continue our clinical trials and commercialize our product candidates. Any inability to manage future growth could harm our ability to commercialize our product candidates, increase our costs and adversely impact our ability to compete effectively.

In order to continue our clinical trials and commercialize our product candidates, we will need to expand the number of our managerial, operational, financial and other employees. We currently anticipate that we will need between 150 and 250 additional employees by the time that Acapodene or Andarine is initially commercialized, including 50 to 80 sales representatives. While to date we have not experienced difficulties in recruiting and hiring qualified individuals, the competition for qualified personnel in the biotechnology field is intense.

Future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively.

Risks Related to the Offering

If you purchase our common stock in this offering, you will incur immediate and substantial dilution in the book value of your shares.

The assumed initial public offering price is substantially higher than the net tangible book value per share of our common stock. Investors purchasing common stock in this offering will pay a price per share that substantially exceeds the book value of our tangible assets after subtracting our liabilities. As a result, investors purchasing common stock in this offering will incur immediate dilution of $10.43 per share, based on an assumed initial public offering price of $14.00 per share. Further, investors purchasing common stock in this offering will contribute approximately 56% of the total amount invested by stockholders since our inception, but will own only approximately 22% of the shares of common stock outstanding.

This dilution is due to our investors who purchased shares prior to this offering having paid substantially less than the price offered to the public in this offering when they purchased their shares and the exercise of stock options granted to our employees. As a result of this dilution, investors purchasing stock in this offering may receive significantly less than the purchase price paid in this offering in the event of a liquidation.

Market volatility may cause our stock price and the value of your investment to decline.

Our stock price is likely to be volatile. Investors purchasing common stock in this offering may not be able to resell their shares at or above the initial public offering price. The market prices for

securities of biopharmaceutical companies in general have been highly volatile and may continue to be highly volatile in the future. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our common stock:

- adverse results or delays in our clinical trials;
- the timing of achievement of our clinical, regulatory and other milestones, such as the commencement of clinical development, the completion of a clinical trial or the receipt of regulatory approval;
- announcement of FDA approval or non-approval of our product candidates or delays in the FDA review process;
- actions taken by regulatory agencies with respect to our product candidates, our clinical trials or our sales and marketing activities;
- the commercial success of any product approved by the FDA or its foreign counterparts;
- regulatory developments in the United States and foreign countries;
- changes in the structure of health care payment systems;
- any intellectual property infringement lawsuit involving us;
- announcements of technological innovations or new products by us or our competitors;
- market conditions for the biotechnology or pharmaceutical industries in general;
- actual or anticipated fluctuations in our results of operation;
- changes in financial estimates or recommendations by securities analysts;
- sales of large blocks of our common stock;
- sales of our common stock by our executive officers, directors and significant stockholders;
- changes in accounting principles; and
- the loss of any of our key scientific or management personnel.

The stock markets in general, and the markets for biotechnology stocks in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. These broad market fluctuations may adversely affect the trading price of our common stock. In the past, class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Any such litigation brought against us could result in substantial costs, which would hurt our financial condition and results of operations and divert management's attention and resources, which could result in delays of our clinical trials or commercialization efforts.

After this offering, our officers, directors and largest stockholders will maintain the ability to control all matters submitted to stockholders for approval.

Based on our outstanding shares as of December 31, 2003, after this offering, our officers, directors and holders of 5% or more of our outstanding common stock will beneficially own approximately 78% of our common stock, after giving effect to the conversion into common stock of all outstanding shares of our preferred stock and dividends accrued thereon through December 31, 2003, but assuming no exercise of the underwriters' over-allotment option and no exercise of outstanding options. As a result, these stockholders, acting together, will be able to control all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with our interests or the interests of other stockholders.

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.

Provisions in our certificate of incorporation and our bylaws that will become effective upon the completion of this offering may delay or prevent an acquisition of us or a change in our management. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our Board of Directors. Because our Board of Directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. These provisions include:

- a classified Board of Directors;
- a prohibition on actions by our stockholders by written consent;
- the ability of our Board of Directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our Board of Directors; and
- limitations on the removal of directors.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. Finally, these provisions establish advance notice requirements for nominations for election to our Board of Directors or for proposing matters that can be acted upon at stockholder meetings. These provisions would apply even if the offer may be considered beneficial by some stockholders.

We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not necessarily improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of our product candidates.

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.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. After this offering, we will have outstanding 24,592,762 shares of common stock based on the number of shares outstanding as of December 31, 2003. This includes the shares that we are selling in this offering, which may be resold in the public market immediately. The remaining 19,192,762 shares, or 78% of our outstanding shares after this offering, are currently restricted as a result of securities laws or lock-up agreements but will be able to be sold in the near future as set forth below.

Number of Shares and % of Total Outstanding	Date Available for Sale Into Public Market
16,302,711 shares, or 66%	180 days after the date of this prospectus due to lock-up agreements between the holders of these shares and the underwriters. However, the underwriters can waive the provisions of these lock-up agreements and allow these stockholders to sell their shares at any time.
2,890,051 shares, or 12%	Between 180 and 365 days after the date of this prospectus, depending on the requirements of the federal securities laws.

Moreover, after this offering, J.R. Hyde, III, Oracle Partners, L.P. and Memphis Biomed Ventures I, L.P., three of our largest stockholders, and their affiliates, who held in the aggregate 11,344,639 shares of common stock as of December 31, 2003, will have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We also intend to register all shares of common stock that we may issue under our employee benefit plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to the lock-up agreements described in "Underwriting." For additional information, see "Shares Eligible for Future Sale" on page 79.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements. The forward-looking statements are contained principally in the sections entitled "Prospectus Summary," "Risk Factors," "Use of Proceeds," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business." These statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. Forward-looking statements include statements about:

- the anticipated progress of our research, development and clinical programs;
- our ability to market, commercialize and achieve market acceptance for our product candidates or products that we may develop;
- our ability to generate additional product candidates for clinical testing;
- our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others; and
- our estimates regarding the sufficiency of our cash resources.

In some cases, you can identify forward-looking statements by terms such as "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "will," "would," and similar expressions intended to identify forward-looking statements. Forward-looking statements reflect our current views with respect to future events, are based on assumptions and subject to risks and uncertainties. We discuss many of these risks in this prospectus in greater detail under the heading "Risk Factors." Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, forward-looking statements represent our estimates and assumptions only as of the date of this prospectus. You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect.

Except as required by law, we assume no obligation to update any forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in any forward-looking statements, even if new information becomes available in the future.

USE OF PROCEEDS

We estimate that our net proceeds from the sale of 5,400,000 shares of common stock in this offering will be approximately $68.0 million and $78.6 million if the underwriters exercise their over-allotment option in full, based upon an assumed initial public offering price of $14.00 per share and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. The principal purposes of this offering are to obtain additional capital and to create a public market for our common stock.

We expect to use approximately $50.3 million of the net proceeds from this offering to fund our clinical trials and other research and development activities and the remainder for general corporate purposes. In addition, we may use a portion of the net proceeds from this offering to acquire equipment, products, technologies or businesses, although we currently have no commitments or agreements relating to any of these types of transactions. We believe that the net proceeds from this offering, our existing cash resources and interest on these funds will be sufficient to meet our projected operating requirements through the end of 2005.

While we have estimated the particular uses for the net proceeds to be received upon the completion of this offering, we cannot specify these uses with certainty. Accordingly, our management will have broad discretion in the application of the net proceeds, and investors will be relying on the judgment of our management regarding the application of the proceeds of this offering. Pending these uses, we plan to invest the net proceeds in short-term, interest bearing obligations, investment grade instruments, certificates of deposit or direct or guaranteed obligations of the United States. The goal with respect to the investment of these net proceeds is capital preservation and liquidity so that such funds are readily available to fund our research and development operations.

DIVIDEND POLICY

The payment of accrued dividends on our outstanding preferred stock will result in the issuance of additional shares of our common stock upon completion of this offering. As of December 31, 2003, approximately $6.8 million of dividends had accrued on our preferred stock. If our preferred stock had been converted into common stock on December 31, 2003, we would have issued 966,756 shares of our common stock in satisfaction of our accrued dividend obligations. We expect to issue approximately 53,500 shares of common stock in satisfaction of our accrued dividend obligations for the month of January 2004.

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain any future earnings to fund the development and expansion of our business, and therefore we do not anticipate paying cash dividends on our common stock in the foreseeable future. Any future determination to pay dividends will be at the discretion of our Board of Directors.

CAPITALIZATION

The following table sets forth our capitalization as of September 30, 2003:

- on an actual basis; and
- on an as adjusted basis to reflect the conversion into common stock of all outstanding shares of preferred stock and dividends accrued thereon through September 30, 2003 and the sale in this offering of 5,400,000 shares of common stock at an assumed initial public offering price of $14.00 per share, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The information in this table is based on shares outstanding as of September 30, 2003 and excludes:

- 799,000 shares of common stock issuable upon exercise of options issued under our current stock option plans, at a weighted average exercise price of $5.97 per share; and
- 483,650 shares of common stock reserved for future issuance under our current stock option plans and 1,700,000 shares of common stock reserved for future issuance under our 2004 Equity Incentive Plan and 2004 Non-Employee Directors' Stock Option Plan, which will become effective upon the completion of this offering.

You should read the information below in conjunction with the financial statements and the related notes thereto and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this prospectus.

	As of September 30, 2003	
	Actual	As Adjusted
	(unaudited) (in thousands, except share data)	
Cash and cash equivalents	$ 19,788	$ 87,796
Cumulative redeemable convertible preferred stock, $0.001 par value:		
1,975,000 shares authorized and 1,231,955 shares issued and outstanding, actual; and no shares authorized, issued or outstanding, as adjusted	162,978	—
Stockholders' (deficit) equity:		
Common stock, par value $0.001 per share:		
25,000,000 shares authorized and 7,735,000 shares issued and outstanding, actual; and 60,000,000 shares authorized and 24,431,780 shares issued and outstanding, as adjusted	8	24
Deferred stock compensation	(3,408)	(3,408)
Additional paid-in capital	4,453	235,692
Deficit accumulated during the development stage	(144,891)	(145,159)
Total stockholders' (deficit) equity	(143,838)	87,149
Total capitalization	$ 19,140	$ 87,149

DILUTION

Our net tangible book value as of September 30, 2003 was $19.1 million, or $1.01 per share of common stock, assuming the conversion of all of our preferred stock and dividends accrued thereon through September 30, 2003 into common stock and giving effect to the 8.5-for-1 stock split of our common stock effected on January 14, 2004. Net tangible book value per share represents the amount of our total tangible assets less total liabilities, divided by the total number of shares of common stock outstanding after giving effect to the conversion of all of our preferred stock and dividends accrued thereon through September 30, 2003 into common stock and the 8.5-for-1 stock split effected on January 14, 2004.

After giving effect to the sale of 5,400,000 shares of common stock offered in this offering at an assumed initial public offering price of $14.00 per share and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, our as adjusted net tangible book value as of September 30, 2003 would have been $87.1 million, or $3.57 per share of common stock. This represents an immediate increase in net tangible book value of $2.56 per share to existing stockholders and an immediate dilution of $10.43 per share to new investors purchasing our common stock in this offering. The following table illustrates this per share dilution to the new investors:

Assumed initial public offering price		$14.00
Net tangible book value per share as of September 30, 2003	$1.01	
Increase in net tangible book value per share attributable to this offering	2.56	
As adjusted net tangible book value per share after this offering		3.57
Dilution per share to new investors in this offering		$10.43

If the underwriters exercise their option to purchase additional shares of our common stock in full in this offering, the as adjusted net tangible book value per share after this offering would be $3.87 per share, the increase in net tangible book value per share to existing stockholders would be $2.86 per share and the dilution to new investors purchasing shares in this offering would be $10.13 per share.

The following table summarizes, on an as adjusted basis as of September 30, 2003, the differences between the number of shares of common stock purchased from us (assuming conversion of all of our preferred stock and dividends accrued thereon through September 30, 2003 into common stock and giving effect to the 8.5-for-1 stock split effected on January 14, 2004), the total consideration and the average price per share paid by existing stockholders and by the new investors, based on an assumed initial public offering price of $14.00 per share, before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us:

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders	19,031,780	78%	$ 59,042,536	44%	$ 3.10
New investors	5,400,000	22	75,600,000	56	14.00
Total	24,431,780	100%	$134,642,536	100%	

If the underwriters exercise their option to purchase additional shares of our common stock in full in this offering, the number of shares held by new investors will increase to 6,210,000, or 25% of the total number of shares of our common stock outstanding after this offering.

The existing stockholders amounts in the table above have been calculated based on shares outstanding as of September 30, 2003 and exclude:

- 799,000 shares of common stock issuable upon exercise of options issued under our current stock option plans, at a weighted average exercise price of $5.97 per share; and
- 483,650 shares of common stock reserved for future issuance under our current stock option plans and 1,700,000 shares of common stock reserved for future issuance under our 2004 Equity Incentive Plan and 2004 Non-Employee Directors' Stock Option Plan, which will become effective upon the completion of this offering.

After this offering and assuming the exercise in full of all outstanding options, our as adjusted net tangible book value per share as of September 30, 2003 would be $3.64 per share, representing an immediate increase in net tangible book value of $2.63 per share to existing stockholders and an immediate dilution in net tangible book value of $10.36 per share to new investors.

SELECTED FINANCIAL DATA

You should read the selected financial data below in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the financial statements, notes thereto and other financial information included elsewhere in this prospectus. We derived the selected financial data for each of the five fiscal years in the period ended December 31, 2002 from our financial statements which have been examined and reported upon by Ernst & Young LLP, independent public accountants. See "Experts." We derived the data presented for the nine-month periods ended September 30, 2002 and September 30, 2003 from unaudited financial statements which include, in the opinion of management, all adjustments, consisting only of normal recurring accruals, necessary to present fairly the data for such periods. The results for the nine-month period ended September 30, 2003 are not necessarily indicative of the results to be expected for the full fiscal year.

We computed pro forma net loss per share for the year ended December 31, 2002 and the nine months ended September 30, 2003 using the weighted average number of shares of common stock outstanding, including the pro forma effects of the automatic conversion of our preferred stock and dividends accrued thereon into shares of common stock effective upon the closing of the offering as if such conversion occurred on January 1, 2002 and January 1, 2003 or at the date of the original issuance, if later. The calculation of pro forma net loss per share attributable to common stockholders excludes incremental common stock issuable upon exercise of options, as its effect would be antidilutive.

	Year Ended December 31,					Nine Months Ended September 30,	
	1998	1999	2000	2001	2002	2002	2003
						(unaudited)	
	(in thousands, except share and per share data)						
Statement of Operations Data:							
Operating expenses:							
Research and development	$ 185	$ 518	$ 2,679	$ 5,744	$ 9,285	$ 6,408	$ 7,123
General and administrative	179	256	1,203	2,187	2,405	1,830	2,339
Depreciation	19	45	80	215	332	240	264
Total operating expenses	383	819	3,962	8,146	12,022	8,478	9,726
Other income:							
Research and development income	225	—	—	—	—	—	—
Interest income	42	69	150	83	156	105	79
Total other income	267	69	150	83	156	105	79
Net loss	(116)	(750)	(3,812)	(8,063)	(11,866)	(8,373)	(9,647)
Accrued preferred stock dividends	—	(83)	(297)	(790)	(2,147)	(1,466)	(2,300)
Adjustment to preferred stock redemption value	—	—	(21,077)	(57)	(7,220)	(7,147)	(76,666)
Net loss attributable to common stockholders	$ (116)	$ (833)	$ (25,186)	$ (8,910)	$ (21,233)	$ (16,986)	$ (88,613)
Net loss per share attributable to common stockholders, basic and diluted:	$ (.01)	$ (.11)	$ (3.26)	$ (1.15)	$ (2.75)	$ (2.20)	$ (11.46)
Weighted average shares used in computing net loss per share attributable to common stockholders, basic and diluted:	7,735,000	7,735,000	7,735,000	7,735,000	7,735,000	7,735,000	7,735,000
Pro forma net loss per share attributable to common stockholders — basic and diluted					$ (0.80)		$ (0.59)
Shares used in computing pro forma net loss per share attributable to common stockholders — basic and diluted					14,811,786		16,455,728

	As of December 31,					As of September 30, 2003
	1998	1999	2000	2001	2002	
				(in thousands)		(unaudited)
Balance Sheet Data:						
Cash and cash equivalents	$ 748	$1,542	$ 2,667	$ 8,834	$ 8,925	$ 19,788
Working capital	743	1,435	2,241	8,544	7,654	18,280
Total assets	870	1,678	3,201	10,117	10,030	21,107
Cumulative redeemable convertible preferred stock	—	1,538	27,912	43,702	64,026	162,978
Deficit accumulated during development stage	(116)	(949)	(26,135)	(35,045)	(56,278)	(144,891)
Total stockholders' (deficit) equity	854	21	(25,165)	(34,075)	(55,308)	(143,838)

MANAGEMENT'S DISCUSSION AND ANALYSIS OF

FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read in conjunction with our financial statements and related notes included elsewhere in this prospectus. This discussion may contain forward-looking statements based upon current expectations that involve risks and uncertainties. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth under "Risk Factors" and elsewhere in this prospectus.

GTx is a biopharmaceutical company dedicated to the discovery, development and commercialization of therapeutics primarily related to the treatment of serious men's health conditions. Our drug discovery and development programs are focused on small molecules that selectively modulate the effects of estrogens and androgens, two essential classes of hormones. We currently have two product candidates that are in human clinical trials. We are developing Acapodene, our most advanced product candidate, through clinical trials for two separate indications: (1) a Phase IIb clinical trial for the reduction in the incidence of prostate cancer in men with precancerous prostate lesions known as high grade prostatic intraepithelial neoplasia, or high grade PIN, and (2) a pivotal Phase III clinical trial for the treatment of serious side effects of advanced prostate cancer therapy known as androgen deprivation therapy. We are initially developing our second product candidate, Andarine, for the treatment of cachexia from various types of cancer. Cancer cachexia is a muscle wasting condition that is a potentially life-threatening complication of many cancers. Andarine is the most advanced of our internally discovered portfolio of compounds designed to modulate the effects of hormones. We plan to build a specialized sales and marketing capability to market our product candidates directly to the relatively small and concentrated community of urologists and medical oncologists in the United States and seek collaborators to commercialize our product candidates where the target physician market is broader than urologists and medical oncologists and outside the United States.

To date, we have not generated any product revenue, and we have financed our operations and internal growth almost exclusively through private placements of preferred stock. We are a development stage company and have incurred significant losses since our inception in 1997 as we have devoted substantially all of our resources to research and development, including our clinical trials. As of September 30, 2003, we had a deficit accumulated during the development stage of $144.9 million. Our accumulated deficit resulted primarily from:

- our research and development activities associated with Acapodene for the reduction in the incidence of prostate cancer in men with high grade PIN, including our Phase IIb clinical trial; Acapodene for the treatment of side effects of androgen deprivation therapy, including two Phase II clinical trials; Andarine for the treatment of cachexia from various forms of cancer, including three Phase I clinical trials; and other product candidates;

- general and administrative expenses; and

- non-cash dividends and adjustments to the preferred stock redemption value of $110.6 million related to our cumulative redeemable convertible preferred stock. See "Critical Accounting Policies — Adjustment to Preferred Stock Redemption Value."

We expect to continue to incur net losses over the next several years as we continue our clinical development and research and development activities, apply for regulatory approvals, establish sales and marketing capabilities and expand our operations.

Research and Development

Since our inception, we have been focused on drug discovery and development programs. Research and development expenses represented approximately 73% of our total operating expenses for the nine-month period ended September 30, 2003 and 76% of our total operating expenses for the nine-month period ended September 30, 2002. Research and development expenses include our expenses for:

- personnel associated with our research activities;
- screening and identification of product candidates;
- formulation and synthesis activities;
- manufacturing;
- preclinical studies, including toxicology studies;
- clinical trials;
- regulatory affairs; and
- quality assurance activities.

The following table identifies for each of our major drug discovery and development programs our lead product candidates, the development phase of each lead product candidate, the status of each lead product candidate and research and development spending for each lead product candidate for each of the periods presented. Research and development spending for past periods is not indicative of spending in future periods.

Research & Development Spending

Program/ Product Candidate/ Indication	Development Phase	Status	Year Ended December 31,			Nine Months Ended September 30,		Inception Through September 30,
			2000	2001	2002	2002	2003	2003
						(in thousands)		
SERM Program								
Acapodene								
• Reduction in the incidence of prostate cancer in men with high grade PIN	Phase IIb clinical trial	Enrollment complete; last patient scheduled to complete trial in May 2004; final results expected in the third quarter of 2004	$1,984	$2,436	$3,168	$2,015	$2,271	$10,562
• Side effects of androgen deprivation therapy	Pivotal Phase III clinical trial	Pivotal Phase III clinical trial initiated in November 2003	$ —	$ —	$ 807	$ 606	$ 661	$ 1,468

Program/ Product Candidate/ Indication	Development Phase	Status	Year Ended December 31, 2000	Year Ended December 31, 2001	Year Ended December 31, 2002	Nine Months Ended September 30, 2002	Nine Months Ended September 30, 2003	Inception Through September 30, 2003
						(in thousands)		
SARM Program								
Andarine								
Cachexia from various types of cancer	Three Phase I clinical trials completed	Phase II clinical trials for treatment of cachexia from non-small cell lung cancer scheduled to begin in the first half of 2004	$ 141	$2,430	$4,134	$2,811	$3,489	$10,194
Other product candidates	Preclinical		$ 554	$ 878	$1,176	$ 976	$ 702	$ 3,310
Total research and development spending			$2,679	$5,744	$9,285	$6,408	$7,123	$25,534

There is a risk that any drug discovery and development program may not produce revenue. Moreover, because of uncertainties inherent in drug discovery and development, including those factors described in the "Risk Factors" section of this prospectus, we may not be able to successfully develop and commercialize any of the product candidates included in the table above.

Drug development in the United States is a process that includes several steps defined by the FDA. The FDA approval process for a new drug involves completion of preclinical studies and the submission of the results of these studies to the FDA, together with proposed clinical protocols, manufacturing information, analytical data and other information in an Investigational New Drug application, or IND, which must become effective before human clinical trials may begin. Clinical development typically involves three phases of study: Phase I, II and III. The most significant costs associated with clinical development are the Phase III clinical trials as they tend to be the longest and largest studies conducted during the drug development process. After completion of clinical trials, a New Drug application, or NDA, may be submitted to the FDA. In responding to an NDA, the FDA may refuse to file the application, or if accepted for filing, the FDA may grant marketing approval, request additional information or deny the application if it determines that the application does not provide an adequate basis for approval.

The successful development of our product candidates is highly uncertain. We cannot reasonably estimate or know the nature, timing and estimated costs of the efforts necessary to complete the development of, or the period in which material net cash inflows are expected to commence from, any of our product candidates due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- the scope, rate of progress and cost of our clinical trials and other research and development activities;
- future clinical trial results;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the cost and timing of regulatory approvals;
- the cost and timing of establishing sales, marketing and distribution capabilities;

- the cost of establishing clinical and commercial supplies of our product candidates and any products that we may develop;
- the effect of competing technological and market developments; and
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

Any failure to complete the development of our product candidates in a timely manner could have a material adverse effect on our operations, financial position and liquidity. A discussion of the risks and uncertainties associated with completing our projects on schedule, or at all, and some consequences of failing to do so, are set forth in the "Risk Factors" section of this prospectus.

Results of Operations

Comparison of Nine Months Ended September 30, 2003 and September 30, 2002

Research and Development. Research and development expenses increased 11.2% to $7.1 million for the nine months ended September 30, 2003 from $6.4 million for the nine months ended September 30, 2002. The increase was due primarily to an increase in research and development expenses for Andarine of approximately $677,000 of Phase I clinical trial expenses. Research and development expenses also increased due to an increase in clinical trial expenses for the Phase IIb clinical trial of Acapodene for the reduction in the incidence of prostate cancer in men with high grade PIN of approximately $256,000, as enrollment in the clinical trial was completed in May 2003. These increases were offset in part by a reduction in research and development spending on other product candidates of approximately $274,000.

We expect that research and development expenditures will continue to increase substantially during 2003 and subsequent years due to (1) the commencement in November 2003 of a pivotal Phase III clinical trial of Acapodene for the treatment of side effects of androgen deprivation therapy, (2) the completion of the current Phase IIb clinical trial in 2004 and planned commencement of a pivotal Phase III clinical trial of Acapodene for the reduction in the incidence of prostate cancer in men with high grade PIN and (3) the continued development of Andarine, including a Phase II clinical trial scheduled to begin in the first half of 2004. We expect to expand the scope of our drug discovery and development programs in future periods, which may result in substantial increases in research and development expenses.

General and Administrative. General and administrative expenses consist primarily of the costs of administrative personnel and related facilities and legal, accounting, human resources, information technology, public relations and other professional services. In the future, general and administrative expenses will also include the costs of sales and marketing. General and administrative costs increased 27.8% to $2.3 million for the nine months ended September 30, 2003 from $1.8 million for the nine months ended September 30, 2002. The increase was primarily due to an increase in salary and benefits expense of approximately $241,000 resulting from increases in staffing levels, annual salary increases and increased health insurance costs and an approximate $98,000 increase in professional fees. The increase in general and administrative expenses for the nine months ended September 30, 2003 included amortization of stock-based compensation expense of $83,000. In September 2003, in anticipation of this offering, we recorded deferred stock-based compensation expense of $3.5 million. The expense will be amortized over the service period, which is generally five years.

We expect that general and administrative expenditures will increase during 2003 and subsequent years due to increasing payroll, public company expenses, our initial commercialization expenses, business development costs and expanded operational infrastructure.

Interest Income. Interest income for the nine months ended September 30, 2003 was $79,000 and decreased from the corresponding period in 2002 as a result of a decrease in the average cash and cash equivalents balance and overall interest rates.

Adjustment to Preferred Stock Redemption Value. The adjustment to preferred stock redemption value consists of the amount of the change in the redemption value, which is the greater of the liquidation value or fair value, of the preferred stock. The adjustment for the nine months ended September 30, 2003 was an increase of $76.7 million, or $56.07 per share, as compared to an increase of $7.1 million, or $9.10 per share, for the nine months ended September 30, 2002. The per share redemption value was $57.66 as of December 31, 2001, $66.76 as of September 30, 2002 and December 31, 2002 and $122.83 as of September 30, 2003. The increases in the redemption value for the nine months ended September 30, 2003 and 2002 were the result of the achievement of significant milestones in clinical trials and general market conditions and, for the nine months ended September 30, 2003, was made in connection with this offering. See "Critical Accounting Policies Adjustment to Preferred Stock Redemption Value."

Comparison of Years Ended December 31, 2002 and December 31, 2001

Research and Development. Research and development expenses increased 61.6% to $9.3 million for the year ended December 31, 2002 from $5.7 million for the year ended December 31, 2001. This increase was primarily due to an increase in clinical trial expenses for the Phase IIb clinical trial of Acapodene for the reduction in the incidence of prostate cancer in men with high grade PIN of approximately $732,000 and an increase in clinical trial expenses for two Phase II clinical trials of Acapodene for the treatment of side effects of androgen deprivation therapy of approximately $807,000. In addition, preclinical toxicology studies, formulation and synthesis activities, manufacturing activities and clinical development activities for Andarine increased research and development expenses by approximately $1.7 million. Research and development expenses related to other product candidates increased by approximately $297,000 for the year ended December 31, 2002 as compared to the prior year.

General and Administrative. General and administrative expenses increased 10% to $2.4 million for the year ended December 31, 2002 from $2.2 million for the year ended December 31, 2001. This increase was primarily due to an increase in salary and benefits expense by approximately $419,000 associated with increases in staffing levels, offset by a reduction in legal fees of approximately $72,000 and travel expenses of approximately $40,000. In addition, general and administrative expenses for the year ended December 31, 2001 included interest expense on notes payable of approximately $71,000. There were no notes outstanding in the year ended December 31, 2002.

Interest Income. Interest income increased 88% to approximately $156,000 for the year ended December 31, 2002 from approximately $83,000 for the year ended December 31, 2001. The increase was principally attributable to higher average cash and cash equivalents balances during the year ended December 31, 2002 as compared to the prior year.

Adjustment to Preferred Stock Redemption Value. The adjustment for the year ended December 31, 2002 was an increase of $7.2 million, or $9.10 per share, as compared to an increase of $57,000 for the year ended December 31, 2001. The per share redemption value was $57.66 as of December 31, 2000 and 2001 and $66.76 as of December 31, 2002. The increase in the redemption value for the year ended December 31, 2002 was the result of the achievement of significant milestones in clinical trials and general market conditions.

Comparison of Years Ended December 31, 2001 and December 31, 2000

Research and Development. Research and development expenses increased 114.4% to $5.7 million for the year ended December 31, 2001 from $2.7 million for the year ended December 31, 2000. This increase was primarily due to an increase in research and development

expenses for Andarine of approximately $2.3 million, which included preclinical toxicology studies, formulation and synthesis activities, manufacturing activities and clinical development activities, and an increase in clinical trial expenses for the Phase IIb clinical trial of Acapodene for the reduction in the incidence of prostate cancer in men with high grade PIN of approximately $450,000. Research and development expenses on other product candidates increased by approximately $325,000 for the year ended December 31, 2001 compared to the prior year.

General and Administrative. General and administrative expenses increased 81.8% to $2.2 million for the year ended December 31, 2001 from $1.2 million for the year ended December 31, 2000. This increase was primarily due to an increase in salary and benefits expense by approximately $460,000 associated with increases in staffing levels, an increase of occupancy expense of approximately $105,000, an increase in legal fees of approximately $112,000, as well as increases in other general and administrative expenses. In addition, general and administrative expenses for the year ended December 31, 2001 included interest expense on notes payable of approximately $71,000. There were no notes outstanding in the year ended December 31, 2000.

Interest Income. Interest income decreased 44.7% to $83,000 for the year ended December 31, 2001 from $150,000 for the year ended December 31, 2000. The decrease was principally attributable to lower average cash and cash equivalents balances during the year ended December 31, 2001 as compared to the prior year.

Adjustment to Preferred Stock Redemption Value. The adjustment for the year ended December 31, 2001 was an increase of $57,000, as compared to an increase of $21.1 million, or $50.38 per share, for the year ended December 31, 2000. The per share redemption value was $7.28 as of December 31, 1999 and $57.66 as of December 31, 2000 and 2001. The increase in the redemption value for the year ended December 31, 2000 was the result of the achievement of significant milestones in clinical trials and general market conditions.

Liquidity and Capital Resources

We have not generated any product revenue, and we have financed our operations and internal growth almost exclusively through private placements of preferred stock. We have incurred significant losses since our inception in 1997. As of September 30, 2003, we had a deficit accumulated during the development stage of $144.9 million, of which $110.6 million related to non-cash dividends and adjustments to the preferred stock redemption value.

The following table summarizes our issuances of preferred stock through September 30, 2003.

Series	Date	Number of Shares	Approximate Gross Proceeds
			(in thousands)
A	May 1999	200,000	$ 1,455
B	July 2000	277,500	5,000
C	October 2001	260,154	15,000
D	July 2002	164,765	11,000
E	August 2003	329,536	20,000

At September 30, 2003, we had cash and cash equivalents of $19.8 million, compared to $8.9 million at December 31, 2002, $8.8 million at December 31, 2001 and $2.7 million at December 31, 2000.

Net cash used in operating activities was $10.6 million for the year ended December 31, 2002 and $9.1 million for the nine months ended September 30, 2003. The use of cash in both periods resulted primarily from funding our net losses.

Net cash used in investing activities was $313,000 for the year ended December 31, 2002 and $60,000 for the nine months ended September 30, 2003, primarily for the purchase of research and development equipment.

Net cash provided by financing activities, which resulted from the sale of preferred stock, was $11.0 million for the year ended December 31, 2002 and $20.0 million for the nine months ended September 30, 2003.

We believe that the net proceeds from this offering, our current cash resources and interest on these funds will be sufficient to meet our projected operating requirements through the end of 2005. In addition to the net proceeds of this offering, we estimate that we will need to raise additional funds in the amount of approximately $70 million, assuming that we do not enter into collaborative arrangements for any of our product candidates, in order to complete development of Acapodene and Andarine for the indications currently being tested.

Our forecast of the period of time through which our financial resources will be adequate to support our projected operating requirements is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed in the "Risk Factors" section of this prospectus. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development of our product candidates and other research and development activities, including risks and uncertainties that could impact the rate of progress of our development activities, we are unable to estimate with certainty the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials and other research and development activities. Our future funding requirements will depend on many factors, including:

- the scope, rate of progress and cost of our clinical trials and other research and development activities;
- future clinical trial results;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the cost and timing of regulatory approvals;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- the cost of establishing clinical and commercial supplies of our product candidates and any products that we may develop;
- the effect of competing technological and market developments;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and
- the extent to which we acquire or invest in businesses, products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

We do not anticipate that we will generate product revenue for a number of years. Until we can generate a sufficient amount of product revenue, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements, as well as through interest income earned on cash balances. We do not currently have any commitments for future external funding. We cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience dilution, and debt financing, if available, may involve restrictive covenants. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs or to obtain funds through collaborations with others that are on

unfavorable terms or that may require us to relinquish rights to some of our technologies or product candidates that we would otherwise seek to develop on our own.

We have no long-term debt, and, as of September 30, 2003, we had contractual obligations related to a facilities lease as follows:

	Payments Due by Period (in thousands)				
	Total	Less than 1 year	1-3 years	4-5 years	After 5 years
Contractual obligations	$404	$202	$202	$ —	$ —

Our long-term commitments under the operating lease shown above consist of payments relating to a lease for laboratory and office space at 3 North Dunlap Street, Memphis, Tennessee. This lease expires on September 30, 2005. This lease is terminable by either party on 90 days' notice. The table above excludes contingent payments under the license agreements to which we are a party.

Critical Accounting Policies

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and related disclosures. Actual results could differ from those estimates. We believe that the following critical accounting policies affect the more significant judgments and estimates used in the preparation of our financial statements.

Accounting for Income Taxes

Our income tax policy records the estimated future tax effects of temporary differences between the tax basis of assets and liabilities and amounts reported in the accompanying balance sheets, as well as operating loss and tax credit carryforwards. We have recorded a full valuation allowance to reduce our deferred tax assets as, based on available objective evidence, it is more likely than not that the deferred tax asset will not be realized. In the event that we determine that we will be able to realize our deferred tax assets in the future, an adjustment to the valuation allowance would increase net income in the period such determination is made.

Stock-Based Compensation

In accordance with Accounting Principles Board Opinion No. 25 and related interpretations, we do not recognize compensation expense when we issue stock options to employees and non-employee directors, unless the exercise price is below the fair market value of the stock on the date of grant. In anticipation of this offering, we determined that, for financial reporting purposes, the estimated value of our common stock was in excess of the exercise price for stock options issued to employees subsequent to June 30, 2003. Accordingly, we recorded deferred stock-based compensation and are amortizing the related expense over the service period, which is generally five years. Our compensation expense would have been approximately $115,000 higher and our diluted net loss per share attributable to common stockholders would have been approximately $0.01 higher in 2002 had we recognized an expense equal to the estimated fair market value of employee stock options granted through December 31, 2002 amortized over the vesting period of the options. For more information on this subject, you should refer to Note 11 to our financial statements included elsewhere in this prospectus.

Adjustment to Preferred Stock Redemption Value

We recognize changes in the redemption value of our preferred stock immediately as they occur and adjust the carrying value of the preferred stock to equal the redemption value at the end

of each reporting period. The preferred stock is subject to redemption on or after August 31, 2006 at a price per share equal to the greater of (1) the liquidation value, which includes accrued dividends or (2) the fair value calculated on an as-if converted to common stock basis. We determine fair value considering factors such as the share price of preferred stock issuances, achievement of significant milestones in the clinical trials and general market conditions. Although we consider these factors in determining fair value, this determination is, by its nature, subjective and subject to change in the future based upon a number of factors. The changes in redemption value affect the loss attributable to common stockholders, the preferred stock carrying values and the deficit accumulated during the development stage.

Quantitative and Qualitative Disclosures about Market Risk

Our exposure to market risk for changes in interest rates relates to our cash equivalents on deposit in highly liquid money market funds. The primary objective of our cash investment activities is to preserve principal while at the same time maximizing the income we receive from our invested cash without significantly increasing risk of loss. We do not use derivative financial instruments in our investment portfolio. Our cash and investments policy emphasizes liquidity and preservation of principal over other portfolio considerations.

We have operated primarily in the United States. Accordingly, we do not have any material exposure to foreign currency rate fluctuations. However, if we are successful in our efforts to commercialize Acapodene, our exposure to foreign currency rate fluctuations may increase because we are obligated to pay Orion in Euros.

Recent Accounting Pronouncements

In December 2002, the Financial Accounting Standards Board, or FASB, issued SFAS No. 148 “Accounting for Stock-Based Compensation — Transition and Disclosure,” which provides alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. SFAS No. 148 also requires that disclosures of the pro forma effect of using the fair value method of accounting for stock-based employee compensation be displayed more prominently and in a tabular format. Additionally, SFAS No. 148 requires disclosure of the pro forma effect in interim financial statements. The transition and annual disclosure requirements of SFAS No. 148 are effective for fiscal years ended after December 15, 2002. The interim disclosure requirements are effective for interim periods beginning after December 15, 2002. The adoption of this standard did not have a material impact on our financial statements.

In January 2003, the FASB issued FASB Interpretation No. 46, “Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51.” FIN 46 requires certain variable interest entities to be consolidated by the primary beneficiary of the entity if the equity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. FIN 46 is effective immediately for all new variable interest entities created or acquired after January 31, 2003. For variable interest entities created or acquired prior to February 1, 2003, the provisions of FIN 46 must be applied for the first interim or annual period ending after December 15, 2003. We did not have any ownership in any variable interest entities as of December 31, 2002. We will apply the consolidation requirement of FIN 46 in future periods if we own any interest in any variable interest entity.

In May 2003, the FASB issued SFAS No. 150, “Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity.” SFAS No. 150 requires that certain financial instruments, which under previous guidance could be accounted for as equity, be classified as liabilities in the statement of financial position. SFAS No. 150 is effective for financial instruments entered into or modified after May 31, 2003. We do not expect the adoption of SFAS No. 150 to have a significant impact on our financial statements.

BUSINESS

Overview

GTx is a biopharmaceutical company dedicated to the discovery, development and commercialization of therapeutics primarily related to the treatment of serious men's health conditions. Our drug discovery and development programs are focused on small molecules that selectively modulate the effects of estrogens and androgens, two essential classes of hormones. We currently have two product candidates that are in human clinical trials. We are developing Acapodene, our most advanced product candidate, through clinical trials for two separate indications: (1) a Phase IIb clinical trial for the reduction in the incidence of prostate cancer in men with precancerous prostate lesions and (2) a pivotal Phase III clinical trial for the treatment of serious side effects of advanced prostate cancer therapy. We are initially developing our second product candidate, Andarine, for the treatment of cachexia from various types of cancer. Cancer cachexia is a muscle wasting condition that is a potentially life-threatening complication of many cancers. Andarine is the most advanced of our internally discovered portfolio of compounds designed to modulate the effects of hormones.

Our most advanced product candidate is Acapodene, which we are developing to reduce the incidence of prostate cancer in men with precancerous prostate lesions known as high grade prostatic intraepithelial neoplasia, or high grade PIN. We have licensed from Orion Corporation the right to develop, market and distribute toremifene, the active pharmaceutical ingredient in Acapodene, worldwide in the field of the prevention and treatment of prostate cancer and the treatment of the principal side effects of prostate cancer therapies. Scientific evidence has established that men who have high grade PIN are at high risk of developing prostate cancer. Currently, there is no therapy for the treatment of high grade PIN. We are conducting a Phase IIb clinical trial in which we have enrolled 515 patients to determine the efficacy and safety of Acapodene in reducing the incidence of prostate cancer in men with high grade PIN. The last patient is scheduled to complete this trial in May 2004, with final results expected in the third quarter of 2004.

We are also developing Acapodene for the treatment of side effects of androgen deprivation therapy, which reduces blood levels of testosterone, the growth factor for prostate cancer. Androgen deprivation therapy is the standard medical treatment for men who have advanced, recurrent or metastatic prostate cancer. Androgen deprivation therapy has serious side effects, including: severe bone loss, or osteoporosis, leading to skeletal fractures; hot flashes; and breast pain and enlargement, or gynecomastia. There are no drugs approved by the FDA for the treatment of these side effects of androgen deprivation therapy. We commenced a pivotal Phase III clinical trial of Acapodene for this indication in November 2003.

Our second product candidate is Andarine, which we are initially developing for the treatment of cachexia from various types of cancer, a potentially life-threatening complication of many cancers. There are no drugs that have been approved by the FDA for the treatment of cancer cachexia. We plan to commence a placebo-controlled, dose-finding Phase II clinical trial for the treatment of cachexia from non-small cell lung cancer in the first half of 2004.

We have multiple product candidates that we are evaluating in preclinical and toxicology studies to support the possible commencement of clinical trials. Our current preclinical product candidates focus on the treatment of major indications in men's health, including benign prostatic hyperplasia, or BPH, a benign prostate enlargement that results in obstruction of the urinary tract; osteoporosis; testosterone deficiency in aging men, or andropause; and prostate cancer.

We believe that our drug discovery capabilities position us well to sustain our clinical pipeline through the design and development of nonsteroidal small molecule drugs that modulate the effects of hormones.

Scientific Background on Estrogens and Androgens

Both estrogens and androgens are hormones that play critical roles in men's health, regulating not only the reproductive system, but also having important effects on the muscular, skeletal, cardiovascular and central nervous systems. In order for the body to function properly, a balance must exist between estrogens and androgens.

Estrogens prevent bone loss and osteoporosis and reduce the risk of skeletal fractures. In aging men, there is a gradual increase in estrogen levels in the blood, which may promote BPH, initiate prostate cancer and cause gynecomastia.

Testosterone is the predominant androgen in men. Testosterone is important for mental well-being and for masculine physical characteristics, such as muscle size and strength, bone strength and male pattern hair growth and loss. Testosterone also stimulates sebaceous glands, which can cause acne. Male reproductive health is also dependent on testosterone to maintain sexual interest, fertility, erectile function and normal prostate growth. In aging men, there is a gradual decrease in testosterone levels, leading to loss of muscle mass and strength, reduced bone mineralization resulting in osteoporosis and bone fractures, erectile dysfunction, decreased sexual interest, depression and mood changes.

In order for estrogens and androgens to perform their physiologic functions, they must interact with and activate their hormone receptors. Hormone receptors are sites located in tissues where hormones bind. Once a hormone binds with its receptor, a series of cellular events is activated, resulting in estrogenic or androgenic tissue effects.

Pharmaceuticals that target hormone receptors for estrogens or androgens have been prescribed for over 50 years. The drugs that have been used to stimulate androgen receptors are natural or synthetic hormones, known as steroids. Steroids activate hormone receptors in all tissue types in a non-selective manner. The absence of selectivity may result in unwanted side effects, such as the potential stimulation of latent prostate cancer, aggravation of existing BPH, acne, hair growth and gynecomastia. Testosterone products also have many pharmacologic limitations, such as an inability to administer them orally. Instead, they must be given by intramuscular injections, patches or gels. The delivery methods of testosterone products are inconvenient for patients and in some cases result in inconsistent levels of testosterone in the blood.

There are also classes of small molecules that are not steroids, but which bind to hormone receptors. These small molecules may either stimulate or block hormone receptors depending on the type of tissue in which the receptor is found. A drug that can either block or stimulate the same hormone receptor is called a receptor modulator. A drug that can either block or stimulate a receptor in a tissue-selective manner may be able to mimic the beneficial, and at the same time minimize the unwanted, effects of natural or synthetic hormones.

A selective estrogen receptor modulator, or SERM, is a small molecule that binds to and selectively modulates estrogen receptors. SERMs have the ability to either stimulate or block estrogen's activity in different tissue types. SERMs have been shown to stimulate estrogen's beneficial action in bone and block estrogen's harmful activity in the breast. In addition, we believe that SERMs have the potential to block estrogen's harmful activity in the prostate. Examples of SERMs currently on the market include tamoxifen, which has been prescribed to treat female and male breast cancer, and raloxifene, which is used to prevent and treat female post-menopausal osteoporosis.

Similarly, a selective androgen receptor modulator, or SARM, is a small molecule that binds to and selectively modulates androgen receptors. In men, we believe that SARMs will be able to stimulate testosterone's beneficial action in bone, muscle and brain, while blocking testosterone's harmful action in the prostate and skin. We further believe that SARMs will have the ability to either cross or not cross into the central nervous system and to selectively modulate receptors depending on tissue type. As a result, although no SARMs have been commercialized to date, we believe that

SARMs could be developed to treat a range of medical conditions and physiological functions, including: (1) low testosterone conditions, such as hypogonadism and andropause; (2) muscle wasting conditions of chronic diseases, such as cancer, AIDS, end stage renal disease, or ESRD, and neurodegenerative disorders, as well as muscle wasting from trauma and burns; (3) disorders of the central nervous system, such as low libido, depression and other mood disorders; (4) male reproductive functions, such as infertility, male contraception and erectile dysfunction; (5) prostate disorders, such as high grade PIN, BPH and prostate cancer; and (6) other conditions, such as anemia, hair loss and male osteoporosis.

Product Candidates

The following table summarizes key information about our product candidates:

Program	Product Candidate/Indication	Development Phase	Status
SERM	**Acapodene** - Reduction in the incidence of prostate cancer in men with high grade PIN	Phase IIb clinical trial	Enrollment complete; last patient scheduled to complete trial in May 2004; final results expected in the third quarter of 2004
	- Side effects of androgen deprivation therapy	Pivotal Phase III clinical trial	Pivotal Phase III clinical trial initiated in November 2003
SARM	**Andarine** - Cachexia from various types of cancer	Three Phase I clinical trials completed	Phase II clinical trials for treatment of cachexia from non- small cell lung cancer scheduled to begin in the first half of 2004
	Prostarine - BPH	Preclinical	Preclinical studies to support IND in progress
	Ostarine - Male osteoporosis and andropause	Preclinical	Preclinical studies to support IND in progress
	Andromustine - Prostate cancer that is not responsive to androgen deprivation therapy	Preclinical	Preclinical studies to support IND in progress

Acapodene

Our most advanced product candidate, Acapodene, is a selective estrogen receptor modulator, or SERM. Acapodene is taken orally and is being developed for a once-a-day dosing schedule. We have licensed from Orion the right to develop, market and distribute toremifene, the active pharmaceutical ingredient in Acapodene, worldwide in the field of the prevention and treatment of prostate cancer and the prevention and treatment of osteoporosis, hot flashes and gynecomastia as side effects of androgen deprivation therapy for prostate cancer. Our license rights are exclusive in North America and Japan. Toremifene is an FDA-approved SERM product for the treatment of advanced breast cancer in post-menopausal women that has been marketed in the United States as Fareston by Shire Pharmaceuticals Group since 1999 and by other companies in other countries for over 10 years. We licensed rights to toremifene based on our belief that a SERM potentially could reduce the incidence of prostate cancer in men with high grade PIN and the established safety and

efficacy record of toremifene in the treatment of post-menopausal women with advanced breast cancer. Orion manufactures commercial quantities of toremifene for Shire and is supplying us with Acapodene under a supply agreement.

The two indications for which we are developing Acapodene target different patient populations: (1) patients who have been diagnosed with high grade PIN, but do not yet have prostate cancer; and (2) patients who have been diagnosed with advanced, recurrent or metastatic prostate cancer and are being treated with androgen deprivation therapy.

Acapodene for the Reduction in the Incidence of Prostate Cancer in Men with High Grade PIN

Scientific Overview. Patients who have an abnormal result from a serum PSA test, a prostate cancer blood test that is commonly administered to men as part of physical examinations, or an abnormal digital rectal examination undergo a prostate biopsy to determine whether they have prostate cancer. Precancerous prostate lesions known as high grade prostatic intraepithelial neoplasia, or high grade PIN, rather than prostate cancer, are detected in approximately 10% of the patients who undergo prostate biopsies. Over the last 17 years, scientific evidence has established that men who have high grade PIN are at high risk of developing prostate cancer. Scientific studies have shown that prostate cancer is found in approximately 30% to 71% of high grade PIN patients within one year of a high grade PIN diagnosis and in 45% to 80% of high grade PIN patients within five years of a high grade PIN diagnosis. Because of this correlation between high grade PIN and prostate cancer, we believe that treating high grade PIN may reduce the incidence of prostate cancer.

Estrogens play an important role in the initiation of prostate cancer. One way estrogens may influence the initiation of prostate cancer is by stimulating high grade PIN and causing it to progress into prostate cancer. Estrogen receptors are found in the prostate and in high grade PIN lesions. In animal models of prostate cancer, blocking estrogens' action has been shown to regress high grade PIN and reduce the incidence of prostate cancer. Because Acapodene is designed to directly block estrogen receptors, we believe that it has the potential to reduce the incidence of prostate cancer in men with high grade PIN.

Potential Market. Prostate cancer is one of the most commonly diagnosed cancers and the second leading cause of cancer-related deaths in men in the United States. There are 400,000 new cases of prostate cancer diagnosed and 239,000 prostate cancer deaths annually worldwide. In the United States, there are over 115,000 new cases of high grade PIN diagnosed each year, and an estimated 9.4 million men unknowingly harbor high grade PIN.

Because there is currently no therapy for the treatment of high grade PIN, patients who are diagnosed with high grade PIN are subjected to repeat biopsies immediately after diagnosis and every three to six months thereafter in order to detect the progression of high grade PIN into prostate cancer. Prostate biopsies are performed through an ultrasound probe placed in the rectum. Hollow needles are then inserted into the prostate to obtain a core of tissue. Complications from this procedure include bleeding, pain, prostate infection and life-threatening blood infection. Because the prostate biopsy technique randomly samples the prostate gland with a relatively thin needle, both prostate cancer and high grade PIN may be missed by the biopsy. Patients with high grade PIN are exposed to the potential complications and the discomfort of invasive, repeat prostate biopsies and suffer the mental anguish of fearing that a diagnosis of prostate cancer may be imminent.

Clinical Trials. In 2000, we completed a Phase IIa clinical trial of Acapodene in 21 patients with high grade PIN. The trial was conducted at the University of Tennessee. Phase IIa clinical trials typically evaluate efficacy and safety and determine the optimal dosing regimen. The primary endpoint of the trial was the presence of high grade PIN. Each participant in the trial received a daily oral dose of Acapodene for four months. The trial was open label and not placebo-controlled, and we did not perform long-term follow-up on the patients in the trial. Each patient underwent a prostate biopsy to detect high grade PIN at the beginning and end of the four-month trial period. Results

showed that 72% of the trial participants had no detectable high grade PIN in the prostate biopsy performed at the end of the trial period. Based on studies reported in scientific literature, only approximately 18% of patients with untreated high grade PIN would be expected to have no high grade PIN detected in their repeat biopsy. There were no serious adverse events attributable to Acapodene in this trial.

Based on the results from our Phase IIa clinical trial, in 2001, we began a placebo-controlled, randomized Phase IIb clinical trial in men with recently diagnosed high grade PIN to determine the efficacy and safety of a daily dose of Acapodene at three dose levels for 12 months. The principal indication of efficacy that we are seeking to verify, or primary endpoint, of the trial is the incidence of prostate cancer, and the ancillary indication of efficacy that we are seeking to verify, or secondary endpoint, of the trial is the presence of high grade PIN. Study patients undergo a series of eight core prostate biopsies at six months and again at 12 months. In order to minimize the inclusion of patients who have, at the time of their enrollment in the trial, prostate cancer that was missed in their initial biopsy, patients in whom prostate cancer is detected six months after enrollment are removed from the trial. Therefore, the prostate cancer incidence will be determined based only on patients who receive Acapodene or the placebo for the entire 12 months. The trial is being conducted at 64 clinical sites across the United States and is fully enrolled with approximately 515 patients.

A planned interim analysis of the first 120 patients in this clinical trial who underwent prostate biopsies at six and again at 12 months was conducted in April 2003. Results of the interim analysis showed that patients who received Acapodene had a 10% to 17% incidence of prostate cancer 12 months after being diagnosed with high grade PIN, depending on the dose of Acapodene, compared to a 23% incidence in the placebo group. This represents an approximately 26% to 57% reduction in prostate cancer incidence in those patients who received Acapodene compared to the placebo group.

To date, four serious adverse events, including one death, have been reported in the 515 patients participating in this Phase IIb clinical trial. Because the safety results are blinded, we do not know whether these events were experienced by participants receiving Acapodene or the placebo. An autopsy was not performed on the 71-year old deceased patient. We have not observed any trend relating these four serious adverse events to Acapodene.

The last patient is scheduled to complete this Phase IIb clinical trial in May 2004, with final results expected in the third quarter of 2004. We believe that this Phase IIb clinical trial of Acapodene together with a single pivotal Phase III clinical trial will be sufficient to support an application with the FDA for marketing approval of Acapodene for this indication. We are evaluating the protocol of this pivotal Phase III trial and anticipate initiating the trial in the second half of 2004.

Acapodene for the Treatment of Side Effects of Androgen Deprivation Therapy

Scientific Overview. The standard medical treatment for patients who have advanced, recurrent or metastatic prostate cancer is androgen deprivation therapy, which reduces blood levels of testosterone, the growth factor for prostate cancer. Androgen deprivation therapy is accomplished either surgically by removal of the testes, or chemically by treatment with luteinizing hormone releasing hormone agonists, known as LHRH agonists. LHRH agonists work by shutting off luteinizing hormone secretion by the pituitary gland, which stops testosterone production by the testes. Examples of commercially marketed LHRH agonists are Lupron and Zoladex.

Side effects associated with LHRH agonists include bone loss leading to osteoporosis and skeletal fractures, muscle weakness, hot flashes, gynecomastia, depression, loss of libido and erectile dysfunction. In particular, of the patients treated with LHRH agonists, approximately 60% experience osteoporosis, 22% develop bone fractures, 55% to 80% experience hot flashes and 25% experience gynecomastia. Bone loss leading to osteoporosis and skeletal fractures is a significant clinical problem because prostate cancer patients who develop skeletal fractures have shorter survival rates compared to patients who do not develop skeletal fractures, with the median survival

time shortened by 39 months. Hot flashes occur because of the lack of testosterone in the brain. Hot flashes experienced by prostate cancer patients taking LHRH agonists tend to be severe, frequent and protracted.

Based on the results of our Phase II clinical trials and our preclinical testing of Acapodene, as well as information known about toremifene, we believe that Acapodene has estrogenic activity both in bone, which may prevent osteoporosis, and in the brain, which may reduce hot flashes. In addition, based on the same data and information, we believe that Acapodene can block estrogens' action in the male breast, which may prevent and treat gynecomastia. As a consequence, we believe that Acapodene has the potential to treat three serious side effects of LHRH agonists: osteoporosis, hot flashes and gynecomastia.

Potential Market. In the United States, more than 675,000 men are currently being treated with androgen deprivation therapy for advanced, recurrent or metastatic prostate cancer, with over 120,000 new patients started on this therapy each year. An increasing number of prostate cancer patients are being treated by androgen deprivation with LHRH agonists earlier than in the past because of two main factors. First, medical studies have shown that early androgen deprivation therapy prolongs the survival of prostate cancer patients. Second, the serum PSA test is detecting disease earlier than in the past. However, the effect of this trend is that the side effects of androgen deprivation therapy now contribute significantly to the morbidity, and in some cases the mortality, of men with prostate cancer. Physicians are prescribing some drugs on an off-label basis to help ameliorate some of the individual side effects of androgen deprivation therapy. These drugs include bisphosphonates for osteoporosis, Megace and antidepressants for hot flashes and tamoxifen for gynecomastia. Radiation is also used to treat gynecomastia. However, no single therapy is available to treat multiple side effects of androgen deprivation therapy.

Clinical Trials. We have completed two Phase II clinical trials of Acapodene for the treatment of osteoporosis and hot flashes in patients with advanced, recurrent or metastatic prostate cancer. The first Phase II trial was conducted at five clinical sites across the United States and treated 43 patients with advanced, recurrent or metastatic prostate cancer shortly after initiation of treatment with LHRH agonists. The second of these trials was conducted at three clinical sites across the United States and treated 46 patients with advanced, recurrent or metastatic prostate cancer who had been receiving LHRH agonists for more than 12 months. In each trial, participants were randomized to either a daily oral dose of Acapodene or a placebo for six months. The primary endpoint of both trials was bone mineral density. The secondary endpoint of both trials was the incidence of hot flashes. We measured bone mineral density and hot flash symptoms at entry into each of the clinical trials and at six months. We did not evaluate the effects of Acapodene on gynecomastia in either of these trials. There were no serious adverse events attributable to Acapodene in either of our Phase II clinical trials.

In our first Phase II clinical trial, which evaluated 43 patients shortly after initiation of treatment with LHRH agonists, patients who received Acapodene at the highest tested dose on average experienced an approximately 2% decrease in lumbar vertebral spine bone mineral density at six months, while the patients who received the placebo on average experienced an approximately 4% decrease in lumbar vertebral spine bone mineral density at six months. At the lower tested doses, Acapodene, as compared to the placebo, did not have a meaningfully different effect on lumbar vertebral spine bone mineral density. There was no significant difference between Acapodene and the placebo in the incidence of hot flashes at any tested dose.

In our second Phase II clinical trial, which evaluated 46 patients who had been receiving LHRH agonists for more than 12 months, patients who received Acapodene at the highest tested dose on average experienced a 3.5% increase in lumbar vertebral spine bone mineral density, while the patients who received the placebo on average experienced a 0.5% decrease in lumbar vertebral spine bone mineral density. Only 12.5% of the patients in this trial who received Acapodene at the highest tested dose, compared to 50% of the patients who received the placebo, reported

experiencing an increase in the frequency of hot flashes during the clinical trial. The magnitude of the bone changes seen in treated patients in this Phase II clinical trial were similar to those reported for each of raloxifene and bisphosphonates in post-menopausal women with osteoporosis and bisphosphonates being prescribed off-label to men with prostate cancer. However, bisphosphonates have not been shown to have any effect on hot flashes. At the lower tested doses, Acapodene, as compared to the placebo, did not have a meaningfully different effect on lumbar vertebral spine bone mineral density or frequency of hot flashes.

In November 2003, we initiated a pivotal Phase III clinical trial of Acapodene in patients undergoing androgen deprivation therapy for advanced, recurrent or metastatic prostate cancer. We designed this pivotal Phase III clinical trial principally based on the results of our Phase II clinical trial that evaluated patients who had been receiving LHRH agonists for more than 12 months. The primary endpoint of the trial is the incidence of skeletal fractures. The secondary endpoints of the trial include the measurement of bone loss and the incidence of hot flashes and gynecomastia. We expect that over 60 clinical sites across the United States will participate in this study. Approximately 1,200 patients with advanced, recurrent or metastatic prostate cancer who have been receiving androgen deprivation therapy for at least 24 months and who have significant existing bone loss, or osteopenia, will be randomized to receive either a placebo or a daily dose of Acapodene for 24 months. We are planning an interim analysis of the measurement of bone loss in the first 200 patients in this clinical trial in the first half of 2005.

Andarine

Our second product candidate, Andarine, a selective androgen receptor modulator, or SARM, is the most advanced of our internally discovered portfolio of compounds designed to target hormone receptors. Andarine is taken orally and is being developed for a once-a-day dosing schedule. We believe that Andarine has the potential to treat testosterone deficiency in aging men, or andropause, and related diseases, including male osteoporosis and muscle wasting. Our strategy is to develop Andarine initially for the treatment of a cachexia from various types of cancer. We selected this indication because it represents a potentially large market and, we believe, has a relatively well-defined clinical and regulatory process. Depending on the results of our initial development efforts, we may also develop Andarine for other andropause-related conditions. For cachexia from various types of cancer, we are developing Andarine for the treatment of both men and women.

Andarine for the Treatment of Cancer Cachexia

Scientific Overview. Cachexia is defined as the loss of over 5% of a patient's original body weight. Most of the weight loss attributable to cachexia comes from the loss of lean body weight, resulting from muscle wasting. Cancer causes the body to go into a starvation-like state that causes cachexia. Muscle wasting weight loss from cancer, or cancer cachexia, is diagnosed in approximately one-third of newly-diagnosed cancer patients and accounts for approximately 20% of cancer deaths. Weight loss is one of the most important indicators of how long a cancer patient will live since the survival of a patient with cancer is greatly impacted by the degree and rate of muscle wasting. A cancer patient's response to cancer chemotherapy is diminished by weight loss. Cachexia results in weakness, fatigue and immobility. A greater lean body weight may increase activity levels, quality of life, response to chemotherapy and, ultimately, survival time.

Testosterone increases lean body weight in both men and women. One of the causes of cancer cachexia may be reduced levels of testosterone. Testosterone therapy, however, is not used for the treatment of cancer cachexia for two reasons. First, the delivery methods for testosterone are inconvenient for patients and in some cases result in inconsistent levels of testosterone in the blood. Testosterone cannot be given orally, but rather is given only by intramuscular injections, patches or gels. Second, testosterone has a number of undesirable side effects, such as the potential stimulation of latent prostate cancer, aggravation of existing BPH and gynecomastia in men and masculinizing effects in women such as acne and facial hair.

We believe that Andarine is similar to testosterone in activating androgen receptors in muscle, thereby promoting lean body weight, but that it does not stimulate sebaceous glands, the cause of hair growth and acne, or the prostate, which exacerbates BPH. In addition, Andarine is taken orally, which makes it convenient to administer.

Potential Market. There are approximately 1.3 million patients diagnosed with cancer each year in the United States. Cancer cachexia afflicts approximately one-third of newly-diagnosed cancer patients. Over 30 clinical trials of supplemental nutritional support alone have reported little or no benefit in counteracting cachexia in cancer patients receiving chemotherapy or radiation. There are no drugs that have been approved by the FDA for the treatment of cancer cachexia. Although there are two commercially available drugs, both steroids, that are being prescribed off-label for the treatment of some types of cancer cachexia, chronic use of these drugs may result in bleeding liver cysts and liver cell tumors.

Clinical Trials. We have completed three Phase I clinical trials of Andarine in a total of 86 healthy male and female volunteers. We tested Andarine for safety and tolerance in single and multiple doses. Results from our Phase I trials support once-a-day oral dosing, and no serious adverse events were observed at any single or multiple dose tested. We observed early indications in the multiple-dose Phase I clinical trial in men that Andarine promoted growth activity, as measured by levels of a growth factor in the blood known as IGF-1, without affecting the sebaceous glands. We believe that these observations support the potential ability of Andarine to selectively modulate androgen receptors in a tissue-specific manner.

We plan to commence a placebo-controlled dose-finding Phase II clinical trial of Andarine in the first half of 2004 for the treatment of cachexia from non-small cell lung cancer. Cancer cachexia occurs frequently with lung cancer, and the ensuing loss of lean body weight cannot be attributed solely to reduced dietary intake. There are a large number of patients, both male and female, with advanced lung cancer and cancer cachexia, and lung cancer is representative of several other types of cancer. As a result, we selected this patient population to determine the safety and efficacy of Andarine in the treatment of cachexia from non-small cell lung cancer. In our planned Phase II clinical trial, we anticipate that approximately 150 patients who have non-small cell lung cancer and cancer cachexia will be randomized to receive either a daily oral dose of Andarine or a placebo for 12 weeks. The primary endpoint of the trial will be muscle performance, and the secondary endpoints will be lean body weight and other body composition measurements.

Prostarine and Ostarine

We are also developing other SARM product candidates, including:

- Prostarine for the treatment of benign prostatic hyperplasia, or BPH, a benign prostate enlargement that results in obstruction of the urinary tract; and
- Ostarine for the treatment of osteoporosis and andropause.

In animal models, Prostarine shrinks the prostate gland, and Ostarine prevents bone loss and builds bone and muscle. We are conducting preclinical and toxicology studies to support the commencement of clinical trials.

Andromustine

Patients who have advanced, recurrent or metastatic prostate cancer are initially treated with androgen deprivation therapy. Since prostate cancer is dependent on androgens, including testosterone, to grow, the reduction in testosterone forces prostate cancer into remission. Unfortunately, with time, prostate cancer circumvents the need for testosterone and comes out of remission. Once prostate cancer no longer responds to androgen deprivation, it is referred to as hormone refractory.

Building on the technology of our selective androgen receptor modulator, or SARM, discovery program, we have designed and are developing a small molecule, Andromustine, that is designed to specifically target androgen receptors and kill cancer cells. The Andromustine molecule has two components: (1) the SARM part of the molecule, which is designed to bind to the androgen receptor located on prostate cancer cells; and (2) the chemotherapeutic part of the molecule, which is designed to damage the DNA of prostate cancer cells. In cell culture, Andromustine selectively kills human metastatic prostate cancer cells. Because advanced prostate cancers, including hormone refractory prostate cancer, have more androgen receptors than the normal prostate, Andromustine is designed to bind to and selectively kill advanced prostate cancer cells.

There are over 675,000 men in the United States being treated with LHRH agonists and other hormonal therapies for prostate cancer. Hormone refractory prostate cancer will eventually occur in a majority of these patients. There is currently no effective chemotherapy for hormone refractory prostate cancer. Once a patient develops hormone refractory prostate cancer, his prognosis is poor.

We are in the process of conducting preclinical and animal toxicology studies to support the commencement of clinical trials of Andromustine.

Drug Discovery

Steroid hormone therapies, which include estrogen and testosterone therapies, have been used to treat humans for many years. Steroid hormones cannot, by their nature, have selective effects in various tissues. As a result, they have unintended side effects, which limit their clinical value.

SERM drugs, such as tamoxifen and raloxifene, have achieved commercial success in treating women as nonsteroidal small molecules that modulate hormone receptors in a tissue selective way and minimize some of the side effects of natural hormones. We believe that the success of SERMs indicates that it is possible to design and develop classes of nonsteroidal small molecule drugs to modulate hormone receptors in addition to estrogen receptors.

We believe that our drug discovery expertise positions us well to sustain our clinical pipeline through the design and development of nonsteroidal small molecule drugs that modulate hormone receptors. Our 19 in-house medicinal chemists and scientists provide us with significant discovery and development expertise. Using our capabilities in hormone receptor biology and medicinal chemistry, we are able to target many hormone receptors and generate compounds that are designed to address the shortcomings of natural hormone therapies. We augment our internal drug discovery capabilities through agreements with two universities that provide for our close collaboration with an additional 15 scientists, whose research is largely dedicated to our drug discovery program.

We design and synthesize new compounds based on computer, or *in silico,* models of a hormone receptor's binding sites. We continually modify and improve these *in silico* models to reflect our study of the activity of new compounds in the laboratory, in which we determine the link between chemical structures and biological activity, or structure-activity relationships.

We also have significant medicinal scale-up capabilities, which facilitate our rapid synthesis and evaluation of new compounds. Throughout our discovery process, we build diversity into our chemistry structures in order to improve our likelihood of success in developing novel compounds that have the potential to treat multiple indications. Through this approach, we have generated a clinical product candidate for the androgen receptor, Andarine, as well as additional preclinical compounds of the SARM class and other structurally diverse classes.

Our Strategy

Our objective is to develop and commercialize small molecule drugs to target serious men's health conditions. Key elements of our strategy to achieve this objective are to:

Maximize Commercial Potential of Acapodene

Obtain Regulatory Approval of Acapodene. We are focused on completing clinical trials, obtaining regulatory approval and preparing for the potential commercial launch of Acapodene.

Retain Commercial Rights to Acapodene and Establish Sales and Marketing Infrastructure. We intend to retain all commercial rights to Acapodene in the United States. We believe that we can effectively market Acapodene to the target physician audience of urologists and medical oncologists, principally urological oncologists, in the United States through a small, specialty sales force that we plan to build. We plan to collaborate with pharmaceutical companies to commercialize, market and sell Acapodene in Europe and Asia.

Extend Life Cycle of Acapodene. We intend to reformulate Acapodene with the goals of seeking longer intellectual property protection in the European and Asian markets and extending its life cycle in the United States.

Develop Noninvasive Diagnostic Test for High Grade PIN. We plan to collaborate with a large diagnostics company to develop a noninvasive, accurate blood test to detect high grade PIN. We believe that men would be more willing to be tested for high grade PIN if the diagnostic test were less invasive than a prostate biopsy. Given the large number of patients with undiagnosed high grade PIN, we believe that the development of a noninvasive test will increase the detection of high grade PIN and thereby expand the already large potential market for Acapodene.

Maximize Commercial Potential of Andarine

Pursue Clinical Development of Andarine. We intend to continue to aggressively pursue the clinical development of Andarine for the treatment of cachexia from various types of cancer. In addition, we may develop Andarine for the treatment of other causes of cachexia, including ESRD, which represents a large potential market with unmet medical needs. Andarine could also potentially be developed and commercialized for other men's health indications.

Strategically Seek Collaborators. Because it would require a large sales force to address the cancer cachexia market and because of the risks and costs of developing Andarine for cachexia from various types of cancer, we plan to seek one or more collaborators for the development and commercialization of Andarine for cancer cachexia resulting from all types of cancer other than urological cancers. We also plan to seek a collaborator for potential Andarine indications requiring a large sales force. For Andarine indications for which the target physician market is likely to overlap with that of Acapodene, including cancer cachexia resulting from urological cancers and indications related to andropause, our plan is to market and sell Andarine ourselves or to co-promote it with a collaborator in the United States, and, in the rest of the world, to seek a collaborator.

Build upon Our SARM and other Drug Discovery Capabilities to Sustain Our Small Molecule Product Candidate Pipeline

We intend to develop additional SARMs and other small molecule products to treat diseases that affect large numbers of patients and that are underserved by available alternatives. While our drug discovery efforts to date have focused on SERM and SARM technologies, we believe that we have the capability to discover additional drug candidates that target other hormone receptors. We plan to further strengthen our drug discovery, medicinal chemistry and preclinical pharmacology groups to sustain our pipeline of nonsteroidal small molecules designed to modulate a range of hormone receptors.

Licenses and Collaborative Relationships

We have established and intend to continue to pursue licenses from and collaborative relationships with pharmaceutical companies and academic institutions.

Orion Corporation

Under a license and supply agreement with Orion, we have a license from Orion to develop, use, market and distribute toremifene, the active pharmaceutical ingredient of Acapodene, under Orion's patents covering the composition of matter of toremifene. This license is limited to the fields of the prevention and treatment of prostate cancer and the prevention and treatment of osteoporosis, hot flashes and gynecomastia as side effects of androgen deprivation therapy in the treatment of prostate cancer. Our license rights are exclusive in North America and Japan. Without this license, we would not have the right to commercialize Acapodene for any indication prior to the expiration of the licensed patents. We have a right of first negotiation on a country-by-country basis to negotiate further agreements with Orion for the development, sale and distribution of specified products containing toremifene that are therapeutic equivalents of Acapodene for other indications excluding breast cancer.

Under the terms of the agreement, we paid Orion an initial license fee and have agreed to pay Orion a royalty based on net sales of Acapodene and a share of any consideration we receive for sublicensing our rights under the agreement. We also are required to pay Orion up to $1.0 million if we are acquired before we receive marketing approval for the use of Acapodene in the licensed field.

The agreement requires us to achieve specified minimum sales requirements of Acapodene in the United States or pay Orion royalties on the shortfall amount. Orion may require us to modify our final Acapodene development plans for specified major markets if such plans could adversely affect Fareston or toremifene outside of the licensed field. We have granted Orion a right of first negotiation for Scandinavian marketing rights to Acapodene and to European rights if we do not have a sublicensee in the United States to whom we have granted European marketing rights. We have also agreed to negotiate with Orion for a limited period of time the terms of an agreement granting Orion the exclusive right to distribute Acapodene in Japan, South Korea, China and Taiwan for use in the licensed field. We and our affiliates are prohibited from selling a product that competes with toremifene in the licensed field in major countries located outside the European Union during the term of the agreement and in major countries in the European Union through October 2006.

The term of our license from Orion continues on a country-by-country basis until the date of expiration or invalidation of the last to expire or be invalidated of patents and patent applications relating to Acapodene that we control. Each party has the right to terminate the license under specified circumstances, including in the event of a material breach by the other party that is not cured, bankruptcy of the other party or if the other party is acquired by a direct competitor with respect to toremifene. We also have the right to terminate the agreement in any country if we decide to discontinue the applications or withdraw the applications for regulatory approval of Acapodene due to adverse reactions or safety issues.

The license includes a right for us to use toremifene for research required to obtain regulatory approval. The results of such research are jointly owned by us and Orion, and may be exploited by Orion outside our licensed field.

University of Tennessee Research Foundation

We have exclusive, worldwide licenses from the University of Tennessee Research Foundation under its method of use patents relating to toremifene for the reduction in the incidence of prostate cancer in men with high grade PIN and its composition of matter and method of use patents and patent applications relating to Andarine to market, distribute and sell licensed products. We also have exclusive, worldwide licenses from the University of Tennessee Research Foundation under its

composition of matter and method of use patent applications relating to Prostarine and Ostarine to market, distribute and sell licensed products. Without these licenses, we would not have the right to commercialize these product candidates for any indication prior to the expiration of the licensed patents.

Under the terms of these license agreements, we have agreed to pay the University of Tennessee Research Foundation a royalty based on net sales of licensed products and sublicense income. We are also obligated to pay the University of Tennessee Research Foundation an annual license maintenance fee under each license agreement. The term of each of the license agreements is the longer of 20 years or the term of any licensed patent having a valid claim covering the licensed technology. After the term of each license agreement expires, we will have a perpetual, royalty-free license to the technology licensed under that agreement. The University of Tennessee Research Foundation has the right to terminate each of the agreements under specified circumstances, including in the event that we breach the agreement and do not cure the breach or in the case of our bankruptcy. We are obligated to use commercially reasonable efforts to develop and commercialize products based on the licensed patents and patent applications.

Pursuant to the license agreements, we assign to the University of Tennessee Research Foundation specified patentable inventions arising out of or related to the licensed patents. Upon our request, the University of Tennessee Research Foundation will amend the license agreements to confirm our exclusive licenses to such inventions assigned by us to the University of Tennessee Research Foundation.

National Cancer Institute

We are providing the National Cancer Institute with Acapodene for their use in an independent Phase II clinical trial of Acapodene at the University of Pittsburgh. The objective of the trial is to assess the biological effects of Acapodene on the prostate gland. In this trial, 80 patients who have been diagnosed with prostate cancer will be given a single oral daily dose of Acapodene for 12 weeks prior to surgical removal of their cancerous prostate.

Manufacturing

We do not currently own or operate manufacturing facilities for the production of clinical or commercial quantities of Acapodene or Andarine. We currently rely and expect to continue to rely on third parties for the manufacture of our product candidates or products that we may develop.

We purchase Acapodene from Orion under a license and supply agreement providing for clinical and commercial supply of Acapodene. Orion has agreed to supply us with, and we have agreed to purchase from Orion, our worldwide requirements of Acapodene in finished tablet form at specified transfer prices. Orion's manufacturing facility also produces commercial quantities of toremifene tablets for Fareston and complies with the FDA's current Good Manufacturing Practice regulations. The methods used to manufacture Acapodene are similar to those used to produce the 60 mg toremifene tablet that has been approved by the FDA for the treatment of advanced breast cancer and is marketed in the United States as Fareston. The raw materials necessary to manufacture toremifene are readily available, but Orion is our only supplier of toremifene tablets.

Orion may terminate its obligation to supply us with toremifene if:

- marketing approval for Acapodene for use in the licensed field is not granted in the United States by December 31, 2007 or upon the expiration or invalidation of the last valid claim of the licensed Orion patent rights in the United States; or

- subject to a prior notice requirement, if Orion permanently ceases the manufacture of toremifene.

Our license and supply agreement with Orion does not provide us with the current right to manufacture toremifene. In addition, under the terms of our agreement with Orion, we have agreed to purchase our requirements of toremifene tablets from Orion during the term of the agreement, which extends beyond the term of Orion's patents with respect to the composition of matter of toremifene. There are a number of circumstances in which Orion is required to grant manufacturing rights to us, including following termination of its supply obligation as set forth above, failure by Orion to supply product for 90 days or to supply product in dosages or formulations other than the dosages and formulations specified in the agreement or termination of the agreement by us following a breach by Orion. However, in the event that Orion terminates the license agreement as a result of a material breach of the agreement by us that is not cured, our bankruptcy or the acquisition of us by a direct competitor of Orion with respect to toremifene, we would not have the right to manufacture Acapodene until Orion's patents with respect to the composition of matter of toremifene expire.

We have entered into an agreement with ChemSyn Laboratories, a department of EaglePicher Technologies, LLC, under which ChemSyn has agreed to manufacture Andarine for us in a quantity that we believe is sufficient to supply clinical trials of Andarine for the treatment of cachexia from various types of cancer and initial commercialization of Andarine for this indication. We do not have a contract with ChemSyn for the supply of Andarine for full-scale commercialization. The active ingredient in Andarine is manufactured using a four-step synthetic process that uses commercially available starting materials and raw materials for each step. There are no complicated chemistries or unusual equipment required in the manufacturing process.

Competition

The biotechnology and biopharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We face competition from many different sources, including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies and private and public research institutions.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, clinical trials, regulatory approvals and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Our commercial opportunity will be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer side effects or are less expensive than any products that we may develop. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies and technology licenses complementary to our programs or advantageous to our business.

Acapodene for the Reduction in the Incidence of Prostate Cancer in Men with High Grade PIN

Currently, there are no products that would compete with Acapodene for the treatment of high grade PIN to reduce the incidence of prostate cancer.

Acapodene for the Treatment of Side Effects of Androgen Deprivation Therapy

Currently, there are no products that have been approved by the FDA to treat multiple side effects of androgen deprivation therapy. We are aware of a number of marketed drugs that are prescribed off-label for the treatment of single side effects. For example, Evista, Eli Lilly's trade name for raloxifene, Fosamax, a bisphosphonate marketed by Merck, and Actonel, a bisphosphonate marketed by Aventis and Proctor & Gamble, are each prescribed off-label for the treatment of osteoporosis. Effexor, marketed by Wyeth Pharmaceuticals, Catapres, marketed by Boehringer Ingelheim, and Megace, marketed by Bristol Myers Squibb, are prescribed off-label to treat hot flashes caused by androgen deprivation therapy. External beam radiation is used to treat

gynecomastia. There are significant side effects associated with the off-label use of these drugs and radiation treatment. Most patients would need to take several different drugs and potentially receive radiation treatments to treat multiple side effects of androgen deprivation therapy. In contrast, we believe that Acapodene, as a single product candidate, has the potential to treat multiple side effects.

Andarine for the Treatment of Cancer Cachexia

There are no drugs that have been approved by the FDA for the treatment of cancer cachexia. Although there are two commercially available drugs, Nandrolone and Oxandrin, that are being prescribed off-label for the treatment of some types of cancer cachexia, chronic use of these drugs may result in bleeding liver cysts and liver cell tumors. Nandrolone is an oral steroid that is available from Steris Laboratories, a subsidiary of Watson Pharmaceuticals. Oxandrin, marketed by Savient Pharmaceuticals, is prescribed for the treatment of involuntary weight loss associated with severe trauma, chronic infection or intensive surgery, as well as off-label for cancer cachexia. Oxandrin is a tissue non-selective steroid that has the potential to stimulate latent prostate cancer and breast cancer and cause virilization in women. Both Nandrolone and Oxandrin, as steroid drugs, have the potential to cause severe liver toxicities. Andarine is not a steroid, and we believe that it will be tissue-selective.

In addition, as to both Acapodene and Andarine, there may be product candidates of which we are not aware at an earlier stage of development. If any are successfully developed and approved, they could compete directly with our product candidates, if approved for commercial sale.

Sales and Marketing

We do not currently have any sales and marketing capabilities. In order to commercialize any products that are approved for commercial sale, we must either develop a sales and marketing infrastructure or collaborate with third parties with sales and marketing experience. We plan to build a small, highly-focused, specialty sales and marketing infrastructure, which we expect to include 50 to 80 sales representatives, to market Acapodene to the relatively small and concentrated community of urologists and medical oncologists, principally urological oncologists, in the United States. We believe that the urology and medical oncology market in the United States is readily accessible by a limited sales and marketing presence due to the concentration of prescribing physicians. We plan to establish collaborations with pharmaceutical companies to commercialize Acapodene in Europe and Asia for prostate cancer-related conditions.

Because it would require a large sales force to address the cancer cachexia market and because of the risks and costs of developing Andarine for cachexia from various types of cancer, we plan to seek one or more collaborators for the development and commercialization of Andarine for cancer cachexia resulting from all types of cancer other than urological cancers. We also plan to seek a collaborator for potential Andarine indications requiring a large sales force. For Andarine indications for which the target physician market is likely to overlap with that of Acapodene, including cancer cachexia resulting from urological cancers and indications related to andropause, our plan is to market and sell Andarine ourselves or to co-promote it with a collaborator in the United States, and, in the rest of the world, to seek a collaborator.

Intellectual Property

We will be able to protect our technology from unauthorized use by third parties only to the extent it is covered by valid and enforceable patents or is effectively maintained as trade secrets. Accordingly, patents and other proprietary rights are an essential element of our business.

For Acapodene, in the United States and internationally we have a license from Orion under its patent covering the composition of matter of toremifene, the active pharmaceutical ingredient in

Acapodene. Our license rights are exclusive in North America and Japan. The patent will expire in the United States in 2009, in Europe in 2003 or 2008, depending on the country, and in Japan in 2005. This patent is likely to expire in countries outside the United States before we commercialize Acapodene. As a result, outside of the United States and in the United States after 2009, we will need to rely primarily on the protection afforded by method of use patents that may issue in respect of our owned or licensed patent applications relating to the use of Acapodene for the relevant indications.

We have licensed from the University of Tennessee Research Foundation method of use patents in the United States and pending patent applications internationally related to the use of Acapodene for the reduction in the incidence of prostate cancer in men with high grade PIN. The method of use patents issued in the United States related to the use of Acapodene for this indication will expire in 2019.

We have our own pending method of use patent applications in the United States and internationally related to the use of Acapodene for the treatment of osteoporosis, gynecomastia and hot flashes as side effects of androgen deprivation therapy.

In all countries in which we hold or have licensed rights to patents or patent applications related to Acapodene, the composition of matter patents will expire before the method of use patents. Furthermore, with respect to the method of use of Acapodene for the treatment of osteoporosis, hot flashes and gynecomastia as side effects of androgen deprivation therapy worldwide and the method of use of Acapodene for the reduction in the incidence of prostate cancer in men with high grade PIN outside the United States, we have only pending patent applications. Method of use patents are more difficult to enforce than composition of matter patents because of the risk of off-label sale or use of the subject compounds.

In the event that patents issue in respect of our pending method of use patent applications, after the expiration of the patent covering the composition of matter of toremifene in a particular country, competitors could market and sell generic versions of toremifene at doses and in formulations that are bioequivalent to Acapodene for uses other than the indications for Acapodene covered by these pending method of use patent applications, and physicians would be permitted to prescribe generic versions of toremifene for indications that are protected by our or our licensors' method of use patents and pending patent applications. After the expiration of the patent covering the composition of matter of toremifene in a particular country, if patents do not issue in respect of our pending method of use patent applications related to the use of Acapodene for the treatment of osteoporosis, hot flashes and gynecomastia as side effects of androgen deprivation therapy worldwide and the method of use of Acapodene for the reduction in the incidence of prostate cancer in men with high grade PIN outside the United States, competitors could market and sell generic versions of toremifene at doses and in formulations that are bioequivalent to Acapodene for these indications.

Our license from Orion is limited to the use of toremifene for the prevention and treatment of prostate cancer and the prevention and treatment of osteoporosis, hot flashes and gynecomastia as side effects of androgen deprivation therapy in the treatment of prostate cancer. Orion has licensed Shire Pharmaceuticals Group in the United States and other parties elsewhere in the world to market, sell and distribute toremifene for the treatment of advanced breast cancer and could license other parties to market, sell and distribute toremifene for other indications in the United States and elsewhere. Shire's product is marketed as Fareston and is currently available only in a 60 mg dose. While we believe that the doses of Acapodene for the indications for which we are developing Acapodene will be different from the dose currently approved by the FDA for Fareston, there may be off-label use of Fareston in place of Acapodene for the indications for which we intend to seek regulatory approval of Acapodene. Additionally, after the expiration of the patent covering the composition of matter of toremifene in some countries, competitors could market and sell generic versions of Fareston in a 60 mg dose. Therefore, if Fareston becomes available at competitive prices

and in doses that are appropriate for the indications for which we are developing Acapodene, off-label sales of Fareston or generic versions of Fareston could reduce sales of Acapodene.

For Andarine, in the United States we have a license from the University of Tennessee Research Foundation under its patents related to the composition of matter and formulations of, and methods of using, the active pharmaceutical ingredient in Andarine. In the United States, the patents covering the composition of matter and formulations of the active pharmaceutical ingredient in Andarine will expire in 2021. We also have a license from the University of Tennessee Research Foundation to its pending patent applications in the United States related to methods of synthesizing the active pharmaceutical ingredient in Andarine and methods for treating cancer cachexia with Andarine. We also have a license from the University of Tennessee Research Foundation to pending patent applications internationally covering the composition of matter of the active pharmaceutical ingredient of Andarine, pharmaceutical compositions of Andarine, formulations of the active pharmaceutical ingredient in Andarine, methods of synthesis of the active pharmaceutical ingredient in Andarine, methods for treating cancer cachexia with Andarine and some other methods of using Andarine. We also have our own pending patent applications in the United States and internationally related to methods of using Andarine.

For Prostarine, we have a license from the University of Tennessee Research Foundation under its pending patent applications in the United States and internationally covering the composition of matter of the active pharmaceutical ingredient in Prostarine, pharmaceutical compositions and formulations of Prostarine and methods of synthesizing the active pharmaceutical ingredient in Prostarine. We also have our own pending patent applications in the United States and internationally related to methods for treating BPH using Prostarine.

For Ostarine, we have a license from the University of Tennessee Research Foundation under its pending patent applications in the United States and internationally covering the composition of matter of the active pharmaceutical ingredient in Ostarine, pharmaceutical compositions and formulations of Ostarine and methods of synthesizing the active pharmaceutical ingredient in Ostarine. We also have our own pending patent applications in the United States and internationally related to methods for treating male osteoporosis and andropause using Ostarine.

For Andromustine, we have pending patent applications of our own in the United States and rights to file internationally covering the composition of matter of the active pharmaceutical ingredient in Andromustine, pharmaceutical compositions of Andromustine, methods of synthesizing the active pharmaceutical ingredient in Andromustine and methods for treating prostate cancer that is not responsive to androgen deprivation therapy using Andromustine.

We also rely on trade secrets, technical know-how and continuing innovation to develop and maintain our competitive position. We seek to protect our proprietary information by requiring our employees, consultants, contractors, outside scientific collaborators and other advisors to execute non-disclosure and assignment of invention agreements on commencement of their employment or engagement, through which we seek to protect our intellectual property. Agreements with our employees also prevent them from bringing the proprietary rights of third parties to us. We also require confidentiality or material transfer agreements from third parties that receive our confidential data or materials.

Government Regulation

New Drug Development and Approval Process

Numerous governmental authorities in the United States and other countries extensively regulate the testing, clinical development, manufacturing and marketing of pharmaceutical products and ongoing research and development activities. In the United States, the FDA rigorously reviews pharmaceutical products under the Federal Food, Drug, and Cosmetic Act and regulations. Non-compliance with applicable requirements can result in administrative and judicial sanctions, including warning letters, clinical holds, fines, recall or seizure of products, injunctions, total or partial suspension of production, refusal of the government to approve marketing applications or allow entry into supply contracts, refusal to permit import or export of products, civil penalties, criminal prosecution and other actions affecting a company and its products. The FDA also has the authority to revoke previously granted marketing authorizations.

To secure FDA approval, an applicant must submit extensive preclinical and clinical data, as well as information about product manufacturing processes and facilities and other supporting information to the FDA for each indication to establish a product candidate's safety and effectiveness. The development and approval process takes many years, requires the expenditure of substantial resources and may be subject to delays or limitations of approval or rejection of the application. Even if the FDA approves a product, the approval is subject to post-marketing surveillance, adverse drug experience and other recordkeeping and reporting obligations, and may involve ongoing requirements for post-marketing studies. The FDA also may place conditions on any approvals that could restrict the commercial applications, advertising, promotion or distribution of these products. Product approvals may be withdrawn if compliance with regulatory standards is not maintained or if problems occur following initial marketing.

Preclinical and Clinical Testing

Preclinical studies involve laboratory evaluation of product characteristics and animal studies to assess the biological activity and safety of the product. In some cases, long-term preclinical studies are conducted while clinical studies are ongoing. The FDA, under its Good Laboratory Practices regulations, regulates preclinical studies. Violations of these regulations can, in some cases, lead to invalidation of the studies, requiring these studies to be replicated. When the preclinical testing is considered adequate by the sponsor to demonstrate the safety and scientific rationale for initial human studies, the results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an Investigational New Drug application, or IND. The IND becomes effective, if not rejected by the FDA, within 30 days after FDA receives the IND. The FDA may, at any time during the 30-day period after filing of an IND or at any future time, impose a clinical hold on proposed or ongoing clinical trials, on various grounds, including that the study subjects are or would be exposed to an unreasonable and significant health risk. If the FDA imposes a clinical hold, clinical trials cannot commence or recommence without FDA authorization and then only under terms authorized by the FDA.

Clinical trials involve the administration of the investigational product candidates to humans under the supervision of a qualified principal investigator. Clinical trials must be conducted in accordance with Good Clinical Practice, or GCP, under protocols submitted to the FDA as part of the IND. In addition, each clinical trial must be approved and conducted under the auspices of an Investigational Review Board, or IRB, and with patient informed consent. The IRB will consider, among other things, ethical factors and the safety of human subjects.

Clinical trials are conducted in three sequential phases, but the phases may overlap. Phase I clinical trials usually involve between 20 and 80 healthy human subjects or more, depending on the disease. The goal of the Phase I clinical trial is to establish initial data about the safety and tolerance of the product candidates in humans. In Phase II clinical trials, controlled studies are

conducted on an expanded population of patients with the targeted disease. The primary purpose of these tests is to evaluate the effectiveness of the drug candidate on the volunteer patients as well as to determine if there are any side effects or other risks associated with the drug. Phase III trials involve even larger patient populations, often with several hundred or even several thousand patients depending on the use for which the drug is being studied. Phase III trials are intended to establish the overall risk-benefit ratio of the drug and provide, if appropriate, an adequate basis for product labeling. During all clinical trials, physicians monitor the patients to determine effectiveness and to observe and report any reactions or other safety risks that may result from use of the drug candidate.

Product Formulation and Manufacture

Concurrent with clinical trials and preclinical studies, companies must develop information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product. In addition, manufacturers, including contract manufacturers, are required to comply with the applicable FDA current Good Manufacturing Practice regulations. The current Good Manufacturing Practice regulations include requirements relating to quality control and quality assurance, as well as the corresponding maintenance of records and documentation. The manufacturing process must be capable of consistently producing quality batches of the product and the manufacturer must develop methods for testing the quality, purity and potency of the final drugs. Additionally, appropriate packaging must be selected and tested and chemistry stability studies must be conducted to demonstrate that the product does not undergo unacceptable deterioration over its shelf-life.

Compliance with current Good Manufacturing Practice regulations also is a condition of new drug application approval. The FDA must approve manufacturing facilities before they can be used in the commercial manufacture of drug products. In addition, manufacturing establishments are subject to preapproval inspections and unannounced periodic inspections.

New Drug Application Process

After the completion of the clinical trial phases of development, if the sponsor concludes that there is substantial evidence that the drug candidate is safe and effective for its intended use, the sponsor may submit a new drug application, or NDA, to the FDA. The application must contain all of the information on the drug candidate gathered to that date, including data from the clinical trials, and be accompanied by a user fee.

The FDA determines whether an NDA as submitted is acceptable for filing. The FDA may refuse to file an application, in which case the FDA retains one-half of the user fee. If the submission is accepted for filing, the FDA begins an in-depth review of the application. As part of this review, the FDA may refer the application to an appropriate advisory committee, typically a panel of clinicians, for review, evaluation and a recommendation. The FDA is not bound by the recommendation of an advisory committee. Under the Prescription Drug User Fee Act, or PDUFA, submission of an NDA with clinical data requires payment of a fee, with some exceptions. In return, FDA assigns a goal of six or 12 months from filing of the application to return of a first “complete response,” in which the FDA may approve the product or request additional information. There can be no assurance that an application will be approved within the performance goal timeframe established under PDUFA.

If the FDA evaluations of the NDA and the manufacturing facilities are favorable, the FDA may issue an approval letter authorizing commercial marketing of the drug candidate for specified indications. The FDA could also issue an approvable letter, which usually contains a number of conditions that must be met in order to secure final approval of the new drug application. When and if those conditions have been met to the FDA’s satisfaction, the FDA will issue an approval letter. On the other hand, if the FDA’s evaluation of the NDA submission or manufacturing facilities is not favorable, the FDA may refuse to approve the NDA or issue a non-approvable letter.

Marketing Approval and Post-marketing Obligations

If the FDA approves an application, the drug becomes available for physicians to prescribe. Periodic reports must be submitted to the FDA, including descriptions of any adverse reactions reported. The FDA may require post-marketing studies, also known as Phase IV studies, as a condition of approval. In addition to studies required by the FDA after approval, trials and studies are often conducted to explore new indications. The purpose of these trials and studies and related publications is to develop data to support additional indications for the drug, which must be approved by the FDA, and to increase its acceptance in the medical community. In addition, some post-marketing studies are done at the request of the FDA to develop additional information regarding the safety of a product.

Any products manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including recordkeeping requirements, reporting of adverse experiences with the drug, drug sampling and distribution requirements, notifying the FDA and gaining its approval of certain manufacturing or labeling changes, complying with certain electronic records and signature requirements, and complying with FDA promotion and advertising requirements. Drug manufacturers and their subcontractors are required to register their establishments and are subject to periodic unannounced inspections for compliance with good manufacturing practice requirements. Also, newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, or even in some instances revocation or withdrawal of the approval.

Drug Price Competition and Patent Term Restoration Act of 1984

Under the Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act, a portion of a product's patent term that was lost during clinical development and application review by the FDA may be restored. The Hatch-Waxman Act also provides for a statutory protection, known as exclusivity, against the FDA's acceptance or approval of certain competitor applications. The Hatch-Waxman Act also provides the legal basis for the approval of abbreviated new drug applications.

Patent term restoration can compensate for time lost during product development and the regulatory review process by returning up to five years of patent life for a patent that covers a new product or its use. This period is generally one-half the time between the effective date of an IND and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application. Patent term restorations, however, are subject to a maximum extension of five years, and the patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years. The application for patent term extension is subject to approval by the United States Patent and Trademark Office in conjunction with the FDA. It takes at least six months to obtain approval of the application for patent term extension.

The Hatch-Waxman Act also provides for a period of statutory protection for new drugs that receive NDA approval from the FDA. If a new drug receives NDA approval as a new chemical entity, meaning that the FDA has not previously approved any other new drug containing the same active entity, then the Hatch-Waxman Act prohibits an abbreviated new drug application or an NDA where the applicant does not own or have a legal right of reference to all of the data required for approval to be submitted by another company for a generic version of such drug, with some exceptions, for a period of five years from the date of approval of the NDA. The statutory protection provided pursuant to the Hatch-Waxman Act will not prevent the filing or approval of a full NDA, as opposed to an abbreviated new drug application or a new drug application in which the applicant does not own or have a legal right of reference to all of the data required for approval, for any drug, including, for example, a drug with the same active ingredient, dosage form, route of administration, strength and conditions of use. In order to obtain an NDA, however, a competitor would be required to conduct its own clinical trials. If NDA approval is received for a new drug containing an active ingredient that

was previously approved by the FDA but the NDA is for a drug that includes an innovation over the previously approved drug, for example, an NDA approval for a new indication or formulation of the drug with the same active ingredient, and if such NDA approval was dependent upon the submission to the FDA of new clinical investigations, other than bioavailability studies, then the Hatch-Waxman Act prohibits the FDA from making effective the approval of an abbreviated new drug application or a new drug application in which the applicant does not own or have a legal right of reference to all of the data required for approval for a generic version of such drug for a period of three years from the date of the NDA approval. This three year exclusivity, however, only covers the innovation associated with the NDA to which it attaches. Thus, the three year exclusivity does not prohibit the FDA, with limited exceptions, from approving abbreviated new drug applications or a new drug application in which the applicant does not own or have a legal right of reference to all of the data required for approval for drugs containing the same active ingredient but without the new innovation.

While the Hatch-Waxman Act provides certain patent restoration and exclusivity protections to innovator drug manufacturers, it also permits the FDA to approve abbreviated new drug applications for generic versions of their drugs. The abbreviated new drug application process permits competitor companies to obtain marketing approval for a drug with the same active ingredient for the same uses but does not require the conduct and submission of clinical studies demonstrating safety and effectiveness for that product. Instead of safety and effectiveness data, an abbreviated new drug application applicant needs only to submit data demonstrating that its product is bioequivalent to the innovator product as well as relevant chemistry, manufacturing and product data. The Hatch-Waxman Act also instituted a third type of drug application that requires the same information as an NDA including full reports of clinical and preclinical studies except that some of the information from the reports required for marketing approval comes from studies which the applicant does not own or have a legal right of reference. This type of application permits a manufacturer to obtain marketing approval for a drug without needing to conduct or obtain a right of reference for all of the required studies.

Finally, the Hatch-Waxman Act requires, in some circumstances, an abbreviated new drug application or a new drug application in which the applicant does not own or have a legal right of reference to all of the data required for approval applicant to notify the patent owner and the holder of the approved NDA of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed. Upon receipt of this notice, the patent owner and the NDA holder have 45 days to bring a patent infringement suit in federal district court and obtain a 30 month stay against the company seeking to reference the NDA. The NDA holder could still file a patent suit after the 45 days, but if they did, they would not have the benefit of the 30 month stay. Alternatively, after this 45-day period, the applicant may file a declaratory judgment action, seeking a determination that the patent is invalid or will not be infringed. Depending on the circumstances, however, the applicant may not be able to demonstrate a controversy sufficient to confer jurisdiction on the court. The discovery, trial and appeals process in such suits can take several years. If such a suit is commenced, the Hatch-Waxman Act provides a 30-month stay on the approval of the competitor's abbreviated new drug application or a new drug application in which the applicant does not own or have a legal right of reference to all of the data required for approval. If the litigation is resolved in favor of the competitor or the challenged patent expires during the 30-month period, unless otherwise extended by court order, the stay is lifted and the FDA may approve the application. Under regulations recently issued by the FDA, and essentially codified under the recent Medicare prescription drug legislation, the patent owner and the NDA holder have the opportunity to trigger only a single 30-month stay per abbreviated new drug application or a new drug application in which the applicant does not own or have a legal right of reference to all of the data required for approval. Once the abbreviated new drug application or a new drug application in which the applicant does not own or have a legal right of reference to all of the data required for approval applicant has notified the patent owner and the NDA holder of the infringement, the applicant cannot be subjected to another 30-month stay, even if the applicant becomes aware of additional patents that may be infringed by its product.

Pharmaceutical Pricing and Reimbursement

In both domestic and foreign markets, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of reimbursement from third-party payors. Third-party payors include government health administrative authorities, managed care providers, private health insurers and other organizations. These third-party payors are increasingly challenging the price and examining the cost-effectiveness of medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare product candidates. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. Our product candidates may not be considered cost-effective. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. The United States and state governments continue to propose and pass legislation designed to reduce the cost of healthcare. Adoption of new legislation could further limit reimbursement for pharmaceuticals.

The marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, an increasing emphasis on managed care in the United States has and will continue to increase the pressure on pharmaceutical pricing.

Facilities

We sublease approximately 18,500 square feet of laboratory and office space in Memphis, Tennessee, under an operating lease through September 2005. This lease is terminable by either party on 90 days' notice. We believe that our existing facilities will be sufficient to meet our requirements through 2005.

Employees

As of December 31, 2003, we had 42 employees, of whom 11 were Ph.D.s and 3 were M.D.s. None of our employees is subject to a collective bargaining agreement. We believe that we have good relations with our employees.

Legal Proceedings

We are not currently involved in any material legal proceedings.

MANAGEMENT

Directors, Executive Officers and Other Key Employees

The following table sets forth information about our directors, executive officers and other key employees as of December 31, 2003.

Name	Age	Position(s)
Directors and Executive Officers		
J.R. Hyde, III(1)(2)(3)	61	Chairman of the Board of Directors
Mitchell S. Steiner, M.D., F.A.C.S.	43	Chief Executive Officer and Vice-Chairman of the Board of Directors
Marc S. Hanover	41	President, Chief Operating Officer and Director
Henry P. Doggrell	55	General Counsel and Secretary
Mark E. Mosteller	41	Chief Financial Officer
Rosemary Mazanet, M.D., Ph.D.(1)(2)(3)	48	Director
John H. Pontius(1)(2)(3)	48	Director
Other Key Employees		
K. Gary Barnette, Ph.D.	36	Director of Regulatory Affairs
T. Gary Bird, Ph.D.	51	Director of Manufacturing
Robert S. Boger, M.D.	56	Director of Clinical Development
Karen A. Veverka, Ph.D.	35	Director of Preclinical Development
Michael A. Whitt, Ph.D.	44	Director of Molecular Biology

(1) Member of the Compensation Committee

(2) Member of the Audit Committee

(3) Member of the Nominating and Corporate Governance Committee

J.R. Hyde, III has served as the Chairman of our Board of Directors since November 2000. Since 1989, Mr. Hyde has been the sole stockholder and President of Pittco Holdings, Inc., a private, institutional investment company. Since 1996, when Mr. Hyde made a substantial contribution to support Dr. Steiner's research, Mr. Hyde has been instrumental in forming and financing GTx and is our largest stockholder. Mr. Hyde was the Chairman of the Board of Directors of AutoZone, Inc. from 1986 to 1997 and the Chief Executive Officer of AutoZone from 1986 to 1996. He was also Chairman and Chief Executive Officer of Malone & Hyde, AutoZone's former parent company, from 1972 until 1988. Mr. Hyde is a director of AutoZone, Inc. and FedEx Corporation.

Mitchell S. Steiner, M.D., F.A.C.S., a co-founder of GTx, has served as our Chief Executive Officer and Vice-Chairman of our Board of Directors since our inception in September 1997. Prior to founding GTx, Dr. Steiner held numerous academic appointments, including Chairman and Professor of Urology, Director of Urologic Oncology and Research and the Chair of Excellence in Urologic Oncology at the University of Tennessee. Dr. Steiner holds a B.A. in Molecular Biology from Vanderbilt University and an M.D. from the University of Tennessee, and performed his surgery and urologic training at The Johns Hopkins Hospital.

Marc S. Hanover, a co-founder of GTx, has served as our President and Chief Operating Officer and a director since our inception in September 1997. Prior to joining GTx, Mr. Hanover was a founder of Equity Partners International, Inc., a private equity firm in Memphis, Tennessee, and participated as a founder and investor in three healthcare companies. From 1985 to 1997, Mr. Hanover was a Senior Vice President and a member of the Executive Management Committee of National Bank of Commerce, now National Commerce Financial Corporation, in Memphis,

Tennessee. Mr. Hanover holds a B.S. in Biology from the University of Memphis and an M.B.A. in Finance from the University of Memphis.

Henry P. Doggrell has served as our General Counsel and Secretary since October 2001. From April 1998 to August 2001, Mr. Doggrell was Senior Vice President, Corporate Affairs at Buckeye Technologies, Inc., a specialty cellulose company, where he was responsible for matters including corporate finance, investor relations, mergers and acquisitions, intellectual property and licensing and strategic development. From 1996 to 1998, Mr. Doggrell served as General Counsel and Secretary of Buckeye Technologies. Prior to joining Buckeye Technologies, Mr. Doggrell was a partner of the Baker, Donelson, Bearman, Caldwell and Berkowitz law firm from 1988 to 1996, where he served as a member of the law firm management committee and Chair of the firm's Corporate Securities department. Mr. Doggrell holds a B.S. in Commerce from the University of Virginia and a J.D. from Vanderbilt University.

Mark E. Mosteller has served as our Chief Financial Officer since August 2001. From April 1997 to August 2001, Mr. Mosteller was an Executive Vice President of Union Planters Bank National Association, a subsidiary of Union Planters Corporation, a bank holding company, and Chief Operating Officer of Union Planters Mortgage, the mortgage division of Union Planters Bank National Association. From 1994 to 1997, Mr. Mosteller was the Chief Financial Officer of Boatmen's National Mortgage, Inc., the mortgage subsidiary of Boatmen's Bancshares, Inc. From 1984 to 1994, Mr. Mosteller was employed as an audit senior manager with Ernst & Young LLP. Mr. Mosteller is a certified public accountant and holds a B.S. in Accounting from the University of Tennessee.

Rosemary Mazanet, M.D., Ph.D. has served as a director since October 2001. Dr. Mazanet has served as Chief Scientific Officer and a General Partner of Oracle Partners, L.P., a private equity fund, since 1998. Prior to joining Oracle Partners, Dr. Mazanet served as the Director of Clinical Research at Amgen, Inc., a pharmaceutical company. Dr. Mazanet is a member of the Board of Directors of the University of Pennsylvania School of Medicine. She trained in internal medicine at the Brigham and Women's Hospital and in oncology at the Dana Farber Cancer Institute, both part of the Harvard Medical system, where she was a staff physician prior to joining Amgen. Dr. Mazanet holds a B.A. in Biology from the University of Virginia and an M.D. and a Ph.D. in Anatomy from the University of Pennsylvania.

John H. Pontius has served as a director since April 1999. Mr. Pontius has been the President of Pittco Management, LLC, since 1991. From 1986 to 1991, Mr. Pontius served as the chief financial officer of the City of Memphis, Tennessee. Mr. Pontius is a certified public accountant and holds a B.S. in Accounting from the University of Tennessee. Mr. Pontius has served as a member of the Board of Trustees of the University of Tennessee since 2002.

K. Gary Barnette, Ph.D. has served as our Director of Regulatory Affairs since December 2001. From May 1998 to December 2001, Dr. Barnette was Assistant Director and then Director, Regulatory Affairs at Solvay Pharmaceuticals, Inc., a specialty pharmaceutical company. From March 1995 to May 1998, Dr. Barnette was a Clinical Pharmacology and Biopharmaceutics Reviewer at the FDA, where he reviewed in the Divisions of Reproductive and Urologic Drug Products, Metabolic and Endocrine Drug Products and Gastrointestinal and Coagulation Drug Products. Dr. Barnette holds a B.S. in Biology from Salem College, and a Ph.D. in Basic Pharmaceutical Sciences from West Virginia University.

T. Gary Bird, Ph.D. has served as our Director of Manufacturing since October 2003. From 1995 to October 2003, Dr. Bird was a Senior Regulatory Scientist, Senior Quality Consultant and Quality Technical Advisor for Biotechnology in Corporate Quality Assurance at Eli Lilly and Company. Dr. Bird provided regulatory and quality direction to the biotechnology component of Eli Lilly with respect to facility construction and operation. From 1992 to 1995, Dr. Bird was the Assistant to the Deputy Director, Center for Biologics Evaluation and Research at the FDA. Dr. Bird holds a B.S. from the University of Memphis in Invertebrate Zoology/Chemistry, an M.S. from the University of

Memphis in Invertebrate Zoology and a Ph.D. in Biochemistry/Entomology from Mississippi State University.

Robert S. Boger, M.D. has served as our Director of Clinical Development since May 2003. From January 2002 until he joined GTx, Dr. Boger was a private consultant specializing in medicine, pharmacology and clinical research. From 1997 to January 2002, Dr. Boger was Director of Clinical Research for Transplantation and Immunology for Novartis Pharmaceuticals. From 1996 to 1997, Dr. Boger served as Director of Medical Research and Clinical Science Leader of Roche's CellCeptTransplant program. Prior to joining Roche, Dr. Boger served as both Associate Director, Clinical Research and Medical Director, Renin Inhibitor Venture for Abbott Laboratories. Dr. Boger holds a B.A. in Biophysics from Amherst College and an M.D. from Harvard Medical School. Dr. Boger is board certified in internal medicine, nephrology and clinical pharmacology.

Karen A. Veverka, Ph.D. has served as our Director of Preclinical Development since August 2000. Dr. Veverka is a co-inventor of several patents held by GTx in the area of medical applications of SARMs. From 1996 to September 2000, Dr. Veverka was a post-doctoral research fellow at St. Jude Children's Research Hospital. Dr. Veverka holds a B.S. in Biochemistry from Kansas State University and a Ph.D. from Mayo Graduate School/The Mayo Foundation.

Michael A. Whitt, Ph.D. has served as our Director of Molecular Biology since April 2001. Dr. Whitt is the co-inventor of several patents licensed to GTx. Dr. Whitt has been on the faculty in the Department of Molecular Sciences at the University of Tennessee Health Sciences since 1991. Dr. Whitt holds a B.A. in Microbiology from the University of Kansas and a Ph.D. in Microbiology from the University of California, Davis. Dr. Whitt received his post-doctoral training at the Yale University School of Medicine.

Board Composition

Upon the completion of this offering, we will have an authorized Board of Directors consisting of five members. In accordance with the terms of our certificate of incorporation and bylaws, which will become effective upon completion of this offering, the Board of Directors will be divided into three classes, Class I, Class II and Class III, with each class serving staggered three-year terms. Upon the completion of this offering, the members of the classes will be divided as follows:

- the class I director will be Dr. Mazanet, and her term will expire at the annual meeting of stockholders to be held in 2005;
- the class II directors will be Mr. Hanover and Mr. Pontius, and their term will expire at the annual meeting of stockholders to be held in 2006; and
- the class III directors will be Dr. Steiner and Mr. Hyde, and their term will expire at the annual meeting of stockholders to be held in 2007.

Our certificate of incorporation that will become effective upon the completion of this offering provides that the authorized number of directors may be changed only by resolution of the Board of Directors. Any additional directorships resulting from an increase in the number of directors will be distributed between the three classes so that, as nearly as possible, each class will consist of one-third of the directors. This classification of the Board of Directors may have the effect of delaying or preventing changes in the control or management of GTx.

Our directors may be removed only for cause by the affirmative vote of the holders of a majority of our voting stock.

Board Committees

Our Board of Directors has an audit committee, a compensation committee and a nominating and corporate governance committee.

Audit Committee

Our audit committee consists of Mr. Hyde, Dr. Mazanet and Mr. Pontius. The functions of the audit committee include:

- meeting with our management periodically to consider the adequacy and effectiveness of our internal controls, the objectivity of our financial reporting and our accounting policies and practices;
- meeting with our independent auditors and with internal financial personnel regarding these matters;
- selecting, overseeing, compensating and engaging our independent auditors;
- reviewing our financial statements and reports and discussing the statements and reports with our management and our independent auditor, including any significant adjustments, management judgments and estimates, new accounting policies and disagreements with management; and
- reviewing our financial plans and reporting recommendations to our full board for approval and to authorize action.

Both our independent auditors and internal financial personnel will regularly meet privately with our audit committee and have unrestricted access to this committee.

Compensation Committee

Our compensation committee consists of Mr. Hyde, Dr. Mazanet and Mr. Pontius. The functions of the compensation committee include:

- reviewing and, as it deems appropriate, recommending to our Board of Directors, policies, practices and procedures relating to the compensation of our directors and executive officers and the establishment and administration of our employee benefit plans;
- exercising administrative authority under our stock plans and employee benefit plans; and
- advising and consulting with our officers regarding managerial personnel and development.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee consists of Mr. Hyde, Dr. Mazanet and Mr. Pontius. The functions of the nominating and corporate governance committee include:

- reviewing and recommending nominees for election as directors;
- assessing the performance of the Board of Directors;
- developing guidelines for board composition; and
- reviewing and administering our corporate governance guidelines and considering other issues relating to corporate governance.

Compensation Committee Interlocks and Insider Participation

From January 2003 through October 2003, Mr. Pontius, Dr. Steiner, our Chief Executive Officer, and Mr. Hanover, our President and Chief Operating Officer, served as the members of our Compensation Committee. In October 2003, Mr. Hyde and Dr. Mazanet replaced Dr. Steiner and Mr. Hanover as members of our Compensation Committee. None of our executive officers currently serves, or in the past year has served, as a member of the Board of Directors or compensation committee of any entity that has one or more executive officers serving on our Board of Directors or compensation committee.

Director Compensation

We have not provided cash compensation to any director for his or her service as a director. However, following the completion of this offering, we intend to provide cash compensation at a rate of $20,000 per year, payable quarterly to each non-employee director. We also intend to pay the chairman of the audit committee a fee of $5,000 per year, payable quarterly. In addition, we will reimburse directors for their reasonable expenses incurred in attending meetings of the Board of Directors.

Our 2004 Non-Employee Directors' Stock Option Plan, which will become effective upon completion of this offering, provides for the automatic grant of options to purchase shares of common stock to our non-employee directors except for Mr. Hyde and any other non-employee director who owns ten percent or more of the combined voting power of our outstanding securities. Prior to adoption of our 2004 Non-Employee Directors' Stock Option Plan, we did not make option grants to our non-employee directors. Upon completion of this offering, each of our non-employee directors, except for Mr. Hyde and any other non-employee director who owns ten percent or more of the voting power of our outstanding securities, will receive an initial option to purchase 10,000 shares of common stock and annual option grants to purchase 2,000 shares of common stock starting at the annual stockholders meeting to be held in 2005. Please refer to the section entitled "Benefit Plans — 2004 Non-Employee Directors' Stock Option Plan" for a more detailed explanation of the terms of these stock options.

Executive Compensation

The following table shows the compensation awarded or paid to, or earned by, our chief executive officer and our three other most highly compensated executive officers for the fiscal years ended December 31, 2002 and December 31, 2003 whose total annual salary and bonus exceeded $100,000. We refer to these executive officers in this prospectus as our "named executive officers."

Summary Compensation Table

		Annual Compensation	Long-Term Compensation Awards
Name and Principal Position	Fiscal Year	Salary ($)	Securities Underlying Options (#)
Mitchell S. Steiner, M.D., F.A.C.S.	2003	$311,666	—
Chief Executive Officer	2002	175,000	—
Marc S. Hanover	2003	180,000	—
President and Chief Operating Officer	2002	180,000	—
Henry P. Doggrell	2003	193,000	12,750
General Counsel and Secretary	2002	178,750	—
Mark E. Mosteller	2003	154,167	42,500
Chief Financial Officer	2002	135,417	17,000

Stock Option Grants in Last Fiscal Year

We have granted and will continue to grant options to our executive officers and employees under our benefit plans. The exercise price per share of each option granted during 2003 was equal to the fair market value of our common stock as determined by our Board of Directors on the date of grant.

The following table shows information regarding grants of stock options to our named executive officers during the fiscal year ended December 31, 2003. We have never granted any stock appreciation rights.

	Option Grants in Last Fiscal Year						
					Potential Realizable Value at Assumed Annual Rates of Stock Price Appreciation for Option Terms(2)		
Name	Number of Securities Underlying Options Granted(#)	Percent of Total Options Granted to Employees(%)(1)	Exercise Price Per Share($)	Expiration Date	0%($)	5%($)	10%($)
Mitchell S. Steiner, M.D., F.A.C.S.	—	—	—	—	—	—	—
Marc S. Hanover	—	—	—	—	—	—	—
Henry P. Doggrell	12,750	2.4%	$6.24	9/1/2013	$ 99,000	$211,258	$383,483
Mark E. Mosteller	17,000	3.2	6.24	8/1/2013	132,000	281,677	511,311
	25,500	4.8	6.24	9/1/2013	198,000	422,515	766,966

(1) Based on aggregate of 533,375 shares subject to options granted to our employees in 2003, including the named executive officers.

(2) Potential realizable values are computed by (1) multiplying the number of shares of common stock subject to a given option by an assumed initial public offering price of $14.00, (2) assuming that the aggregate stock value derived from that calculation compounds at the annual 0%, 5% or 10% rate shown in the table for the entire ten-year term of the option and (3) subtracting from that result the aggregate option exercise price. The 0%, 5% and 10% assumed annual rates of stock price appreciation are mandated by the rules of the SEC and do not reflect our estimate or projection of future stock prices. Actual gains, if any, on stock option exercises will depend on the future performance of the common stock and the date on which the options are exercised.

Fiscal Year End Option Values

The following table sets forth the number of shares of common stock subject to vested and unvested stock options held as of December 31, 2003 by each of our named executive officers. Because there was no public market for our common stock as of December 31, 2003, amounts described in the following table under the heading “Value of Unexercised In-the-Money Options at December 31, 2003” are determined by multiplying the number of shares underlying the options by the difference between an assumed initial public offering price of $14.00 per share and the per share option exercise price. None of our named executive officers exercised any stock options during 2003.

	Number of Securities Underlying Unexercised Options at December 31, 2003 (#)		Value of Unexercised In-the-Money Options at December 31, 2003 ($)	
Name	Exercisable	Unexercisable	Exercisable	Unexercisable
Mitchell S. Steiner, M.D., F.A.C.S.	—	—	—	—
Marc S. Hanover	—	—	—	—
Henry P. Doggrell	51,000	89,250	$368,040	$651,060
Mark E. Mosteller	—	85,000	—	636,700

Change in Control Arrangements

Our 1999 Stock Option Plan, 2000 Stock Option Plan, 2001 Stock Option Plan and 2002 Stock Option Plan provide that in the event of a change in control of us, all shares subject to option awards under the plans will immediately vest and be converted into cash, options or stock of equivalent value in the surviving organization under terms and conditions that substantially preserve the economic status of plan participants. For this purpose, a change in control includes (1) a sale or

disposition of more than 50% of our issued and outstanding voting stock; (2) a merger or consolidation in which our stockholders immediately before the transaction own less than 50% of the outstanding voting securities of the surviving entity immediately after the transaction; or (3) a sale or disposition of all or substantially all of our assets.

Our employment agreements with our executive officers and other key employees contain provisions triggered by a change of control. See "Employment Agreements."

Our 2004 Equity Incentive Plan provides that in the event of specified corporate transactions, all outstanding options and stock appreciation rights under the incentive plan will be assumed, continued or substituted for by any surviving or acquiring entity. If the surviving or acquiring entity elects not to assume, continue or substitute for such awards, such equity awards will become fully vested, and, if applicable, exercisable and such equity awards will be terminated if not exercised prior to the effective date of the corporate transaction. Other forms of equity awards, such as restricted stock awards, may have their repurchase or forfeiture rights assigned to the surviving or acquiring entity. If such repurchase or forfeiture rights are not assigned, then such equity awards will become fully vested. Following specified change in control transactions, the vesting and exercisability of specified equity awards generally will be accelerated only if the awardee's award agreement so specifies. The standard form of stock option agreement provides for the option to become fully vested and exercisable if the option holder's service with the company or its successor terminates within 12 months after a change of control and the termination of service is a result of an involuntary termination without cause or a constructive termination.

Our 2004 Non-Employee Directors' Stock Option Plan provides that in the event of specified corporate transactions, all outstanding options under the plan will be either assumed, continued or substituted for by any surviving entity. If the surviving or acquiring entity elects not to assume, continue or substitute for such options, the vesting and exercisability of such options will be accelerated in full and such options will be terminated if not exercised prior to the effective date of such corporate transaction. In the event of specified changes in control, the outstanding options under the Plan granted to non-employee directors will become fully vested and exercisable as of such change in control. In addition, such non-employee director's options shall become fully vested and exercisable if such director must resign as a condition of the change in control.

Employment Agreements

Each of our named executive officers has entered into an employment agreement with us. These employment agreements provide for salary as well as other customary benefits and terms. Pursuant to their employment agreements, Dr. Steiner, Mr. Hanover, Mr. Doggrell and Mr. Mosteller are currently entitled to receive an annual salary of $375,000, $180,000, $202,000 and $160,000. In addition, our Board of Directors has the discretion to award bonus compensation to our named executive officers. Each employment agreement is terminable by either us or the named executive officer at any time. If we experience a change of control and the named executive officer's employment is terminated without cause, or if the named executive officer terminates his employment for good reason, at any time within six months after the change in control, then such named executive officer will receive continued payment of his then base salary for a period of one year after the termination date. Dr. Steiner and Mr. Hanover have each agreed not to compete with us during the term of their employment and for a period of two years after their employment ends. If we undergo a change in control, the two year period will be shortened to one year.

Benefit Plans

1999 Stock Option Plan and 2000 Stock Option Plan

We adopted the 1999 Stock Option Plan in August 1999 and the 2000 Stock Option Plan in November 2000. Neither the 1999 Stock Option Plan nor the 2000 Stock Option Plan has a stated termination date. However, the committee of the Board of Directors that administers the 1999 Stock Option Plan and 2000 Stock Option Plan may terminate or suspend the 1999 Stock Option Plan and 2000 Stock Option Plan at any time. The 1999 Stock Option Plan and 2000 Stock Option Plan provide for the grant of nonstatutory stock options to directors, officers and employees.

Share Reserve. An aggregate of 24,650 shares of common stock are reserved for issuance under the 1999 Stock Option Plan. No options were outstanding under the 1999 Stock Option Plan as of December 31, 2003. An aggregate of 108,375 shares of common stock are reserved for issuance under the 2000 Stock Option Plan. Options to purchase an aggregate of 74,375 shares of common stock were outstanding under the 2000 Stock Option Plan as of December 31, 2003.

Shares subject to stock options that have expired or otherwise terminated under the 1999 Stock Option Plan or 2000 Stock Option Plan without having been exercised in full and grants that are settled in cash rather than stock again become available for the grant of awards under the 1999 Stock Option Plan or 2000 Stock Option Plan. Shares issued under the 1999 Stock Option Plan or 2000 Stock Option Plan may be previously unissued shares or reacquired shares bought on the market or otherwise.

Administration. The 1999 Stock Option Plan and 2000 Stock Option Plan are administered by a committee of our Board of Directors. Subject to the terms of the 1999 Stock Option Plan and 2000 Stock Option Plan, the committee determines the recipients, the number of stock options to be granted and the terms and conditions of the stock options. Subject to the limitations set forth below, the committee also determines the exercise price of options granted.

Stock Options. Stock options under the 1999 Stock Option Plan and 2000 Stock Option Plan are granted pursuant to stock option agreements. The exercise price for a stock option cannot be less than the fair market value of the common stock on the date of grant. Options granted under the 1999 Stock Option Plan and 2000 Stock Option Plan vest one-third on the third anniversary of the date of grant, one-third on the fourth anniversary of the date of grant, and one-third on the fifth anniversary of the date of grant. If the 1999 Stock Option Plan or the 2000 Stock Option Plan is terminated, all outstanding options will become fully vested and exercisable.

The term of stock options granted under the 1999 Stock Option Plan and 2000 Stock Option Plan may not exceed 10 years. If an optionee's service relationship with us ceases due to voluntary retirement, at or after age 65 or after age 55 with no fewer than 10 years of service, death, disability or involuntary termination, other than a termination for cause, but including any involuntary termination as a result of a change of control, any vested shares may be exercised at any time within 10 years following the date of grant of the option. If an optionee's relationship with us ceases for any other reason, any unvested option shall be forfeited immediately and the date of such termination will be the last date on which a vested option can be exercised. Any vested but unexercised options will terminate upon the optionee competing with us.

Acceptable consideration for the purchase of common stock issued under the 1999 Stock Option Plan and 2000 Stock Option Plan include cash or, at the discretion of the committee, common stock, a deferred payment arrangement or other legal consideration approved by the committee. Generally, an optionee may not transfer a stock option granted under the 1999 Stock Option Plan and 2000 Stock Option Plan, other than by will or the laws of descent and distribution unless the optionee holds a nonstatutory stock option that provides otherwise.

Changes in Control. The 1999 Stock Option Plan and 2000 Stock Option Plan provide that in the event of a change in control of us, all shares subject to option awards under the plans shall immediately vest and be converted into cash, options or stock of equivalent value in the surviving

organization under terms and conditions that substantially preserve the economic status of plan participants. For this purpose, a change in control includes (1) a sale or disposition of more than 50% of our issued and outstanding voting stock; (2) a merger or consolidation in which our stockholders immediately before the transaction own less than 50% of the outstanding voting securities of the surviving entity immediately after the transaction; or (3) a sale or disposition of all or substantially all of our assets.

2001 Stock Option Plan and 2002 Stock Option Plan

In October 2001, we adopted the 2001 Stock Option Plan. Our Board of Directors amended the 2001 Stock Option Plan in November 2001. The 2001 Stock Option Plan will terminate in October 2011 unless the Board of Directors terminates it earlier. In August 2002, we adopted the 2002 Stock Option Plan. The 2002 Stock Option Plan will terminate in August 2012 unless the Board of Directors terminates it earlier. The 2001 Stock Option Plan and the 2002 Stock Option Plan provide for the grant of options that are:

- incentive stock options, as defined under the Internal Revenue Code of 1986, as amended, or the Code, which may be granted solely to employees, including officers; and

- nonstatutory stock options, which may be granted to directors, employees, including officers, or consultants.

Share Reserve. An aggregate of 298,775 shares of common stock are reserved for issuance under the 2001 Stock Option Plan. Options to purchase an aggregate of 261,375 shares of common stock were outstanding under the 2001 Stock Option Plan as of December 31, 2003. An aggregate of 850,000 shares of common stock are reserved for issuance under the 2002 Stock Option Plan. Options to purchase an aggregate of 493,000 shares of common stock were outstanding under the 2002 Stock Option Plan as of December 31, 2003.

Shares subject to stock options that have expired or otherwise terminated under the 2001 Stock Option Plan or 2002 Stock Option Plan without having been exercised in full again become available for the grant of awards under the 2001 Stock Option Plan or 2002 Stock Option Plan. Shares issued under the 2001 Stock Option Plan or 2002 Stock Option Plan may be previously unissued shares or reacquired shares bought on the market or otherwise.

Administration. The 2001 Stock Option Plan and 2002 Stock Option Plan are administered by a committee of our Board of Directors. Subject to the terms of the 2001 Stock Option Plan and 2002 Stock Option Plan, the committee determines the recipients, the number and type of stock options to be granted and the terms and conditions of the stock options. Subject to the limitations set forth below, the committee also determines the exercise price of options granted.

Stock Options. Stock options are granted under the 2001 Stock Option Plan and 2002 Stock Option Plan pursuant to stock option agreements. The exercise price for an incentive stock option cannot be less than the fair market value of the common stock on the date of grant. There is no restriction on the exercise price for a nonstatutory stock option. Unless otherwise specified in an option agreement, options granted under the 2001 Stock Option Plan or 2002 Stock Option Plan vest one-third on the third anniversary of the date of grant, one-third on the fourth anniversary of the date of grant, and one-third on the fifth anniversary of the date of grant.

The term of stock options granted under the 2001 Stock Option Plan or 2002 Stock Option Plan may not exceed 10 years. Unless otherwise provided for in the stock option agreement, options granted under the 2001 Stock Option Plan or 2002 Stock Option Plan terminate three months after termination of the optionee's employment or service as a director of GTx or an affiliate unless (1) the termination is due to the optionee's disability, in which case the option may provide that it may be exercised at any time within one year following termination of employment or relationship; (2) the termination is due to the death of optionee or death occurs within three months after the termination of the optionee, in which case the option may provide that it may be exercised at any time within

18 months following the death of optionee; or (3) the termination is due to voluntary retirement, subject to some conditions, in which case the option may be exercised at any time within five years of the date of retirement subject to the express term of the option. Any vested but unexercised options will terminate upon the optionee competing with us.

Acceptable consideration for the purchase of common stock issued under the 2001 Stock Option Plan or 2002 Stock Option Plan include cash or, at the discretion of the committee, common stock, a deferred payment arrangement or other legal consideration approved by the committee. Generally, an optionee may not transfer a stock option granted under the 2001 Stock Option Plan or 2002 Stock Option Plan, other than by will or the laws of descent and distribution unless the optionee holds a nonstatutory stock option that provides otherwise.

Tax Limitations on Stock Option Grants. Incentive stock options may be granted only to our employees. The aggregate fair market value, determined at the time of grant, of shares of our common stock with respect to incentive stock options that are exercisable for the first time by an optionee during any calendar year under all of our stock plans may not exceed $100,000. The options or portions of options that exceed this limit are treated as nonstatutory stock options. No incentive stock option, and before our stock is publicly traded, no nonstatutory stock option, may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or any affiliate unless the following conditions are satisfied:

- the option exercise price must be at least 110% of the fair market value of the stock subject to the option on the date of grant; and
- the term of any incentive stock option award must not exceed five years from the date of grant.

Changes in Control. The 2001 Stock Option Plan and 2002 Stock Option Plan provide that in the event of a change in control of us, all shares subject to option awards under the plans shall immediately vest and be converted into cash, options or stock of equivalent value in the surviving organization under terms and conditions that substantially preserve the economic status of plan participants. For this purpose, a change in control includes (1) a sale or disposition of more than 50% of our issued and outstanding voting stock; (2) a merger or consolidation in which our stockholders immediately before the transaction own less than 50% of the outstanding voting securities of the surviving entity immediately after the transaction; or (3) a sale or disposition of all or substantially all of our assets.

2004 Equity Incentive Plan

We adopted and our stockholders approved our 2004 Equity Incentive Plan in January 2004 to become effective upon the closing of this offering. The 2004 Equity Incentive Plan will terminate when the Board of Directors terminates the plan. The 2004 Equity Incentive Plan provides for the grant of nonstatutory stock options, restricted stock awards, stock appreciation rights, phantom stock rights and other forms of equity compensation, which may be granted to employees, including officers, non-employee directors and consultants.

Share Reserve. An aggregate of 1,500,000 shares of common stock will be reserved for issuance under the 2004 Equity Incentive Plan, which amount will be increased annually on January 1st of each year, from 2005 until 2013, by five percent of the number of shares of common stock outstanding on such date. However, the Board of Directors has the authority to designate a smaller number of shares by which the authorized number of shares of common stock will be increased on such date. As of the date hereof, no shares of common stock have been issued under the 2004 Equity Incentive Plan.

The following types of shares issued under the 2004 Equity Incentive Plan may again become available for the grant of new awards under the 2004 Equity Incentive Plan: restricted stock that is

repurchased or forfeited prior to it becoming fully vested; shares withheld for taxes; shares used to pay the exercise price of an option in a net exercise; and shares tendered to the company to pay the exercise price of an option. In addition, shares subject to stock options that have expired or otherwise terminated without having been exercised in full may again become available for the grant of new awards under the 2004 Equity Incentive Plan. Shares issued under the 2004 Equity Incentive Plan may be previously unissued shares or reacquired shares bought on the market or otherwise.

Administration. Our Board of Directors will administer the 2004 Equity Incentive Plan. The Board of Directors may delegate authority to administer the 2004 Equity Incentive Plan to a committee. Subject to the terms of the 2004 Equity Incentive Plan, our Board of Directors or its authorized committee, the plan administrator, determines recipients, grant dates, the numbers and types of equity awards to be granted and the terms and conditions of the equity awards, including the period of their exercisability and vesting. Subject to the limitations set forth below, the plan administrator will also determine the exercise price of options granted, the purchase price for rights to purchase restricted stock and, if applicable, phantom stock and the strike price for stock appreciation rights. The plan administrator may also amend the terms of the plan and outstanding equity awards. Amendments to the 2004 Equity Incentive Plan are subject to shareholder approval to the extent required by law, rule or regulation. In addition, the plan administrator may amend an option to lower its exercise price or exchange an option for an option with a lower exercise price, another equity award, cash or any other valuable consideration or may take any other action that is treated as a repricing under generally accepted accounting principles.

Nonstatutory Stock Options. Nonstatutory stock options will be granted pursuant to nonstatutory stock option agreements. The plan administrator determines the exercise price for a nonstatutory stock option. Options granted under the 2004 Equity Incentive Plan vest at the rate specified in the option agreement.

Generally, the plan administrator determines the term of nonstatutory stock options granted under the 2004 Equity Incentive Plan. Unless the terms of an optionee's nonstatutory stock option agreement provide otherwise, if an optionee's service relationship with us, or any of our affiliates, ceases due to disability or death, the optionee, or his or her beneficiary, may exercise any vested options up to 12 months in the event of disability, 18 months in the event of death and 24 months in the event of retirement, after the date such service relationship ends. If an optionee's relationship with us, or any affiliate of ours, ceases for any reason other than disability, death or retirement the optionee may exercise any vested options up to three months from cessation of service, unless the terms of the stock option agreement provide for earlier or later termination.

Acceptable consideration for the purchase of common stock issued upon the exercise of a nonstatutory stock option will be determined by the plan administrator and may include cash, common stock previously owned by the optionee, a broker assisted exercise and the net exercise of the option.

Generally, an optionee may not transfer a nonstatutory stock option other than by will or the laws of descent and distribution unless the nonstatutory stock option agreement provides otherwise. However, an optionee may designate a beneficiary who may exercise the option following the optionee's death.

Restricted Stock Awards. Restricted stock awards are purchased through a restricted stock award agreement. The purchase price for restricted stock awards must be at least the par value of the stock. The purchase price for a restricted stock award may be payable in cash or the recipient's past or future services performed or to be performed for us or any of our affiliates. Rights to acquire shares under a restricted stock award may not be transferred other than by will or by the laws of descent and distribution.

Stock Appreciation Rights. Stock appreciation rights are granted pursuant to stock appreciation rights agreements. The plan administrator determines the strike price for a stock

appreciation right. A stock appreciation right granted under the 2004 Equity Incentive Plan vests at the rate specified in the stock appreciation right agreement.

The plan administrator determines the term of stock appreciation rights granted under the 2004 Equity Incentive Plan. If an awardee's service relationship with us, or any of our affiliates, ceases due to disability or death, the awardee, or his or her beneficiary, may exercise any vested stock appreciation right up to three months or such longer or shorter period of time provided in the stock appreciation rights agreement. Different post-termination exercise periods may be provided in the stock appreciation rights agreement for specific terminations of service such as death, disability or retirement.

Phantom Stock Awards. Phantom stock awards are granted pursuant to phantom stock award agreements. A phantom stock award may require the payment of at least par value. Payment of any purchase price may be made in any form of legal consideration acceptable to the plan administrator. Rights to acquire shares under a phantom stock agreement may not be transferred other than by will or by the laws of descent and distribution.

Other Equity Awards. The plan administrator may grant other awards based in whole or in part by reference to our common stock. The plan administrator will set the number of shares under the award, the purchase price, if any, the timing of exercise and vesting and any repurchase rights associated with such awards. Unless otherwise specifically provided for in the award agreement, such awards may not be transferred other than by will or by the laws of descent and distribution.

Changes in Control. In the event of specified corporate transactions, all outstanding options and stock appreciation rights under the incentive plan either will be assumed, continued or substituted for by any surviving or acquiring entity. If the surviving or acquiring entity elects not to assume, continue or substitute for such awards, such equity awards will become fully vested and exercisable and such equity awards will be terminated if not exercised prior to the effective date of the corporate transaction. Other forms of equity awards such as restricted stock awards may have their repurchase or forfeiture rights assigned to the surviving or acquiring entity. If such repurchase or forfeiture rights are not assigned, then such equity awards will become fully vested. Following specified change in control transactions, the vesting and exercisability of specified equity awards generally will be accelerated only if the awardee's award agreement so specifies. The standard form of stock option agreement provides for options to become fully vested and exercisable if an optionee is involuntarily terminated without cause or has a constructive termination, in either case, within twelve months after the change in control.

2004 Non-Employee Directors' Stock Option Plan

We adopted and our stockholders approved our 2004 Non-Employee Directors' Stock Option Plan in January 2004 to become effective upon the closing of this offering. The 2004 Non-Employee Directors' Stock Option Plan provides for the automatic grant of nonstatutory stock options to purchase shares of common stock to our non-employee directors who own less than ten percent of the combined voting power of our then outstanding securities.

Share Reserve. The aggregate number of shares of common stock that may be issued pursuant to options granted under the 2004 Non-Employee Directors' Stock Option Plan is 200,000 shares, which amount will be increased annually on January 1st of each year, from 2005 and until 2013, by the number of shares of common stock subject to options granted during the prior calendar year. However, the Board of Directors has the authority to designate a smaller number of shares by which the authorized number of shares of common stock will be increased. As of the date hereof, no shares of common stock have been issued under the 2004 Non-Employee Directors' Stock Option Plan.

Administration. Our Board of Directors will administer the 2004 Non-Employee Directors' Stock Option Plan. The exercise price of the options granted under the 2004 Non-Employee Directors' Stock Option Plan will be equal to the fair market value of the common stock on the date of grant; provided,

however that initial grants made within three months after the initial public offering will have an exercise price equal to the offering price. No option granted under the 2004 Non-Employee Directors' Stock Option Plan may be exercised after the expiration of ten years from the date it was granted. Options granted under the 2004 Non-Employee Directors' Stock Option Plan are transferable only to the extent permitted under the rules of a Form S-8 registration statement. In addition, such options are transferable by will or by the laws of descent and distribution. Such options are exercisable during the life of the optionee only by the optionee or a permitted transferee. An optionee may designate a beneficiary who may exercise the option following the optionee's death. An optionee whose service relationship with the us or any of our affiliates, whether as a non-employee director of the company or subsequently as an employee, director or consultant of either the company or an affiliate, ceases for any reason may exercise vested options for the term provided in the option agreement, three months generally, 12 months in the event of disability and 18 months in the event of death and 12 months after a termination of service occurring on or as a condition of a change in control.

Automatic Grants. Upon the completion of this offering, each eligible non-employee director will automatically be granted an option to purchase 10,000 shares of common stock, the initial grant. Any individual who becomes an eligible non-employee director after this offering will automatically be granted the initial grant upon election to the Board of Directors. Any person who is an eligible non-employee director on the day after an annual meeting of our stockholders, commencing with our annual meeting in 2005, automatically will be granted an option to purchase 2,000 shares of common stock, the annual grant, on such date; *provided, however,* that an eligible non-employee director will not receive an annual grant until the first annual meeting that is at least one year after the date of his or her initial grant. Initial grants and annual grants vest in three equal annual installments.

Changes in Control. In the event of specified corporate transactions, all outstanding options under the 2004 Non-Employee Directors' Stock Option Plan will be either assumed, continued or substituted for by any surviving entity. If the surviving or acquiring entity elects not to assume, continue or substitute for such options, such options will become fully vested and exercisable and such options will be terminated if not exercised prior to the effective date of such corporate transaction. In the event of specified changes in control, outstanding options granted under the 2004 Non-Employee Directors' Stock Option Plan granted to non-employee directors will become fully vested and exercisable as of the change in control. In addition, options held by non-employee directors will become fully vested and exercisable if such director must resign from our Board of Directors as a condition of a change in control.

401(k) Plan

We maintain a retirement and deferred savings plan for our employees. The retirement and deferred savings plan is intended to qualify as a tax-qualified plan under Section 401 of the Code. The retirement and deferred savings plan provides that each participant may contribute up to 15% of his or her pre-tax compensation, up to a statutory limit, which for most employees is $13,000 in 2004. Under the plan, each employee is fully vested in his or her deferred salary contributions. Employee contributions are held and invested by the plan's trustee. The retirement and deferred savings plan also permits us to make discretionary contributions and matching contributions, subject to established limits and a vesting schedule. To date, we have not made any discretionary contributions to the retirement and deferred savings plan on behalf of participating employees.

Limitations on Directors' Liability and Indemnification Agreements

As permitted by Delaware law, we have adopted provisions in our certificate of incorporation and bylaws, both of which will become effective upon the completion of this offering, that limit or eliminate the personal liability of directors for a breach of their fiduciary duty of care as a director. The duty of care generally requires that, when acting on behalf of the corporation, a director exercise an informed business judgment based on all material information reasonably available to him or her.

Consequently, a director will not be personally liable to us or our stockholders for monetary damages or breach of fiduciary duty as a director, except for liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- any act related to unlawful stock repurchases, redemptions or other distributions or payments of dividends; or
- any transaction from which the director derived an improper personal benefit.

These limitations of liability do not limit or eliminate our rights or any stockholder's rights to seek non-monetary relief, such as injunctive relief or rescission. These provisions will not alter a director's liability under federal securities laws. Our certificate of incorporation that will become effective upon the completion of this offering also authorizes us to indemnify our officers, directors and other agents to the fullest extent permitted under Delaware law.

As permitted by Delaware law, our bylaws also provide that:

- we will indemnify our directors, officers, employees and other agents to the fullest extent permitted by law;
- we may advance expenses to our directors, officers, employees and other agents in connection with a legal proceeding to the fullest extent permitted by law; and
- the rights provided in our bylaws are not exclusive.

We believe that indemnification under our bylaws covers at least negligence and gross negligence on the part of indemnified parties. Our bylaws also permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in connection with their services to us, regardless of whether our bylaws permit such indemnification. We have obtained such insurance.

In addition to the indemnification provided for in our certificate of incorporation and bylaws, we have entered, and intend to continue to enter, into separate indemnification agreements with each of our directors and executive officers which may be broader than the specific indemnification provisions contained in the Delaware General Corporation Law. These indemnification agreements may require us, among other things, to indemnify our directors and executive officers for some expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or executive officer in any action or proceeding arising out of his service as one of our directors or executive officers, or any of our subsidiaries or any other company or enterprise to which the person provides services at our request. We believe that these provisions and agreements are necessary to attract and retain qualified individuals to serve as directors and executive officers. There is no pending litigation or proceeding involving any of our directors or executive officers to which indemnification is required or permitted, and we are not aware of any threatened litigation or proceeding that may result in a claim for indemnification.

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The following is a description of transactions since May 1999 to which we have been a party, in which the amount involved in the transaction exceeds $60,000, and in which any of our directors, executive officers or holders of more than five percent of our capital stock had or will have a direct or indirect material interest, other than the employment agreements described elsewhere.

Preferred Stock Issuances

We sold shares of our preferred stock in private financings as follows:

- 200,000 shares of our Series A preferred stock at a price of $7.275 per share in May 1999;
- 277,500 shares of our Series B preferred stock at a price of $18.018 per share in July 2000;
- 260,154 shares of our Series C preferred stock at a price of $57.658 per share in October 2001;
- 164,765 shares of our Series D preferred stock at a price of $66.762 per share in July 2002; and
- 329,536 shares of our Series E preferred stock at a price of $60.692 per share in August 2003.

Upon the closing of this offering, all of these shares of preferred stock and dividends accrued thereon through December 31, 2003 will convert into 11,456,912 shares of our common stock.

The investors in these financings included the following executive officers, directors, holders of more than five percent of our securities and the immediate family members and affiliated entities of each:

Investors	Series A Preferred Stock	Series B Preferred Stock	Series C Preferred Stock	Series D Preferred Stock	Series E Preferred Stock
Directors					
J.R. Hyde, III	200,000	277,500	77,718	74,894	283,777
John H. Pontius	—	—	—	—	1,648
Executive Officers					
Mark E. Mosteller	—	—	—	—	824
Henry P. Doggrell	—	—	—	—	1,236
Immediate Family Members					
Patricia B. Pontius	—	—	—	—	1,648
Kathryn K. Mosteller	—	—	—	—	824
Beverly R. Doggrell	—	—	—	—	412
5% Stockholders					
Entities affiliated with Oracle Partners, L.P.	—	—	173,436	74,894	16,478
Affiliated Entities					
Pittco Associates, L.P.(1)	—	—	9,000	—	—
Memphis Biomed Ventures I, L.P.(2)	—	—	—	14,977	16,477
Equity Partners XII, LLC(3)	—	—	—	—	6,212

(1) Pittco Associates, L.P. is affiliated with both Mr. Hyde and Mr. Pontius.

(2) Memphis Biomed Ventures I, L.P. is affiliated with Mr. Hyde.

(3) Mr. Hanover is the sole managing member of Equity Partners XII, LLC.

Registration Rights Agreements

We have entered into registration rights agreements with three of our preferred stockholders and their affiliates and transferees. Pursuant to the registration rights agreements, if we propose to register any of our securities under the Securities Act either for our own account or for the account of other security holders after this offering, as of December 31, 2003, the holders of registration rights will be entitled to include their 11,344,639 shares of common stock in the related registration statement. In addition, as of December 31, 2003, the holders of approximately 11,055,783 shares of common stock and their transferees may require us, on not more than two occasions from each holder of demand registration rights at any time after the closing of this offering, to file a registration statement under the Securities Act with respect to their shares of common stock. For more information concerning the registration rights agreements, please see "Description of Capital Stock — Registration Rights Agreements."

Indemnification Agreements

We have entered into separate indemnification agreements with our directors and executive officers, in addition to the indemnification provided for in our bylaws. See "Management — Limitations on Directors' Liability and Indemnification Agreements."

Transactions with Mr. Hyde

In July 2001, we borrowed $4.25 million from Mr. Hyde pursuant to the terms of a promissory note that bore interest at a rate of 9% per annum. All amounts due under the note were paid in full in October 2001. We paid Mr. Hyde $71,000 of interest in 2001. During 2003, we paid to Pittco, Inc., an affiliate of Mr. Hyde's, lease payments totaling $10,352 for the use of Pittco's airplane.

PRINCIPAL STOCKHOLDERS

The following table sets forth information as of December 31, 2003 regarding the beneficial ownership of our common stock by:

- each person, or group of affiliated persons, who is known by us to own beneficially five percent or more of our common stock;
- each of our directors;
- each of our named executive officers; and
- all our directors and executive officers as a group.

The number of shares owned and percentage ownership in the following table is based on 7,735,850 shares of common stock outstanding on December 31, 2003, the conversion of all outstanding shares of our preferred stock and the dividends accrued thereon through December 31, 2003 into 11,456,912 shares of common stock and the issuance of 5,400,000 shares in this offering. The information assumes no exercise of the underwriters' over-allotment option.

Each individual or entity shown on the table has furnished information with respect to beneficial ownership. Except as otherwise indicated below, the address of each officer, director and five percent stockholder listed below is c/o GTx, Inc., 3 N. Dunlap Street, 3rd Floor, Van Vleet Building, Memphis, Tennessee 38163.

We have determined beneficial ownership in accordance with the rules of the Securities and Exchange Commission. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, the rules include shares of common stock issuable pursuant to the exercise of stock options that are either immediately exercisable or exercisable within 60 days of December 31, 2003. These shares are deemed to be outstanding and beneficially owned by the person holding those options for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them.

Name and Address of Beneficial Owner	Number of Shares Owned	Percentage of Shares Outstanding	
		Before Offering	After Offering
5% Stockholders			
Entities affiliated with Oracle Partners, L.P.(1) 200 Greenwich Avenue Greenwich, CT 06830	2,616,929	13.6%	10.6%
Directors and Named Executive Officers			
J.R. Hyde, III(2)	8,630,084	45.0	35.1
Mitchell S. Steiner, M.D., F.A.C.S.(3)	4,897,156	25.5	19.9
Marc S. Hanover(4)	1,991,321	10.4	8.1
Mark E. Mosteller(5)	14,450	*	*
Henry P. Doggrell(6)	158,049	*	*
John H. Pontius(7)	967,088	5.0	3.9
Rosemary Mazanet, M.D., Ph.D.	—	—	—
All executive officers and directors as a group (7 persons)(8)	16,512,797	86.0	67.1

* Represents beneficial ownership of less than 1% of our outstanding common stock.

(1) Consists of 693,098 shares held by Oracle Partners, L.P., 1,750,550 shares held by Oracle Investment Management, Inc. and 173,281 shares held by Oracle Institutional Partners, L.P. Larry N. Feinberg is the managing member of the general partner of Oracle Partners, L.P. and Oracle Institutional Partners, L.P. and the President of Oracle Investment Management, Inc. Mr. Feinberg disclaims beneficial ownership of these shares except to the extent of his pecuniary interest in the named entities.

(2) Includes 90,916 shares held by Pittco Associates, L.P., an entity controlled by Mr. Hyde, 188,700 shares held by trusts of which Mr. Hyde is the trustee or co-trustee, 288,856 shares held by Memphis Biomed Ventures I, L.P., an entity controlled by Mr. Hyde, and 187,009 shares held by Mr. Hyde's wife, of which Mr. Hyde disclaims beneficial ownership.

(3) Consists of shares held by LD, Jr., LLC, an entity owned by Dr. Steiner.

(4) Includes 819,477 shares held by Equity Partners XII, LLC, an entity controlled by Mr. Hanover, and 870,222 shares held by trusts of which Mr. Hanover is the trustee.

(5) Includes 7,225 shares held by Mr. Mosteller's wife of which Mr. Mosteller disclaims beneficial ownership.

(6) Includes 94,350 shares held by a trust of which Mr. Doggrell is the co-trustee with Mr. Hyde, 51,000 shares that Mr. Doggrell has the right to acquire within 60 days of December 31, 2003 through the exercise of stock options and 3,613 shares held by Mr. Doggrell's wife, of which Mr. Doggrell disclaims beneficial ownership.

(7) Includes 853,273 shares held by trusts of which Mr. Pontius is the trustee, 17,510 shares held by trusts of which Mr. Pontius' wife is the trustee and 48,153 shares beneficially owned by Mr. Pontius' wife. Mr. Pontius disclaims beneficial ownership of the shares held by trusts of which his wife is trustee and shares beneficially owned by her.

(8) For purposes of determining the number of shares beneficially owned by directors and executive officers as a group, any shares held in the trust of which both Mr. Doggrell and Mr. Hyde are co- trustees are counted only once.

DESCRIPTION OF CAPITAL STOCK

The following description of our capital stock gives effect to the amendment and restatement of our certificate of incorporation and bylaws, which will occur upon the closing of this offering, and the conversion of our preferred stock and dividends accrued thereon through December 31, 2003 into 11,456,912 shares of common stock, which will occur upon the closing of this offering, as if such conversion had occurred on December 31, 2003.

Upon the closing of this offering, our authorized capital stock will consist of 60,000,000 shares of common stock, par value $0.001 per share, and 5,000,000 shares of preferred stock, par value $0.001 per share.

Common Stock

Outstanding Shares

As of December 31, 2003, we had 36 stockholders, 7,735,850 shares of common stock issued and outstanding and 1,231,955 shares of preferred stock issued and outstanding, which, together with dividends accrued thereon through December 31, 2003, are convertible into 11,456,912 shares of common stock. In addition, as of December 31, 2003, options to purchase 828,750 shares of common stock were issued and outstanding. Based on our outstanding capital stock as of December 31, 2003, upon completion of this offering, there will be 24,592,762 shares of common stock outstanding, assuming no exercise of the underwriters' over-allotment option or exercise of outstanding stock options.

Voting Rights

Each holder of our common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. Under our certificate of incorporation and bylaws, our stockholders will not have cumulative voting rights. Because of this, the holders of a majority of the shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they should so choose.

Dividends

Subject to preferences that may be applicable to any then outstanding preferred stock, holders of common stock are entitled to receive ratably those dividends, if any, as may be declared from time to time by the Board of Directors out of legally available funds.

Liquidation

In the event of our liquidation, dissolution or winding up, holders of common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any outstanding shares of preferred stock.

Rights and Preferences

Holders of common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to the common stock. The rights, preferences and privileges of the holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate in the future.

Fully Paid and Nonassessable

All of our outstanding shares of common stock are, and the shares of common stock to be issued pursuant to this offering will be, fully paid and nonassessable.

Preferred Stock

Upon the closing of this offering, the Board of Directors will have the authority, without further action by the stockholders, to issue up to 5,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon, and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding. The Board of Directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of GTx and may adversely affect the market price of the common stock and the voting and other rights of the holders of common stock.

Registration Rights

Demand Registration Rights

As of December 31, 2003, at any time after the closing of this offering, the holders of 11,055,783 shares of our common stock and their transferees may require us, on not more than two occasions from each holder of demand rights, to file a registration statement under the Securities Act with respect to their shares of common stock, and we will be required to use our best efforts to effect the registration.

Piggyback Registration Rights

As of December 31, 2003, at any time after the closing of this offering, if we propose to register any of our securities under the Securities Act either for our own account or for the account of other stockholders, the holders of approximately 11,344,639 shares of common stock will be entitled to notice of the registration and will be entitled to include their shares of common stock in the registration statement. These registration rights are subject to specified conditions and limitations, including the right of the underwriters to limit the number of shares included in any such registration under some circumstances.

Expenses of Registration

We will pay all expenses relating to any demand or piggyback registration, other than underwriting discounts and commissions.

Expiration

These registration rights expire only upon the sale of all shares of common stock that have registration rights. However, we are not required to maintain the effectiveness of a registration statement if the shares of common stock included in such registration statement may be sold without restriction pursuant to Rule 144(k) under the Securities Act.

Delaware Anti-Takeover Law and Certain Provisions of our Certificate of Incorporation and Bylaws

Delaware Law

We are governed by Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a public Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. A "business combination" includes mergers, asset sales or other transactions resulting in a financial benefit to the stockholder. An "interested stockholder" is a person who, together with affiliates and associates, owns, or within three years, did own, 15% or more of the corporation's outstanding voting stock. These provisions may have the effect of delaying, deferring or preventing a change in our control.

Certificate of Incorporation and Bylaw Provisions

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

- provide that any action required or permitted to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and may not be effected by any consent in writing;
- provide that the authorized number of directors may be changed only by resolution of the Board of Directors; and
- eliminate cumulative voting for the election of directors.

In addition, our bylaws that will become effective upon completion of this offering will provide that special meetings of our stockholders may be called only by the chairman of the Board of Directors, our chief executive officer or by the Board of Directors pursuant to a resolution adopted by a majority of the directors then in office.

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

Nasdaq National Market Listing

We have applied to quote our common stock on the Nasdaq National Market under the proposed trading symbol "GTXI".

Transfer Agent and Registrar

The Transfer Agent and Registrar for our common stock is EquiServe. The transfer agent's address is 525 Washington Blvd., P.O. Box 2533, Suite 4691, 9th Floor, Jersey City, NJ 07310.

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock. Market sales of shares or the availability of shares for sale may decrease the market price of our common stock prevailing from time to time. As described below, only a portion of our outstanding shares of common stock will be available for sale shortly after this offering due to contractual and legal restrictions to resale. Nevertheless, sales of substantial amounts of common stock in the public market after these restrictions lapse, or the perception that such sales could occur, could adversely affect the market price of the common stock and could impair our future ability to raise capital through the sale of our equity securities.

Future sales of our common stock and the availability of our common stock for sale may depress the market price for our common stock. Upon completion of this offering, 24,592,762 shares of common stock will be outstanding, assuming no exercise of the underwriters' over-allotment option and no exercise of options. All of the 5,400,000 shares sold in this offering will be freely tradable. The remaining 19,192,762 shares of common stock, based on the number of shares outstanding as of December 31, 2003, are restricted as a result of securities laws or lock-up agreements. 16,302,711 of these shares will be available for sale in the public market 180 days after the date of this prospectus. The remaining 2,890,051 shares will be available for sale in the public market between 180 and 365 days after the date of this prospectus, subject to early release from lock-up agreements as described below. A portion of the restricted shares will be subject to volume limitations pursuant to Rule 144.

Rule 144

In general, under Rule 144 under the Securities Act of 1933, as currently in effect, a person who has beneficially owned shares of our common stock for at least one year would be entitled to sell within any three-month period a number of shares that does not exceed the greater of:

- one percent of the number of shares of our common stock then outstanding, which will equal 245,928 shares immediately after this offering; or
- the average weekly trading volume of our common stock on the Nasdaq National Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Sales under Rule 144 are also subject to manner of sale provisions and notice requirements and to the availability of current public information about us.

Rule 144(k)

Under Rule 144(k), a person who is not deemed to have been one of our affiliates at any time during the 90 days preceding a sale, and who has beneficially owned the shares proposed to be sold for at least two years, including the holding period of any prior owner other than an affiliate, is entitled to sell the shares without complying with the manner of sale, public information, volume limitation or notice provisions of Rule 144.

Rule 701

Rule 701, as currently in effect, permits resales of shares in reliance upon Rule 144 but without compliance with some restrictions of Rule 144, including the holding period requirement. Our employees, officers, directors or consultants who purchased shares under a written compensatory plan or contract may be entitled to rely on the resale provisions of Rule 701, but all holders of Rule 701 shares are required to wait until 90 days after the date of this prospectus before selling their shares.

Lock-Up Agreements

Each of our officers, directors and stockholders and the holders of substantially all of our outstanding options have agreed, subject to specified exceptions, that, without the prior written consent of Goldman, Sachs & Co., they will not, directly or indirectly, sell, offer, contract to sell, transfer the economic risk of ownership in, make any short sale, pledge or otherwise dispose of any shares of our capital stock or any securities convertible into or exchangeable or exercisable for or any other rights to purchase or acquire our capital stock for a period of 180 days from the date of this prospectus. Goldman, Sachs & Co. may, in its sole discretion, permit early release of shares subject to the lock-up agreements.

Registration Rights

Upon completion of this offering, the holders of 11,344,640 shares of our common stock, or their transferees, will be entitled to rights with respect to the registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act immediately upon the effectiveness of the registration. See “Description of Capital Stock — Registration Rights.”

Stock Options

Immediately after this offering, we intend to file with the SEC a registration statement under the Securities Act covering the 2,982,650 shares of common stock reserved for issuance under our stock option plans. The registration statement is expected to be filed and become effective as soon as practicable after the closing of this offering. Accordingly, shares registered under the registration statement will, subject to Rule 144 volume limitations applicable to affiliates and the lock-up agreements described above, be available for sale in the open market.

UNDERWRITING

GTx and the underwriters named below have entered into an underwriting agreement with respect to the shares being offered. Subject to certain conditions, each underwriter has severally agreed to purchase the number of shares indicated in the following table. Goldman, Sachs & Co., SG Cowen Securities Corporation and Lazard Frères & Co. LLC are the representatives of the underwriters.

Underwriters	Number of Shares
Goldman, Sachs & Co.	
SG Cowen Securities Corporation	
Lazard Frères & Co. LLC	
Total	5,400,000

The underwriters are committed to take and pay for all of the shares being offered, if any are taken, other than the shares covered by the option described below unless and until this option is exercised.

If the underwriters sell more shares than the total number set forth in the table above, the underwriters have an option to buy up to an additional 810,000 shares from GTx to cover such sales. They may exercise that option for 30 days. If any shares are purchased pursuant to this option, the underwriters will severally purchase shares in approximately the same proportion as set forth in the table above.

The following table shows the per share and total underwriting discounts and commissions to be paid to the underwriters by GTx. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase 810,000 additional shares.

	Paid By GTx	
	No Exercise	Full Exercise
Per Share	$	$
Total	$	$

Shares sold by the underwriters to the public will initially be offered at the initial public offering price set forth on the cover of this prospectus. Any shares sold by the underwriters to securities dealers may be sold at a discount of up to $ per share from the initial public offering price. Any such securities dealers may resell any shares purchased from the underwriters to certain other brokers or dealers at a discount of up to $ per share from the initial public offering price. If all the shares are not sold at the initial public offering price, the representatives may change the offering price and the other selling terms.

GTx and its officers, directors and principal stockholders have agreed with the underwriters not to dispose of or hedge any of their common stock or securities convertible into or exchangeable for shares of common stock during the period from the date of this prospectus continuing through the date 180 days after the date of this prospectus, except with the prior written consent of Goldman, Sachs & Co. This agreement does not apply to the issuance of shares by GTx pursuant to any existing employee benefit plans. See "Shares Eligible for Future Sale" for a discussion of certain transfer restrictions.

At the request of GTx, the underwriters are reserving for sale, at the initial public offering price, to directors, officers, employees and friends through a directed share program up to 5% of the shares being offered. The number of shares available for sale to the general public in the offering will be reduced to the extent these persons purchase these reserved shares. Any reserved shares not so purchased will be offered to the general public on the same basis as the other shares offered under this prospectus.

Prior to the offering, there has been no public market for the shares. The initial public offering price has been negotiated among GTx and the representatives. Among the factors to be considered in determining the initial public offering price of the shares, in addition to prevailing market conditions, will be GTx's historical performance, estimates of the business potential and earnings prospects of GTx, an assessment of GTx's management and the consideration of the above factors in relation to market valuation of companies in related businesses.

An application has been made to quote the common stock on the Nasdaq National Market under the symbol "GTXI".

A prospectus in electronic format may be made available on a website maintained by one or more of the representatives of the underwriters and may also be made available on a website maintained by other underwriters. The underwriters may agree to allocate a number of shares to underwriters for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives of the underwriters to underwriters that may make Internet distributions on the same basis as other allocations.

In connection with the offering, the underwriters may purchase and sell shares of common stock in the open market. These transactions may include short sales, stabilizing transactions and purchases to cover positions created by short sales. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering. "Covered" short sales are sales made in an amount not greater than the underwriters' option to purchase additional shares from GTx in the offering. The underwriters may close out any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase additional shares pursuant to the option granted to them. "Naked" short sales are any sales in excess of such option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of common stock made by the underwriters in the open market prior to the completion of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Purchases to cover a short position and stabilizing transactions may have the effect of preventing or retarding a decline in the market price of GTx's stock, and together with the imposition of a penalty bid, may stabilize, maintain or otherwise affect the market price of the common stock. As a result, the price of the common stock may be higher than the price that otherwise might exist in the open market. If these activities are commenced, they may be discontinued at any time. These transactions may be effected on the Nasdaq National Market, in the over-the-counter market or otherwise.

Each underwriter has represented that: (1) it has not offered or sold and, prior to the expiry of a period of six months from the closing date, will not offer or sell any shares to persons in the United Kingdom except to persons whose ordinary activities involve them in acquiring, holding, managing or disposing of investments, as principal or agent, for the purposes of their businesses or otherwise in circumstances which have not resulted and will not result in an offer to the public in the United Kingdom within the meaning of the Public Offers of Securities Regulations 1995; (2) it has only communicated or caused to be communicated and will only communicate or cause to be communicated any invitation or inducement to engage in investment activity, within the meaning of section 21 Financial Services and Markets Act of 2000, or the FSMA, received by it in connection

with the issue or sale of any shares in circumstances in which section 21(1) of the FSMA does not apply to GTx; and (3) it has complied and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the shares in, from or otherwise involving the United Kingdom.

The shares may not be offered or sold, transferred or delivered, as part of their initial distribution or at any time thereafter, directly or indirectly, to any individual or legal entity in the Netherlands other than to individuals or legal entities who or which trade or invest in securities in the conduct of their profession or trade, which includes banks, securities intermediaries, insurance companies, pension funds, other institutional investors and commercial enterprises which, as an ancillary activity, regularly trade or invest in securities.

No underwriter has offered or sold, or will offer or sell, in Hong Kong, by means of any document, any shares other than to persons whose ordinary business it is to buy or sell shares or debentures, whether as principal or agent, or under circumstances which do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap. 32) of Hong Kong, nor has it issued or had in its possession for the purpose of issue, nor will it issue or have in its possession for the purpose of issue, any invitation or advertisement relating to the shares in Hong Kong (except as permitted by the securities laws of Hong Kong) other than with respect to shares which are intended to be disposed of to persons outside Hong Kong or to be disposed of only to persons whose business involves the acquisition, disposal, or holding of securities (whether as principal or as agent).

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation or subscription or purchase, of the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than under circumstances in which such offer, sale or invitation does not constitute an offer or sale, or invitation for subscription or purchase, of the shares to the public in Singapore.

Each underwriter has acknowledged and agreed that the shares have not been registered under the Securities and Exchange Law of Japan and are not being offered or sold and may not be offered or sold, directly or indirectly, in Japan or to or for the account of any resident of Japan, except pursuant to an exemption from the registration requirements of the Securities and Exchange Law of Japan and in compliance with any other applicable requirements of Japanese law.

The underwriters do not expect sales to discretionary accounts to exceed five percent of the total number of shares offered.

GTx estimates that its share of the total expenses of the offering, excluding underwriting discounts and commissions, will be approximately $2.3 million.

GTx has agreed to indemnify the several underwriters against certain liabilities, including liabilities under the Securities Act of 1933.

Certain of the underwriters and their respective affiliates may in the future perform various financial advising and investment banking services for GTx, for which they may receive customary fees and expenses.

VALIDITY OF THE COMMON STOCK

The validity of the shares of common stock offered hereby and certain other legal matters will be passed upon for us by Cooley Godward LLP, Palo Alto, California. Certain legal matters will also be passed upon for us by Bass, Berry & Sims PLC, Memphis, Tennessee. Certain legal matters will be passed upon for the underwriters by Hale and Dorr LLP, Boston, Massachusetts.

EXPERTS

The financial statements of GTx, Inc. as of December 31, 2002 and 2001 and for each of the three years in the period ended December 31, 2002 appearing in this prospectus and registration statement, have been audited by Ernst & Young LLP, independent auditors, as set forth in their report thereon appearing elsewhere herein, and are included in reliance upon such report, given on the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the Securities and Exchange Commission, or SEC, a registration statement on Form S-1 under the Securities Act of 1933 with respect to the shares of common stock offered under this prospectus. This prospectus does not contain all of the information in the registration statement and the exhibits. For further information with respect to us and our common stock, we refer you to the registration statement and to the exhibits. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

You can read our SEC filings, including the registration statement, over the Internet at the SEC's web site at www.sec.gov. You may also read and copy any document we file with the SEC at its public reference facility at 450 Fifth Street, N.W., Washington, D.C. 20549. You may also obtain copies of the document at prescribed rates by writing to the Public Reference Section of the SEC at 450 Fifth Street, N.W., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facility.

Upon completion of this offering, we will be subject to the information reporting requirements of the Securities Exchange Act of 1934, as amended, and we will file reports, proxy statements and other information with the SEC. We also intend to furnish our stockholders with annual reports containing our financial statements audited by an independent public accounting firm and quarterly reports containing our unaudited financial information.

GTx, Inc.

(a development stage company)

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REPORT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS

Board of Directors and Stockholders

GTx, Inc.

We have audited the accompanying balance sheets of GTx, Inc. (a development stage company) as of December 31, 2002 and 2001, and the related statements of operations, cumulative redeemable convertible preferred stock and stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2002. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

Since the date of completion of our audit of the accompanying financial statements and initial issuance of our report thereon dated May 9, 2003, which report contained an explanatory paragraph regarding the Company's ability to continue as a going concern, the Company, as discussed in the second paragraph of Note 2, has completed an issuance of preferred stock with net proceeds of approximately $20 million and plans, if additional funding efforts are unsuccessful, to reduce its cash expenditures such that it will continue its operations beyond December 31, 2004. Therefore, the conditions that raised substantial doubt about whether the Company will continue as a going concern no longer exist.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of GTx, Inc. (a development stage company) at December 31, 2002 and 2001, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2002, in conformity with accounting principles generally accepted in the United States.

/s/ Ernst & Young LLP

Memphis, Tennessee

May 9, 2003,
Except for Note 1, as to which the date is
December 1, 2003, and
except for Note 13, as to which the date is
January 14, 2004

GTx, Inc.

(a development stage company)

BALANCE SHEETS

(in thousands, except share data)

	December 31,		September 30,	Pro Forma Stockholders' Equity at
	2001	2002	2003	September 30, 2003
			(unaudited)	(unaudited)
ASSETS				
Current assets:				
Cash and cash equivalents	$ 8,834	$ 8,925	$ 19,788	
Acapodene inventory	154	—	121	
Prepaid expenses and other current assets	46	41	338	
Total current assets	9,034	8,966	20,247	
Property and equipment, net	1,083	1,064	860	
Total assets	$ 10,117	$ 10,030	$ 21,107	
LIABILITIES, CUMULATIVE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)				
Current liabilities:				
Accounts payable	$ 261	$ 601	$ 747	
Accrued expenses	229	711	1,220	
Total current liabilities	490	1,312	1,967	
8% Cumulative Redeemable Convertible Preferred Stock, at redemption value:				
Series A, $0.001 par value; 200,000 shares authorized, issued and outstanding at all periods, liquidation value of $1,770 at December 31, 2001, $1,889 at December 31, 2002 and $1,983 at September 30, 2003 (unaudited)	11,847	13,855	25,691	
Series B, $0.001 par value; 277,500 shares authorized, issued and outstanding at all periods, liquidation value of $5,581 at December 31, 2001, $5,989 at December 31, 2002 and $6,313 at September 30, 2003 (unaudited)	16,581	19,671	36,882	
Series C, $0.001 par value; 450,000 shares authorized, 260,154 issued and outstanding at all periods, liquidation value of $15,274 at December 31, 2001, $16,496 at December 31, 2002 and $17,468 at September 30, 2003 (unaudited)	15,274	19,102	37,213	
Series D, $0.001 par value; 300,000 shares authorized, 164,765 issued and outstanding at December 31, 2002 and September 30, 2003, liquidation value of $0 at December 31, 2001, $11,398 at December 31, 2002 and $12,073 at September 30, 2003 (unaudited)	—	11,398	22,238	
Series E, $0.001 par value; 450,000 shares authorized, 329,536 issued and outstanding at September 30, 2003, liquidation value of $0 at December 31, 2001 and December 31, 2002 and $20,236 at September 30, 2003 (unaudited)	—	—	40,954	
Total cumulative redeemable convertible preferred stock	43,702	64,026	162,978	
Stockholders' equity (deficit):				
Common stock, $0.001 par value: 25,000,000 shares authorized; 7,735,000 shares issued and outstanding at December 31, 2001 and 2002 and September 30, 2003 (unaudited); 19,031,780 shares outstanding on a pro forma basis (unaudited)	8	8	8	19
Deferred stock compensation	—	—	(3,408)	(3,408)
Additional paid-in capital	962	962	4,453	167,688
Deficit accumulated during the development stage	(35,045)	(56,278)	(144,891)	(145,159)
Total stockholders' (deficit) equity	(34,075)	(55,308)	(143,838)	$ 19,140
Total liabilities and stockholders' deficit	$ 10,117	$ 10,030	$ 21,107	

The accompanying notes are an integral part of these financial statements.

GTx, Inc.

(a development stage company)

STATEMENTS OF OPERATIONS

(in thousands, except share and per share data)

	Year Ended December 31,			Nine Months Ended September 30,		Cumulative Period from September 24, 1997 (date of inception) to September 30, 2003
	2000	2001	2002	2002	2003	
				(unaudited)	(unaudited)	(unaudited)
Operating expenses:						
Research and development	$ 2,679	$ 5,744	$ 9,285	$ 6,408	$ 7,123	$ 25,534
General and administrative	1,203	2,187	2,405	1,830	2,339	8,569
Depreciation	80	215	332	240	264	955
Total operating expenses	3,962	8,146	12,022	8,478	9,726	35,058
Other income:						
Research and development income	—	—	—	—	—	225
Interest income	150	83	156	105	79	579
Total other income	150	83	156	105	79	804
Net loss	(3,812)	(8,063)	(11,866)	(8,373)	(9,647)	(34,254)
Accrued preferred stock dividends	(297)	(790)	(2,147)	(1,466)	(2,300)	(5,617)
Adjustments to preferred stock redemption value	(21,077)	(57)	(7,220)	(7,147)	(76,666)	(105,020)
Net loss attributable to common stockholders	$ (25,186)	$ (8,910)	$ (21,233)	$ (16,986)	$ (88,613)	$(144,891)
Net loss per share attributable to common stockholders, basic and diluted:	$ (3.26)	$ (1.15)	$ (2.75)	$ (2.20)	$ (11.46)	
Weighted average shares used in computing net loss per share attributable to common stockholders, basic and diluted	7,735,000	7,735,000	7,735,000	7,735,000	7,735,000	
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)			$ (0.80)		$ (0.59)	
Shares used in computing pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)			14,811,786		16,455,728	

The accompanying notes are an integral part of these financial statements.

GTx, Inc.

(a development stage company)

STATEMENTS OF CUMULATIVE REDEEMABLE CONVERTIBLE PREFERRED STOCK AND

STOCKHOLDERS' EQUITY (DEFICIT)
For the Period From September 24, 1997 (date of inception) To September 30, 2003
(in thousands, except share and per share data)

	Cumulative Redeemable Convertible Preferred Stock		Stockholders' Equity (Deficit)					
			Common Stock		Deferred Stock Compensation	Additional Paid-in Capital	Deficit Accumulated During the Development Stage	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balances at September 24, 1997	—	$ —	—	$ —	$ —	$ —	$ —	$ —
Issuance of common stock	—	—	7,650,000	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—
Balances at December 31, 1997	—	—	7,650,000	—	—	—	—	—
Issuance of common stock	—	—	850,000	8	—	962	—	970
Net loss	—	—	—	—	—	—	(116)	(116)
Balances at December 31, 1998	—	—	8,500,000	8	—	962	(116)	854
Sale of Series A Redeemable Convertible Preferred Stock at $7.275	200,000	1,455	—	—	—	—	—	—
Preferred stock dividends	—	83	—	—	—	—	(83)	(83)
Net loss	—	—	—	—	—	—	(750)	(750)
Balances at December 31, 1999	200,000	1,538	8,500,000	8	—	962	(949)	21
Sale of Series B Redeemable Convertible Preferred Stock at $18.018	277,500	5,000	—	—	—	—	—	—
Preferred stock dividends	—	297	—	—	—	—	(297)	(297)
Preferred stock adjustment to redemption value	—	21,077	—	—	—	—	(21,077)	(21,077)
Common stock redemption	—	—	765,000	—	—	—	—	—
Net loss	—	—	—	—	—	—	(3,812)	(3,812)
Balances at December 31, 2000	477,500	27,912	7,735,000	8	—	962	(26,135)	(25,165)
Sale of Series C Redeemable Convertible Preferred Stock at $57.658, net of issuance costs of $57	260,154	14,943	—	—	—	—	—	—
Preferred stock dividends	—	790	—	—	—	—	(790)	(790)
Preferred stock adjustment to redemption value	—	57	—	—	—	—	(57)	(57)
Net loss	—	—	—	—	—	—	(8,063)	(8,063)
Balances at December 31, 2001	737,654	43,702	7,735,000	8	—	962	(35,045)	(34,075)
Sale of Series D Redeemable Convertible Preferred Stock at $66.762, net	164,765	10,957	—	—	—	—	—	—

of issuance costs of $43								
Preferred stock dividends	—	2,147	—	—	—	—	(2,147)	(2,147)
Preferred stock adjustment to redemption value	—	7,220	—	—	—	—	(7,220)	(7,220)
Net loss	—	—	—	—	—	—	(11,866)	(11,866)
Balances at December 31, 2002	902,419	64,026	7,735,000	8	—	962	(56,278)	(55,308)
Sale of Series E Redeemable Convertible Preferred Stock at $60.692, net of issuance costs of $14	329,536	19,986	—	—	—	—	—	—
Preferred stock dividends	—	2,300	—	—	—	—	(2,300)	(2,300)
Preferred stock adjustment to redemption value	—	76,666	—	—	—	—	(76,666)	(76,666)
Deferred stock- based compensation	—	—	—	—	(3,491)	3,491	—	—
Amortization of stock-based compensation	—	—	—	—	83	—	—	83
Net loss	—	—	—	—	—	—	(9,647)	(9,647)
Balances at September 30, 2003 (unaudited)	1,231,955	$162,978	7,735,000	$ 8	$(3,408)	$4,453	$(144,891)	$(143,838)

The accompanying notes are an integral part of these financial statements.

GTx, Inc.

(a development stage company)

STATEMENTS OF CASH FLOWS

(in thousands)

	Year Ended December 31,			Nine Months Ended September 30,		Cumulative Period from September 24, 1997 (date of inception) to September 30, 2003
	2000	2001	2002	2002	2003	
				(unaudited)	(unaudited)	(unaudited)
Cash flows from operating activities:						
Net loss	$ (3,812)	$ (8,063)	$ (11,866)	$ (8,373)	$ (9,647)	$ (34,254)
Adjustments to reconcile net loss to net cash used in operating activities:						
Depreciation	80	215	332	240	264	955
Stock-based compensation expense	—	—	—	—	83	83
Changes in assets and liabilities:						
Acapodene inventory	—	(154)	154	—	(121)	(121)
Prepaid expenses and other assets	(16)	(18)	5	8	(297)	(338)
Accounts payable	(5)	261	340	89	146	747
Accrued expenses	340	(225)	482	537	509	1,220
Net cash used in operating activities	(3,413)	(7,984)	(10,553)	(7,499)	(9,063)	(31,708)
Cash flows from investing activities:						
Purchase of property and equipment	(462)	(792)	(313)	(295)	(60)	(1,815)
Net cash used in investing activities	(462)	(792)	(313)	(295)	(60)	(1,815)
Cash flows from financing activities:						
Proceeds from issuance of notes payable — related party	—	4,250	—	—	—	4,250
Payment of notes payable — related party	—	(4,250)	—	—	—	(4,250)
Proceeds from issuance of common stock	—	—	—	—	—	970
Proceeds from issuance of preferred stock, net	5,000	14,943	10,957	10,957	19,986	52,341
Net cash provided by financing activities	5,000	14,943	10,957	10,957	19,986	53,311
Net increase (decrease) in cash and cash equivalents	1,125	6,167	91	3,163	10,863	19,788
Cash and cash equivalents, beginning of period	1,542	2,667	8,834	8,834	8,925	—
Cash and cash equivalents, end of period	$ 2,667	$ 8,834	$ 8,925	$11,997	$19,788	$ 19,788
Supplemental schedule of non-cash investing and financing activities:						
Preferred stock dividends	$ 297	$ 790	$ 2,147	$ 1,466	$ 2,300	$ 5,617
Preferred stock adjustment to redemption value	$21,077	$ 57	$ 7,220	$ 7,147	$76,666	$105,020

The accompanying notes are an integral part of these financial statements.

GTx, Inc.

(a development stage company)

NOTES TO FINANCIAL STATEMENTS

(in thousands, except share and per share data)

1. Organization

GTx, Inc. (the "Company") is a biopharmaceutical company dedicated to the discovery, development and commercialization of therapeutics primarily related to the treatment of serious men's health conditions. The Company's drug discovery and development programs are focused on small molecules that selectively modulate the effects of estrogens and androgens, two essential classes of hormones. The Company currently has two product candidates that are in human clinical trials. The Company is developing Acapodene, its most advanced product candidate, through clinical trials for two separate indications: (1) a Phase IIb clinical trial for the reduction in the incidence of prostate cancer in men with precancerous prostate lesions and (2) a pivotal Phase III clinical trial for the treatment of serious side effects of advanced prostate cancer therapy. The Company is initially developing its second product candidate, Andarine, for the treatment of cachexia from various types of cancer. Andarine is the most advanced of its internally discovered portfolio of compounds designed to modulate the effects of hormones. The Company plans to build a specialized sales and marketing capability to market its product candidates directly to the relatively small and concentrated community of urologists and medical oncologists in the United States and seek collaborators to commercialize its product candidates where the target physician market is broader than urologists and medical oncologists and outside the United States.

The Company was incorporated in Tennessee on September 24, 1997. On September 4, 2003, the Company formed a wholly-owned subsidiary in the State of Delaware with 25,000,000 authorized shares of common stock with a par value of $0.001 per share and 1,975,000 shares of preferred stock with a par value of $0.001 per share. On December 1, 2003, the Company was merged into the subsidiary to effect a reincorporation in Delaware. The financial statements reflect the capital structure of the Delaware subsidiary from the Company's inception. From its inception through the merger with the Company, the Delaware subsidiary had no assets or liabilities.

2. Significant Accounting Policies

Basis of Presentation

From September 24, 1997 (inception) through December 31, 2002, the Company has been primarily engaged in research and development, clinical development, and raising capital and is still in a development stage. The Company operates as one business segment.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has experienced negative cash flows from operations since inception and had an accumulated deficit at December 31, 2002 and September 30, 2003 (unaudited) of approximately $56,278 and $144,891, respectively. The Company's accumulated deficit at September 30, 2003 (unaudited) resulted primarily from funding its operating losses as well as non-cash dividends and adjustments to preferred stock redemption value of $110,637. The Company has funded its activities to date almost exclusively from debt and equity financings. In August 2003, the Company issued additional preferred stock (see Note 13) for proceeds of approximately $20,000. The Company will continue to require substantial funds to continue research and development, including preclinical studies and clinical trials of its product candidates, and to commence sales and marketing efforts, if the FDA or other regulatory approvals are obtained. Management's plans in order to meet its operating cash flow requirements include an initial public offering of its common stock, as well as entering into research collaborations through licensing opportunities, which will provide funding for certain research projects. While the Company believes that it will be successful in

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NOTES TO FINANCIAL STATEMENTS — (Continued)

obtaining the necessary financing to fund its operations, there are no assurances that such additional funding will be achieved. In that event, the Company has the intent and ability to reduce its cash expenditures by delaying its initiation of certain research and development efforts such that it will continue its operations beyond December 31, 2004.

Unaudited Interim Financial Information

The interim financial statements for the nine months ended September 30, 2002 and September 30, 2003 and the cumulative period from September 24, 1997 to September 30, 2003, together with the related notes, are unaudited and have been prepared on the same basis as the annual financial statements. In the opinion of management, all adjustments, consisting of normal recurring adjustments necessary for the fair presentation of the financial statements, have been included. The results of operations of any interim period are not necessarily indicative of the results of operations for the full year or any other interim period.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual amounts and results could differ from those estimates.

Preferred Stock Redemption Value

In connection with the public filing for an initial registration of its common stock, the Company changed its accounting policy to recognize changes in the redemption value of its preferred stock immediately as they occur and adjust the carrying value of the preferred stock to equal the redemption value at the end of each reporting period. Previously, the Company had adjusted the carrying value of its preferred stock to its liquidation value at the end of each reporting period.

The preferred stock is subject to redemption on or after August 31, 2006, at a price per share equal to the greater of the liquidation value, which includes accrued dividends, or the fair value calculated on an as-if converted to common stock basis. The Company determines redemption value (fair value) considering factors such as the share price of preferred stock issuances, achievement of significant milestones in clinical trials and general market conditions. The changes in redemption value affect the loss attributable to common stockholders.

Cash and Cash Equivalents

The Company considers highly liquid investments with initial maturities of three months or less to be cash equivalents.

Acapodene Inventory

Acapodene inventory consists of a drug that is manufactured by a third-party and delivered to the Company as a finished good. Inventories are stated at the lower of cost (first-in, first-out method) or market. The inventory is expensed by the Company at the time it is sent to clinical trial facilities.

GTx, Inc.
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NOTES TO FINANCIAL STATEMENTS — (Continued)

Property and Equipment

Property and equipment is recorded at cost. Depreciation of equipment and furniture and fixtures is computed based on the straight-line method over estimated useful lives of three to five years. Amortization of leasehold improvements is recognized over the shorter of the lease term or the estimated useful life of the leasehold improvement.

Impairment

The Company accounts for long-lived assets in accordance with Statement of Financial Accounting Standards ("SFAS") No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets and for Long-Lived Assets to be Disposed of,* which requires that companies consider whether events or changes in facts and circumstances, both internally and externally, may indicate that an impairment of long-lived assets held for use are present. Management periodically evaluates the carrying value of long-lived assets and has determined that there was no impairment as of December 31, 2001 and December 31, 2002. Should there be impairment in the future, the Company would recognize the amount of the impairment based on the expected future cash flows from the impaired assets. The cash flow estimates would be based on management's best estimates, using appropriate and customary assumptions and projections at the time.

Fair Value of Financial Instruments

Financial instruments consist of cash and cash equivalents, accounts payable and preferred stock. The carrying values of cash and cash equivalents and accounts payable approximate the fair value due to the short-term nature of such instruments. Preferred stock is carried at redemption value which approximates fair value.

Concentration of Risks

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents. The Company maintains its cash and cash equivalents in accounts with several major financial institutions in the United States. Deposits in these institutions may exceed the amount of insurance provided on such deposits. The amounts in excess of FDIC insurance amounts are $8,734 and $8,625 at December 31, 2001 and December 31, 2002, respectively.

The Company faces competition from established pharmaceutical and biotechnology companies, as well as from academic institutions, government agencies and private and public research institutions. Various products are currently marketed or sold and used off-label for some of the diseases and conditions that the Company is targeting, and a number of companies are or may be developing new treatments. In addition, physicians are permitted to prescribe legally available drugs for uses that are not described in the drug's labeling and that differ from those uses tested and approved by the FDA. Such off-label uses are common across medical specialties. The occurrence of such off-label uses could significantly reduce the Company's ability to market and sell any products that it may develop.

Currently, the Company relies on Orion Corporation as a single source supplier for Acapodene, and the Company is currently purchasing Andarine from ChemSyn Laboratories, a department of EaglePicher Technologies, LLC, as a single supplier. Establishing additional or replacement suppliers for Acapodene or Andarine may take a substantial amount of time, and in some circumstances the Company's agreement with Orion may prevent it from obtaining an alternate supplier with respect to

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NOTES TO FINANCIAL STATEMENTS — (Continued)

Acapodene. If the Company has to switch to a replacement supplier, the Company may face additional regulatory delays, and the manufacture and delivery of Acapodene or Andarine could be interrupted for an extended period of time, which may delay completion of the Company's clinical trials or commercialization of Acapodene or Andarine. If the Company is unable to obtain an adequate supply of Acapodene or Andarine, its clinical trials will be delayed. As a result, regulatory approval of Acapodene or Andarine could be delayed, or may not be received at all.

Research and Development Costs

The Company expenses research and development costs in the period in which they are incurred. These costs consist of direct and indirect costs associated with specific projects as well as fees paid to various entities that perform research and clinical trial studies on behalf of the Company.

Patent Costs

The Company expenses patent costs, including legal expenses, in the period in which they are incurred. Patent expenses are included in general and administrative expenses in the Company's statements of operations.

Income Taxes

The Company accounts for deferred taxes by recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse.

Research and Development Income

Indigo, a Johnson & Johnson subsidiary, and Johnson & Johnson Development Corporation, ("JJDC") entered into an option agreement with the Company on March 9, 1998. The option agreement was established to allow Indigo and JJDC to determine their level of interest in establishing an exclusive worldwide license with respect to the Company's gene therapy products and related technology. The agreement required the Company during the period of the agreement, which ended in June 1998, to not negotiate with other third parties related to gene therapy products and related technology. Upon expiration of the option, the Company recognized research and development income of $225 for the option proceeds. The Company is no longer pursuing any research and development related to gene therapy products or technology.

Stock Compensation

Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* ("APB No. 25"), and its related interpretations are applied to measure compensation expense for stock-based compensation plans. The Company complies with the disclosure provisions of Statement of Financial Accounting Standards No. 123., *Accounting for Stock-Based Compensation* ("SFAS No. 123"), as amended by SFAS No. 148, *Accounting for Stock-Based Compensation, Transition and Disclosure.* Under APB No. 25, unearned stock compensation is based on the difference, if any, on the date of grant, between the fair value of the Company's common stock and the exercise price. See Note 11 for a description of the plans and the assumptions underlying the pro forma calculations below.

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(a development stage company)

NOTES TO FINANCIAL STATEMENTS — (Continued)

If compensation cost for stock-based compensation plans had been determined under SFAS 123, pro forma stock option compensation expense and net loss attributable to common stockholders, assuming all options were valued on the date of grant using the minimum value option pricing model, would have been as follows:

	Years Ended December 31,			Nine Months Ended September 30,	
	2000	2001	2002	2002	2003
					(unaudited)
Net loss attributable to common stockholders, as reported	$(25,186)	$(8,910)	$(21,233)	$(16,986)	$(88,613)
Add: Employee stock-based compensation expense included in reported net earnings	—	—	—	—	83
Deduct: Employee stock-based compensation determined under fair value method	(4)	(37)	(115)	(84)	(190)
Adjusted net loss attributable to common stockholders	$(25,190)	$(8,947)	$(21,348)	$(17,070)	$(88,720)
Pro forma SFAS 123 disclosure:					
Net loss attributable to common stockholders per common share:					
As reported, basic and diluted	$ (3.26)	$ (1.15)	$ (2.75)	$ (2.20)	$ (11.46)
As adjusted, basic and diluted	$ (3.26)	$ (1.16)	$ (2.76)	$ (2.21)	$ (11.47)

Net Loss Per Share

Basic net loss per share attributable to common stockholders is calculated based on the weighted average number of common shares outstanding during the period. Diluted net loss per share attributable to common stockholders would give effect to the dilutive effect of potential common stock consisting of stock options and convertible preferred stock.

The 765,000 common shares that were redeemed in 2000 were excluded from the weighted average common shares outstanding because the shares were contingently returnable to the Company if the holder's employment terminated prior to a certain date. These shares were treated as stock options in the earnings per share calculation.

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NOTES TO FINANCIAL STATEMENTS — (Continued)

A reconciliation of shares used in the calculation is as follows:

	Years Ended December 31,			Nine Months Ended September 30,	
	2000	2001	2002	2002	2003
				(unaudited)	
Basic net loss per share attributable to common shareholders:					
Numerator					
Net loss attributable to common stockholders	$ (25,186)	$ (8,910)	$ (21,233)	$ (16,986)	$ (88,613)
Denominator					
Weighted average common shares outstanding	7,735,000	7,735,000	7,735,000	7,735,000	7,735,000
Net loss per share attributable to common stockholders, basic and diluted	$ (3.26)	$ (1.15)	$ (2.75)	$ (2.20)	$ (11.46)
Pro Forma					
Net loss as reported			$ (11,866)		$ (9,647)
Shares used above			7,735,000		7,735,000
Pro forma adjustments to reflect assumed weighted average effect of conversion of preferred stock			7,076,786		8,720,728
Shares used in computing pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)			14,811,786		16,455,728
Pro forma basic and diluted net loss per share			$ (0.80)		$ (0.59)

Pro forma net loss per share for the year ended December 31, 2002 and the nine months ended September 30, 2003 is computed using the weighted average number of shares of common stock outstanding, including the pro forma effects of the automatic conversion of the Company's preferred stock into shares of common stock effective upon the closing of the offering as if such conversion occurred on January 1, 2002 and January 1, 2003 or at the date of the original issuance, if later. The resulting pro forma adjustments include an increase in the weighted average shares used to compute basic and diluted net loss per share attributable to common stockholders of 7,076,786 shares and 8,720,728 shares for the year ended December 31, 2002 and for the nine months ended September 30, 2003, respectively. The calculation of pro forma net loss per share attributable to common stockholders excludes incremental common stock issuable upon exercise of options, as their effect would be antidilutive.

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NOTES TO FINANCIAL STATEMENTS — (Continued)

The following outstanding stock options and convertible preferred stock (on an as converted to common stock basis) were excluded from the computation of diluted net loss per share attributable to common stockholders as they had an antidilutive effect:

	Years Ended December 31,			Nine Months Ended September 30,	
	2000	2001	2002	2002	2003
				(unaudited)	
Shares issuable upon exercise of stock options	133,875	328,100	363,375	363,375	799,000
Shares issuable upon conversion of convertible preferred stock	4,114,765	6,442,660	8,151,679	8,055,663	11,296,780
	4,248,640	6,770,760	8,515,054	8,419,038	12,095,780

Comprehensive Loss

The Company has adopted the provisions of SFAS No. 130, *Comprehensive Income*. SFAS 130 establishes standards for the reporting and display of comprehensive income and its components for general purpose financial statements. For all periods presented, there were no differences between net loss and comprehensive loss.

Recent Accounting Pronouncements

In December 2002, the FASB issued SFAS No. 148, which provides alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. SFAS No. 148 also requires that disclosures of the pro forma effect of using the fair value method of accounting for stock-based employee compensation be displayed more prominently and in a tabular format. Additionally, SFAS No. 148 requires disclosure of the pro forma effect in interim financial statements. The transition and annual disclosure requirements of SFAS No. 148 are effective for fiscal years ended after December 15, 2002. The interim disclosure requirements are effective for interim periods beginning after December 15, 2002. The adoption of this standard did not have a material impact on the Company's financial statements.

In January 2003, the FASB issued FASB Interpretation No. 46 ("FIN 46"), *Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51*. FIN 46 requires certain variable interest entities to be consolidated by the primary beneficiary of the entity if the equity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. FIN 46 is effective immediately for all new variable interest entities created or acquired after January 31, 2003. For variable interest entities created or acquired prior to February 1, 2003, the provisions of FIN 46 must be applied for the first interim or annual period ending after December 15, 2003. The Company does not have any ownership in any variable interest entities as of December 31, 2002. The Company will apply the consolidation requirement of FIN 46 in future periods if it should own any interest in a variable interest entity.

In May 2003, the FASB issued SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity*. SFAS No. 150 establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liability and equity. SFAS No. 150 is effective for the Company's financial instruments entered into or modified after May 31, 2003, and otherwise is effective on July 1, 2003. The Company has evaluated the

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NOTES TO FINANCIAL STATEMENTS — (Continued)

impact of SFAS No. 150 and has determined that its financial instruments (common stock and preferred stock) will not be affected unless the terms of these financial instruments are modified.

3. Property and Equipment

Property and equipment consist of the following:

	December 31,	
	2001	2002
Leasehold improvements	$ 108	$ 113
Equipment	1,198	1,494
Furniture and fixtures	102	114
	1,408	1,721
Less: accumulated depreciation and amortization	325	657
	$1,083	$1,064

Depreciation expense for the years ended December 31, 2000, 2001, and 2002 was $80, $215, and $332, respectively.

4. Accrued Expenses

Accrued expenses consist of the following:

	December 31,	
	2001	2002
Travel	$ 27	$ –
Professional fees	109	–
Research and development	71	246
Clinical trial	14	449
Other	8	16
	$229	$711

5. Cumulative Redeemable Convertible Preferred Stock

In 1999, the Company authorized and issued 200,000 shares of 8% Series A Cumulative Redeemable Convertible Preferred Stock (“Series A”) to a common stockholder of the Company for $1,455. In 2000, the Company authorized and issued 277,500 shares of 8% Series B Cumulative Convertible Redeemable Preferred Stock (“Series B”) to the same common stockholder of the Company for $5,000. In 2001, the Company authorized 450,000 shares and issued 260,154 shares (86,718 shares were issued to a common and preferred stockholder of the Company) of 8% Series C Cumulative Convertible Redeemable Preferred Stock (“Series C”) for $14,943. In 2002, the Company authorized 300,000 and issued 164,765 shares (74,894 shares were issued to a common and preferred stockholder of the Company) of 8% Series D Cumulative Convertible Redeemable Preferred Stock (“Series D”) for $10,957.

The Company is authorized to issue 140,000 shares of a series of preferred stock designated as Series A-2 Convertible Preferred Stock (“Series A-2”). No shares of the Series A-2 are currently outstanding. Series A-2 will be issued only in payment of dividends accrued on Series A.

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NOTES TO FINANCIAL STATEMENTS — (Continued)

The Company is authorized to issue 157,500 shares of a series of preferred stock designated as Series B-2 Convertible Preferred Stock ("Series B-2"). No shares of Series B-2 are currently outstanding. Series B-2 will be issued only in payment of dividends accrued on Series B.

Significant terms of the Series A, Series A-2, Series B, Series B-2, Series C and Series D are as follows:

- Shares of Series A, Series A-2, Series B, Series B-2, Series C and Series D shall be redeemed at the election of the respective holders at any time on or after August 31, 2006 at a price per share equal to the greater of the liquidation value, which includes accrued dividends, or the fair value calculated on an if converted to common stock basis. The per share liquidation value of Series A and Series A-2 is $7.28, Series B and Series B-2 is $18.02, Series C is $57.66 and Series D is $66.76, in each case, plus accrued dividends. The preferred stock per share redemption value was $57.66, $57.66, $66.76, $66.76 and $122.83 as of December 31, 2000, 2001 and 2002 and as of September 30, 2002 and 2003 (unaudited), respectively. If for any reason, the Company defaults on its obligation to pay all or any of the redemption price, then the unpaid principal portion will bear interest at a rate of 14% per year. The default provisions were amended upon the issuance of the Series E Cumulative Convertible Redeemable Preferred Stock ("Series E") (see Note 13).

- Shares of Series A, Series A-2, Series B, Series B-2, Series C and Series D shall be converted into shares of common stock at the election of the respective holders at any time or automatically upon the closing of a Qualified Public Offering. As defined in the Company's Certificate of Incorporation, a Qualified Public Offering is an offering to the public of common stock or convertible securities in which (i) the net proceeds to the Company are not less than $25,000 and (ii) the price per share of common stock, or common stock equivalent in the case of convertible securities, is not less than $13.57 (adjusted for stock splits, stock dividends and other similar changes to the common stock) (see Note 13). The number of shares issuable upon conversion will be determined by dividing the applicable aggregate liquidation value by the applicable conversion price. As a result of the issuance of Series E in August 2003, the conversion price of the Series D was reduced to $7.75 per share (see Note 13). The per share conversion prices for shares of preferred stock are as follows: Series A-$0.86, Series B-$2.12, Series C, A-2 and B-2-$6.78, Series D-$7.75 and Series E-$7.14 as a result of the stock split in January 2004 (see Note 13).

- Shares of Series A, Series B, Series C and Series D have voting rights equivalent to the number of shares of common stock into which they are convertible.

- Dividends on shares of Series A, Series B, Series C and Series D accrue, compound annually after the date of issuance of Series C, which was October 5, 2001, are cumulative at the annual rate of 8% of the respective liquidation value and are payable at such time as such shares are converted or redeemed (including liquidation). Each such dividend will be payable solely in shares of Series A-2 for Series A, Series B-2 for Series B, Series C for Series C and Series D for Series D at the time of conversion or redemption with the number of shares determined by dividing the amount of accrued dividends by the per share liquidation value of the applicable preferred stock.

- In the event of a liquidation, dissolution, or winding up of the Company, prior to the holders of common stock, the holders of Series A, Series A-2, Series B, Series B-2, Series C and Series D shall receive an amount equal to the aggregate liquidation value including all accrued dividends. If the funds available for distribution to the holders of Series A,

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NOTES TO FINANCIAL STATEMENTS — (Continued)

Series A-2, Series B, Series B-2, Series C or Series D are insufficient, then the assets to be distributed shall be distributed ratably among the preferred stockholders based upon the aggregate liquidation value.

- In accordance with the Company's certificate of incorporation, on or after the Series C or the Series D issuance dates, as applicable, if the Company issues or sells, or is deemed to have issued or sold any shares of its common stock for a consideration per share less than the conversion price with respect to Series C or Series D, then immediately upon such issue or sale, or deemed issue or sale, the conversion price shall be reduced to the conversion price determined by multiplying the conversion price in effect immediately prior to such issuance or sale by a price adjustment factor. The price adjustment factor causes the holders of the Series C and/or Series D stock to hold an adjusted number of shares equal to their total ownership before such issuance. If such a transaction occurs, the increase in preferred shares for the Series C and/or Series D holders will be accounted for as a deemed dividend by the Company. As a result of the issuance of Series E in August 2003, the conversion price of the Series D was reduced to $7.75 per share (see Note 13).

6. Common Stock

The Company's certificate of incorporation authorizes the Company to issue 25,000,000 shares of common stock with $0.001 par value per share. The Company's certificate of incorporation authorizes no other classes of common stock. The Company is prohibited from declaring dividends on common stock while any shares of preferred stock are outstanding.

The Company had reserved shares of its authorized common stock for future issuance as summarized in the table below:

	December 31, 2002	September 30, 2003
		(Unaudited)
For conversion of Series A	1,763,963	1,777,860
For conversion of Series B	2,504,500	2,552,261
For conversion of Series C	2,431,986	2,575,202
For conversion of Series D	1,451,230	1,557,430
For conversion of Series E	—	2,834,027
Outstanding employee stock options	363,375	799,000
Possible future issuance under stock option plans	915,025	483,650
	9,430,079	12,579,430

7. Notes Payable-Related Party

Demand notes of $4,250 were issued in 2001 to a holder of common stock of the Company to fund working capital needs. In October 2001, a portion of the proceeds from the issuance of Series C was used to repay all outstanding principal and accrued interest on the notes payable-related party. Interest expense incurred on the notes payable-related party based on an annual interest rate of 9% was $71 in 2001, which was included in general and administrative expenses in the Company's Statement of Operations.

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NOTES TO FINANCIAL STATEMENTS — (Continued)

8. License, Research and Development Agreements

License Agreements

In August 2002, the Company executed an Amended and Restated Exclusive License Agreement with The University of Tennessee Research Foundation ("UTRF") granting the Company a worldwide exclusive license under its method of use patents relating to Acapodene to market, distribute and sell licensed products, licensed processes or generic products. Under the terms of the agreement, the Company is required (i) to make annual maintenance fee payments and (ii) to make future royalty payments.

The amended license agreement with UTRF superseded a 1998 license agreement related to chemoprevention of prostate cancer between the Company and UTRF. Under the 1998 license agreement, the Company reimbursed UTRF for certain patent expenses incurred by UTRF and agreed to make sublicense fee payments and future royalty payments.

In June 2002, the Company executed two Amended and Restated Exclusive License Agreements with UTRF granting the Company worldwide exclusive licenses under its method of use patents relating to Andarine to market, distribute and sell licensed products, licensed processes or generic products. Under the terms of the agreements, the Company is required (i) to make annual maintenance fee payments and (ii) to make future royalty payments.

The amended license agreement with UTRF superseded a 2000 license agreement related to ARTA between the Company and UTRF. Under the 2000 license agreement, the Company reimbursed UTRF for certain patent expenses incurred by UTRF and agreed to make sublicense fee payments and future royalty payments.

Sponsored Research Agreement

The Company entered into a series of sponsored research agreements with the research foundation of a major university for one of the Company's programs. Under the terms of the agreements, the Company will reimburse the research foundation for the cost of research performed on the Company's behalf, in accordance with the terms of the agreements. The estimated cost of the research to be performed over a four-year period is approximately $4,000. The Company incurred expenses of $1,638, $956, $682, and 3,276 under these agreements for the years ended December 31, 2000, December 31, 2001, December 31, 2002, and from inception to December 31, 2002, respectively, which were included in research and development costs in the Company's Statements of Operations. The Company has the right to terminate the sponsored research agreement at any time. Upon termination, the Company will reimburse the research foundation for all research costs incurred on the Company's behalf not yet reimbursed by the Company.

Contract Research Organization ("CRO")

In 2000, the Company began a Phase IIb clinical trial for Acapodene for the reduction in the incidence of prostate cancer in men with high grade PIN. The last patient is scheduled to complete the trial in May 2004. The Company incurred expenses related to the Phase IIb clinical trial for the years ended December 31, 2000, 2001 and 2002 of approximately $1,290, $2,299 and $2,802, respectively, and approximately $6,391 from inception to December 31, 2002. The Company has specified rights to terminate the clinical trial and pay the CROs for fees incurred for the clinical trial not yet reimbursed by the Company.

GTx, Inc.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS — (Continued)

In 2002, the Company began two additional Phase II clinical trials for Acapodene. These Phase II clinical trials are expected to be completed in 2003. The Company incurred expenses related to the Phase II clinical trials for the year ended December 31, 2002 of approximately $680, which was included in research and development costs in the Company's Statements of Operations. The Company estimates the total cost of these clinical trials to be approximately $936.

In 2002, the Company completed a Phase I clinical trial for Andarine. The Company incurred expenses related to the clinical trial for the year ended December 31, 2002 of approximately $370, which was included in research and development costs in the Company's Statements of Operations.

License and Supply Agreement

In 2000, the Company entered into a license and supply agreement with Orion Corporation for one of the Company's products. Under the terms of the agreement, the Company paid an initial license fee of $400 and is required to make future sublicense fee payments in the event the Company grants a sublicense under the licensed patents and future royalty payments in the event the Company sells products developed from the licensed patents.

9. Income Taxes

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes.

The principal components of the Company's net deferred income taxes consist of the following:

	December 31,	
	2002	2001
Deferred income tax assets:		
Net operating loss carryforwards	$ 9,134	$ 4,906
Research credits	783	390
Cash basis method	496	84
Total deferred tax assets	10,413	5,380
Deferred income tax liabilities:		
Depreciation	50	31
Total deferred tax liabilities	50	31
Net deferred income tax assets	10,363	5,349
Valuation allowance	(10,363)	(5,349)
	$ —	$ —

At December 31, 2002, the Company has net operating loss carryforwards of approximately $23,420, which expire for federal purposes from 2020 through 2022 and for state purposes from 2015 to 2017, and research credits, which expire from 2013 through 2022. Utilization of the net operating loss carryforwards and credits may be subject to a substantial annual limitation due to an ownership change as provided by the Internal Revenue Code of 1986, as amended, and similar state provisions. The annual limitation may result in the expiration of net operating losses and credits before utilization.

GTx, Inc.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS — (Continued)

10. Operating Leases

The Company leases laboratory facilities and office space pursuant to leases accounted for as operating leases. Rent expense was approximately $34, $155, $170 and $401 for the years ended December 31, 2000, December 31, 2001, December 31, 2002, and from inception to December 31, 2002, respectively.

11. Stock Option Plans

In 1999, 2000, 2001 and 2002, the Company adopted the Genotherapeutics, Inc. Stock Option Plan ("1999 Plan"), the GTx, Inc. 2000 Stock Option Plan ("2000 Plan"), the GTx, Inc. 2001 Stock Option Plan ("2001 Plan") and the GTx, Inc. 2002 Stock Option Plan ("2002 Plan"), respectively (collectively, the "Plans"). The Plans provide for the Company to issue options to directors, officers and employees of the Company. The options are granted with an exercise price per share as determined by the Board of Directors. The exercise price per share will not be less than the fair market value of the stock on the date of grant. The Board of Directors cannot issue more than 25,500 options under the 1999 Plan, 108,375 options under the 2000 Plan, 298,775 options under the 2001 Plan and 850,000 options under the 2002 Plan in the aggregate at any time. The options generally vest one-third on the third anniversary, one-third on the fourth anniversary, and one-third on the fifth anniversary of the grant date. However, 127,500 of the 2001 options vest one-fifth per year beginning on the first anniversary of the date the options were granted. All options expire no later than the tenth anniversary of the grant date. In the event of a change in control of the Company, all stock options will become fully vested and be converted to cash, options or stock of equivalent value. None of the Company's stock options were exercisable at December 31, 2001 or 2000. At December 31, 2002, 34,000 of the Company's stock options were exercisable.

The following is a summary of option transactions:

	Options	Weighted Average Exercise Price Per Share
Balances at December 31, 1997 and 1998	—	
Options granted	25,500	$0.94
Balances at December 31, 1999	25,500	0.94
Options granted	108,375	2.24
Balances at December 31, 2000	133,875	1.99
Options granted	237,575	6.78
Options forfeited	(43,350)	2.32
Balances at December 31, 2001	328,100	5.42
Options granted	46,750	7.17
Options forfeited	(11,475)	3.41
Balances at December 31, 2002	363,375	5.71
Options granted (unaudited)	450,500	6.24
Options forfeited (unaudited)	(14,875)	7.40
Balances at September 30, 2003 (unaudited)	799,000	$5.97

GTx, Inc.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS — (Continued)

The following table summarizes information about stock options outstanding at December 31, 2002:

Exercise Price	Options Outstanding	Weighted Average Remaining Contractual Life (years)	Weighted Average Exercise Price	Options Exercisable
$0.94	25,500	6.58	$0.94	8,500
2.24	57,375	7.92	2.24	—
6.78	263,500	8.81	6.78	25,500
7.85	17,000	9.75	7.85	—
	363,375	8.55	$5.71	34,000

The Company accounts for its Plans in accordance with APB Opinion No. 25. Prior to June 30, 2003, the Company did not recognize compensation expense for stock options because the exercise price of the stock options equaled or exceeded the market price of the underlying stock on the date of grant, which is the measurement date. In anticipation of the Company's initial public offering, the Company has determined that, for financial reporting purposes, the estimated value of its common stock was in excess of the exercise price for stock options issued to employees subsequent to June 30, 2003. Accordingly, the Company has recorded deferred stock-based compensation and is amortizing the related expense over the service period, which is generally five years. If the alternative method of accounting for stock incentive plans prescribed by SFAS No. 123 had been followed, the Company's net loss would have increased by approximately, $4, $37, and $115 for the years ended December 31, 2000, 2001, and 2002, respectively. The pro forma disclosures may not be representative of that to be expected in future years. The weighted average fair value of options granted was determined using the minimum value option pricing model assuming no expected dividends, a risk-free interest rate of 6.32% and a weighted average expected life of 10 years for the 1999, a risk-free interest rate of 5.47% and a weighted average expected life of 10 years for the 2000 grants, a risk-free interest rate of 4.24% and a weighted average expected life of 8 years for the 2001 grants, and a weighted average risk-free interest rate of 4.76% and a weighted average expected life of 8 years for the 2002 grants. The weighted average grant date fair value of options granted were $0.83, $1.65, and $1.75 for the years ended December 31, 2000, December 31, 2001, and December 31, 2002, respectively.

12. Employee Benefit Plan

In 2000, the Company established a 401(k) retirement savings plan that is available to all regular employees who have reached age 21. The plan is intended to qualify under Section 401(k) of the Internal Revenue Code of 1986, as amended. The plan provides that each participant may contribute up to 15% of their pre-tax compensation (up to a statutory limit, which was $11 in calendar year 2002). Employee contributions are held in the employees' name and invested by the plan's trustee. The plan also permits the Company to make matching contributions, subject to established limits. To date, the Company has not made any matching contributions to the plan on behalf of participating employees.

GTx, Inc.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS — (Continued)

13. Subsequent Events

Issuance of Series E

On August 7, 2003, the Company authorized 450,000 shares and issued 329,536 shares of Series E at a purchase price of $60.69 per share resulting in gross cash proceeds of $20,000. The Company incurred issuance costs of $14 related to this series. Upon the issuance of Series E, the default provisions of all outstanding preferred stock were amended. If for any reason the Company defaults on its obligation to pay all or any portion of the redemption price, then the unpaid principal portion will bear interest at the greater of the prime rate plus 4% or 8%. Series E has similar terms to the other series of preferred stock. As a result of the issuance of Series E, the conversion price of the Series D was reduced to $7.75 per share as a result of the anti-dilution provisions of the Company's Certificate of Incorporation.

Initial Public Offering

In October 2003, the Board of Directors authorized the Company to file a Registration Statement with the Securities and Exchange Commission ("SEC") permitting the Company to sell shares of common stock in an initial public offering ("IPO"). In January 2004, the stockholders agreed that the IPO would constitute a Qualified Public Offering under the Company's Certificate of Incorporation (see Note 5). Upon the closing of the IPO, all shares of the Series A, Series A-2, Series B, Series B-2, Series C and Series E preferred stock will automatically convert into shares of common stock at a 8.5-for-1 conversion ratio and all shares of the Series D preferred stock will automatically convert into shares of common stock at a 8.61-for-1 conversion ratio.

Based on the Company's outstanding shares as of December 31, 2003, if the IPO is closed, all of the cumulative redeemable convertible preferred stock outstanding and dividends accrued thereon through December 31, 2003 will automatically convert into approximately 11,456,912 shares of common stock.

Issuance of Stock Options

On May 21, 2003, the Company issued 25,500 stock options under the 2001 stock option plan. The shares were issued at an exercise price of $6.24 a share. The shares vest one-third on the third anniversary, one-third on the fourth anniversary and one-third on the fifth anniversary of the grant date. The weighted average fair value of the options granted was $1.39. The weighted average fair value was determined using the minimum value option pricing model assuming no expected dividends, a risk-free interest rate of 3.15% and a weighted average expected life of 8 years.

On August 1, 2003, the Company issued 187,000 stock options under the 2002 stock option plan. The shares were issued at an exercise price of $6.24 a share. The shares vest one-third on the third anniversary, one-third on the fourth anniversary and one-third on the fifth anniversary of the grant date. The weighted average fair value of options granted was $1.84. The weighted average fair value was determined using the minimum value option pricing model assuming no expected dividends, a risk-free interest rate of 4.36% and a weighted average expected life of 8 years.

On September 1, 2003, the Company issued 238,000 stock options under the 2002 stock option plan. The shares were issued at an exercise price of $6.24 a share. The shares vest one-third on the third anniversary, one-third on the fourth anniversary and one-third on the fifth anniversary of the grant date. The weighted average fair value of options granted was $1.84. The weighted average fair value was determined using the minimum value option pricing model assuming no expected dividends, a risk-free interest rate of 4.36% and a weighted average expected life of 8 years.

GTx, Inc.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS — (Continued)

On January 14, 2004, the Company adopted its 2004 Equity Incentive Plan and 2004 Non-Employee Directors' Stock Option Plan, both of which will become effective upon consummation of the Company's initial public offering of its common stock. The Company may issue awards for up to 1,500,000 shares of common stock under the 2004 Equity Incentive Plan and options for up to 200,000 shares of common stock under the 2004 Non-Employee Directors' Stock Option Plan.

Stock Split

On January 14, 2004, the Company effected an 8.5-for-1 stock split of its common stock in the form of a stock dividend. All common stock share and per share amounts in these financial statements have been adjusted retroactively to reflect the stock split. In connection with the stock split, the Company amended its Certificate of Incorporation to authorize 25,000,000 shares of common stock and 1,975,000 shares of preferred stock.

No dealer, salesperson or other person is authorized to give any information or to represent anything not contained in this prospectus. You must not rely on any unauthorized information or representations. This prospectus is an offer to sell only the shares offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus is current only as of its date.

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Through and including , 2004 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

5,400,000 Shares

GTx, Inc.

Common Stock

GTx
The Men's Health Biotech Company

Goldman, Sachs & Co.

SG Cowen
Lazard

Representatives of the Underwriters

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. *Other Expenses of Issuance and Distribution*

The following table sets forth the costs and expenses to be paid by us in connection with the sale of the shares of common stock being registered hereby. All amounts are estimates except for the SEC registration fee, the NASD filing fee and the Nasdaq National Market filing fee.

	Amount to be Paid
SEC registration fee	$ 7,535
NASD filing fee	9,125
Nasdaq National Market filing fee	100,000*
Printing and engraving expenses	230,000*
Blue sky qualification fees and expenses	5,000*
Accounting fees and expenses	600,000*
Legal fees and expenses	1,160,000*
Transfer agent and registrar fees	7,500*
Miscellaneous expenses	180,840*
Total	$2,300,000*

* Estimated

Item 14. *Indemnification of Directors and Officers*

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

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of the law;
- any act related to unlawful stock repurchases, redemptions or other distribution or payments of dividends; or
- any transaction from which the director derived an improper personal benefit.

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

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

We have entered into indemnity agreements with each of our current directors and certain of our executive officers to give such directors and officers additional contractual assurances regarding the scope of the indemnification set forth in our certificate of incorporation and bylaws and to provide additional procedural protections. At present, there is no pending litigation or proceeding involving

any of our directors, officers or employees for which indemnification is sought, nor are we aware of any threatened litigation that may result in claims for indemnification.

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

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

Reference is made to the following documents filed as exhibits to this registration statement regarding relevant indemnification provisions described above and elsewhere herein:

Exhibit Document	Number
Form of Underwriting Agreement(2)	1.1
Restated Certificate of Incorporation, as amended(2)	3.1
Amended and Restated Certificate of Incorporation(1)	3.3
Amended and Restated Bylaws(1)	3.4
Registration Rights Agreement with Oracle Partners, L.P.(1)	4.3
Registration Rights Agreement with J.R. Hyde, III(1)	4.4
Registration Rights Agreement with Memphis Biomed Ventures I, L.P.(1)	4.5
Form of Indemnification Agreement(1)	10.12

(1) Previously filed.

(2) Filed herewith.

Item 15. ***Recent Sales of Unregistered Securities***

1. In July 2000, we issued and sold an aggregate of 277,500 shares of our 8% Series B Cumulative Convertible Preferred Stock to one accredited investor at $18.018 per share, for an aggregate offering price of $4,999,995.

2. In October 2001, we issued and sold an aggregate of 260,154 shares of our 8% Series C Cumulative Convertible Preferred Stock to three accredited investors at $57.658 per share, for an aggregate offering price of $14,999,959.

3. In July 2002, we issued and sold an aggregate of 164,765 shares of our 8% Series D Cumulative Convertible Preferred Stock to four accredited investors at $66.762 per share for an aggregate offering price of $11,000,041.

4. In August 2003, we issued and sold an aggregate of 329,536 shares of our 8% Series E Cumulative Convertible Preferred Stock to 11 accredited investors at $60.692 per share for an aggregate offering price of $20,000,199.

5. We have granted stock options under our stock option plans covering an aggregate of 828,750 shares of common stock (net of exercises, expirations and cancellations) as of December 31, 2003, at exercise prices ranging from $0.94 to $7.85 per share. Of these, options to purchase an aggregate of 850 shares of common stock have been exercised for an aggregate purchase price of $800.00, or a weighted exercise price of $1.06 per share.

We claimed exemption from registration under the Securities Act for the sales and issuances of securities in the transactions described in paragraphs (1) through (3) above by virtue of Section 4(2) of the Securities Act in that such sales and issuances did not involve a public offering. The recipients of securities in each of these transactions represented their intention to acquire the securities for investment only and not with view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the share certificates and instruments issued in such transactions. All recipients had adequate access, through their relationships with us, to information about us.

We claimed exemption from registration under the Securities Act for the sales and issuances of securities in the transactions described in paragraph (4) by virtue of Section 4(2) of the Securities Act and Rule 506 of Regulation D. Such sales and issuances did not involve any public offering, were made without general solicitation or advertising and each purchaser was a sophisticated investor with access to all relevant information necessary to evaluate the investment and represented to us that the shares were being acquired for investment.

We claim exemption from registration under the Securities Act for the sale and issuance of securities in the transactions described in paragraph (5) above by virtue of Rule 701 promulgated under Section 3(b) of the Securities Act as a transaction under a compensatory benefit plan under Rule 701.

Item 16. ***Exhibits and Financial Statement Schedules***

(a) Exhibits

Number	Description
1.1	Underwriting Agreement(2)
3.1	Restated Certificate of Incorporation of GTx, Inc. filed December 1, 2003, as amended(2)
3.2	Bylaws of GTx, Inc.(1)
3.3	Form of Amended and Restated Certificate of Incorporation of GTx, Inc. to be effective upon completion of this offering(1)
3.4	Form of Amended and Restated Bylaws of GTx, Inc. to become effective upon completion of this offering(1)
3.5	Second Amended and Restated Voting and Shareholder Agreement dated August 7, 2003 (1)
4.1	Reference is made to Exhibits 3.1, 3.2, 3.3 and 3.4
4.2	Specimen of Common Stock Certificate(1)
4.3	Amended and Restated Registration Rights Agreement between Registrant and Oracle Partners, L.P. dated August 7, 2003(1)
4.4	Amended and Restated Registration Rights Agreement between Registrant and J. R. Hyde, III dated August 7, 2003(1)
4.5	Amended and Restated Registration Rights Agreement between Registrant and Memphis Biomed Ventures dated August 7, 2003(1)
5.1	Opinion of Cooley Godward LLP(2)
10.1	Genotherapeutics, Inc. 1999 Stock Option Plan(1)
10.2	GTx, Inc. 2000 Stock Option Plan(1)
10.3	GTx, Inc. 2001 Stock Option Plan(1)
10.4	GTx, Inc. 2002 Stock Option Plan(1)
10.5	2004 Equity Incentive Plan and Form of Stock Option Agreement(2)
10.6	2004 Non-Employee Directors' Stock Option Plan and Form of Stock Option Agreement(2)
10.7	Reserved
10.8	Employment Agreement dated October 1, 2003, between Registrant and Mitchell S. Steiner, M.D.(1)
10.9	Employment Agreement dated October 1, 2003, between Registrant and Marc S. Hanover(1)
10.10	Employment Agreement dated October 1, 2003, between Registrant and Mark E. Mosteller(1)
10.11	Employment Agreement dated October 1, 2003, between Registrant and Henry P. Doggrell(1)
10.12	Form of Indemnification Agreement(1)

Number	Description
10.13	Lease Agreement, dated March 7, 2001, between The University of Tennessee and TriStar Enterprises, Inc.(1)
10.14	Sublease Agreement dated October 1, 2000, as amended, between Registrant and TriStar Enterprises, Inc.(1)
10.15†	Amended and Restated License and Supply Agreement dated October 22, 2001, between Registrant and Orion Corporation(1)
10.16†	Amendment No. 1 to the License and Supply Agreement dated March 5, 2003, between Registrant and Orion Corporation(1)
10.17†	Production and Manufacturing Agreement dated September 9, 2002, between Registrant and ChemSyn Laboratories (Department of EaglePicher Technologies, LLC)(2)
10.18†	Amendment No. 1 to the Production and Manufacturing Agreement dated September 30, 2003, between Registrant and ChemSyn Laboratories (Department of EaglePicher Technologies, LLC)(1)
10.19†	Quotation Agreement dated August 8, 2003 between Registrant and EaglePicher Pharmaceutical Services(1)
10.20†	Amended and Restated Exclusive License Agreement dated June 3, 2002, between Registrant and University of Tennessee Research Foundation(1)
10.21†	Amended and Restated Exclusive License Agreement dated June 14, 2002, between Registrant and University of Tennessee Research Foundation(1)
10.22†	Amended and Restated Exclusive License Agreement dated August 30, 2002, between Registrant and University of Tennessee Research Foundation(1)
10.23†	Amendment No. 2 to the License and Supply Agreement dated December 29, 2003, between Registrant and Orion Corporation(2)
23.1	Consent of Ernst & Young LLP(2)
23.2	Consent of Cooley Godward LLP (included in Exhibit 5.1)

* To be filed by amendment.

† Confidential treatment requested. The redacted portions have been filed separately with the SEC as required by Rule 406 of Regulation C.

(1) Previously filed.

(2) Filed herewith.

Item 17. ***Undertakings***

The undersigned Registrant hereby undertakes to provide to the underwriters at the closing specified in the Underwriting Agreement, certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

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

it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned Registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, GTx, Inc. has duly caused this Amendment No. 3 to the Registration Statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Memphis, State of Tennessee, on the 14th day of January, 2004.

GTX, INC.

By: /s/ MITCHELL S. STEINER

Mitchell S. Steiner, M.D., F.A.C.S.
Chief Executive Officer

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

Signature	Title	Date
/s/ MITCHELL S. STEINER Mitchell S. Steiner, M.D., F.A.C.S.	Chief Executive Officer, Vice-Chairman and Director	January 14, 2004
/s/ MARK E. MOSTELLER Mark E. Mosteller	Chief Financial Officer	January 14, 2004
* J.R. Hyde, III	Chairman of the Board of Directors	January 14, 2004
* Marc S. Hanover	Director	January 14, 2004
* John H. Pontius	Director	January 14, 2004
* Rosemary Mazanet, M.D., Ph.D.	Director	January 14, 2004
* Pursuant to Power of Attorney /s/ MITCHELL S. STEINER Attorney-in-fact		

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10.18†	Amendment No. 1 to the Production and Manufacturing Agreement dated September 30, 2003, between Registrant and ChemSyn Laboratories (Department of EaglePicher Technologies, LLC)(1)
10.19†	Quotation Agreement dated August 8, 2003 between Registrant and EaglePicher Pharmaceutical Services(1)
10.20†	Amended and Restated Exclusive License Agreement dated June 3, 2002, between Registrant and University of Tennessee Research Foundation(1)
10.21†	Amended and Restated Exclusive License Agreement dated June 14, 2002, between Registrant and University of Tennessee Research Foundation(1)
10.22†	Amended and Restated Exclusive License Agreement dated August 30, 2002, between Registrant and University of Tennessee Research Foundation(1)
10.23†	Amendment No. 2 to the License and Supply Agreement dated December 29, 2003, between Registrant and Orion Corporation(2)
23.1	Consent of Ernst & Young LLP(2)
23.2	Consent of Cooley Godward LLP (included in Exhibit 5.1)

* To be filed by amendment.

† Confidential treatment requested. The redacted portions have been filed separately with the SEC as required by Rule 406 of Regulation C.

(1) Previously filed.

(2) Filed herewith.

EXHIBIT 1.1

GTX, INC.

COMMON STOCK
(PAR VALUE $0.001 PER SHARE)

UNDERWRITING AGREEMENT

....., 2004

Goldman, Sachs & Co.,
SG Cowen Securities Corporation,
Lazard Freres & Co. LLC,
As representatives of the several Underwriters
named in Schedule I hereto,
c/o Goldman, Sachs & Co.,
85 Broad Street,
New York, New York 10004.

Ladies and Gentlemen:

GTx, Inc., a Delaware corporation (the "Company"), proposes, subject to the terms and conditions stated herein, to issue and sell to the Underwriters named in Schedule I hereto (the "Underwriters") an aggregate of ..... shares (the "Firm Shares") and, at the election of the Underwriters, up to ..... additional shares (the "Optional Shares") of common stock, par value $0.001 per share ("Stock") of the Company (the Firm Shares and the Optional Shares that the Underwriters elect to purchase pursuant to Section 2 hereof being collectively called the "Shares").

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

(a) A registration statement on Form S-1 (File No. 333-109700) (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 to you, and, excluding exhibits thereto, to you 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 has heretofore been filed with the Commission; 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) of the rules and regulations of the Commission 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 including the information contained in the form of final prospectus filed with the Commission pursuant to Rule 424(b) under the Act in accordance with Section 5(a) hereof and deemed by virtue of Rule 430A under the Act to be part of the Initial Registration Statement at the time it was declared effective, each as amended at the time such part of the Initial Registration Statement became effective or such part of the Rule 462(b) Registration Statement, if any, became or hereafter becomes effective, are hereinafter collectively called the "Registration Statement"; and such final prospectus, in the form first filed pursuant to Rule 424(b) under the Act, is hereinafter called the "Prospectus";

(b) No order preventing or suspending the use of any Preliminary Prospectus has been issued by the Commission, and each Preliminary Prospectus, at the time of filing thereof, conformed in all material respects to the requirements of the Act and the rules and regulations of the Commission thereunder, and did 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, in the light of the circumstances under which they were made, 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 through Goldman, Sachs & Co. expressly for use therein;

(c) The Registration Statement conforms, and the Prospectus 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 through Goldman, Sachs & Co. expressly for use therein;

(d) The Company has not sustained since the date of the latest audited financial statements included 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 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 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; and GTx, Inc., a Tennessee corporation and predecessor of the Company ("GTx Tennessee"), was duly incorporated in the State of Tennessee and, until the merger of GTx Tennessee with and into the Company (the "Merger") (all references to the Company herein shall, with respect to the period prior to the Merger, include GTx Tennessee), validly existing as a corporation in good standing under the laws of the State of Tennessee, with power and corporate authority to own its properties and conduct its business as theretofore conducted;

(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, are fully paid and non-assessable and conform to the description of the Stock contained in the Prospectus;

(i) The unissued Shares to be issued and sold by the Company to the Underwriters hereunder have been duly and validly authorized and, when issued and delivered against payment therefor as provided herein, will be duly and validly issued and fully paid and non-assessable and will conform to the description of the Stock contained in the Prospectus;

(j) The Company and GTx Tennessee, as applicable, have filed all notices, reports, documents or other information required to be filed by them pursuant to, and have obtained any and all authorizations, approvals, orders, consents, licenses, certificates, permits, registrations or qualifications required to be obtained under, and have otherwise complied with all requirements of, all applicable laws of the State of Tennessee and the State of Delaware in connection with the consummation of the Merger; the Merger is legal, effective and valid and in accordance with the laws of the State of Tennessee and the State of Delaware; and the consummation of the Merger did 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 it is bound or to which any of the properties or assets of the Company is subject, other than any conflict, breach or violation that would not have a Material Adverse Effect, and which will not affect the validity, performance or consummation of the Merger or the transactions contemplated by this Agreement, and has not resulted and will not result in any violation of the provisions of the Fifth Amended and Restated Charter or By-laws of GTx Tennessee or the Certificate of Incorporation or By-laws of the Company or any statute, rule or regulation, or, to the Company's knowledge, any order or decree of any court or regulatory authority or other governmental agency or body having jurisdiction over GTx Tennessee, the Company or any of its properties;

(k) The issue and sale of the Shares by the Company and the compliance by the Company with all of the provisions of this Agreement and the consummation of the transactions herein contemplated 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, except the registration under the Act of the Shares 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;

(l) 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;

(m) 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 Stock, and under the captions "Risk Factors - [_____]", "Business - [_____]" and "Underwriting", insofar as they purport to describe the provisions of the laws and documents referred to therein, are accurate, complete and fair;

(n) 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;

(o) 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;

(p) 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;

(q) 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;

(r) The financial statements of the Company (together with the related notes thereto) included in the Registration Statement and the Prospectus (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 selected financial data included in the Registration Statement and the Prospectus fairly present the information shown therein and have been compiled on a consistent basis with that of the audited financial information included in the Registration Statement and the Prospectus; the pro forma financial information and the related

notes thereto included in the Registration Statement and the Prospectus fairly present the pro forma financial position of the Company after giving effect to the pro forma transactions and assumptions described in the notes thereto as at the respective dates thereof and have 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;

(s) The Company has made and keeps books, records and accounts, which, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company; the Company has devised and maintains a system of internal accounting controls sufficient to provide reasonable assurances that (i) transactions are executed in accordance with management's general or specific authorization, (ii) transactions are recorded as necessary to permit preparation of financial statements of the Company in conformity with generally accepted accounting principles and to maintain accountability for assets of the Company, (iii) access to assets of the Company is permitted only in accordance with management's general or specific authorization and (iv) the recorded accountability for assets of the Company is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences; the Company maintains "disclosure controls and procedures" (as defined in Rule 13a-15(e) and Rule 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")), and such controls and procedures are (i) designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Commission's rules and forms and (ii) effective, in that they provide reasonable assurance that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Commission's rules and regulations and forms; the Company does not have any significant deficiencies or material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; 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; and the Company is otherwise 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;

(t) Except as disclosed in the Prospectus, 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, technology and know-how (including trade secrets and other unpatented proprietary intellectual property rights) necessary or used in any material respect to conduct its business in the manner in which it is being conducted and in the manner in which it is contemplated to be conducted as set forth in the Prospectus (collectively, the "Company Intellectual Property") and necessary in connection with the commercialization of the products described in the Prospectus as being under development; none of the patents owned or licensed by the Company is unenforceable or invalid; the Company owns or possesses valid licenses or other rights to use the patents and patent applications set forth on the schedule (the "Patent Schedule") separately delivered to Goldman, Sachs & Co. on behalf of the Underwriters prior to the date hereof and the Patent Schedule lists all such patents and patent applications necessary or used in any material respect to conduct the business of the Company in the manner described in the Prospectus and necessary in connection with the commercialization of the existing products of the Company and the products described in the Prospectus as being under development; the Company's patent

applications were filed in compliance with relevant laws; the Company is not obligated to pay a royalty, grant a license, or provide other consideration to any third party in connection with the Company Intellectual Property other than as disclosed in the Prospectus; and, 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 Company Intellectual Property; there are no pending nor has there been any notice of threatened actions, suits, proceedings or claims by others that the Company is infringing any patent, trade secret trademark, service mark, copyright or other proprietary information or materials; none of the products described in the Prospectus as being under development and processes of the Company referred to in the Prospectus, to the Company's knowledge, infringe or conflict with any patent of any third party, which could reasonably be expected to have a Material Adverse Effect; to the Company's knowledge, the patents and patent applications within Company Intellectual Property that cover the products described in the Prospectus as being under development disclose patentable subject matter, and the Company has not been notified of any inventorship challenges nor has any interference been declared or provoked nor is any material fact known by the Company with respect to such patents and patent applications that would preclude the issuance of patents with respect to such applications or would render such patents invalid or unenforceable; to the Company's knowledge, no third party, including any academic or governmental organization, possesses rights to the Company Intellectual Property which, if exercised, could enable such party to develop products competitive to those of the Company as described in the Prospectus 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 necessary to conduct the Company's business in the manner in which it is described in the Prospectus; 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 of which the Company is aware other than those described in the Prospectus; the Company is not aware that any of its employees 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, 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, to the best of the Company's knowledge, 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 to the Company's knowledge, 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;

(u) 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"), including the duty to disclose to the PTO all information believed to be material to the patentability of the Company's patents and pending U.S. patent applications within Company Intellectual Property; the Company, the University of Tennessee Research Corporation ("UTRC") and Orion Corporation ("Orion") are identified in the records of the PTO as the holder of record of the U.S. patents and patent applications as set forth in the Patent Schedule and, except as indicated in the Patent Schedule, no other entity or individual has any rights, title or interest in the patents or patent applications listed in the Patent Schedule; the Company, UTRC and Orion are similarly listed in the records of corresponding foreign agencies with respect to the foreign counterparts of the foregoing as listed in the Patent Schedule; there are no legal or governmental proceedings pending relating to Company Intellectual Property owned, controlled or prosecuted by the

Company, other than PTO (or patent offices in other jurisdictions) review of pending applications for patents, and, to the Company's knowledge, no such proceedings are threatened or contemplated by governmental authorities or others; and the Company is diligently prosecuting, and shall continue to diligently prosecute, claims in the patent applications within Company Intellectual Property which claims cover products described in the Prospectus as being under development;

(v) The Company possesses all 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, including without limitation, all such 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 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 revocation, suspension, modification or termination of any certificate, authorization or permit held by others, known to the Company that could lead to, the revocation, suspension, modification or termination of any such 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;

(w) The Company has been and is in compliance with all applicable federal, state, local and foreign laws, rules, regulations, standards, orders and decrees governing its business, 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 that would constitute non-compliance with any applicable federal, state, local or foreign laws, rules, regulations or standards;

(x) 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 were and, if still pending, are being, conducted in all material respects in accordance with experimental protocols, procedures and controls pursuant to, where applicable, accepted professional and scientific standards; the descriptions of the tests and preclinical and clinical studies conducted by or on behalf of the Company contained in the Registration Statement and the Prospectus 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 being under development, which termination, suspension, material modification or clinical hold would reasonably be expected to have a Material Adverse Effect;

(y) 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, 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;

(z) 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 or as have been waived in writing by such person in connection with the offering of the Shares contemplated hereby;

(aa) 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, (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;

(ab) 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;

(ac) 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; 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;

(ad) 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 no party has repudiated any material provision of any such contract, agreement or license;

(ae) The directed share program as referred to under the caption "Underwriting" in the Prospectus (the "Directed Share Program"), when instituted and administered in accordance with its terms, including the distribution of any Preliminary Prospectus and the Prospectus to the participants in such program and all communications and dealings by the Company, its officers, directors, employees and affiliates and any person acting on its or their behalf in connection therewith, do not and will not contravene applicable laws, regulations or rules of the relevant jurisdictions; and no consent, approval, authorization, order, registration, clearance or qualification of or with any governmental agency or body of any of the relevant jurisdictions is required in connection with the offering or sale of any shares of Stock pursuant to the Directed Share Program;

(af) The Company has not offered, or caused the Underwriters or their affiliates to offer, shares of Stock to any person pursuant to the Directed Share Program with the intent to unlawfully influence (i) a customer or supplier of the Company to alter the customer's or supplier's level or type of business with the Company or (ii) a trade journalist or publication to write or publish favorable information about the Company or its products; and

(ag) The statistical and market-related data included in the Registration Statement and the Prospectus 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.

2. Subject to the terms and conditions herein set forth, (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 a purchase price per share of $....., 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 per share set forth in clause (a) of this Section 2, that portion of the number of Optional Shares as to which such election shall have been exercised (to be adjusted by you so as to eliminate fractional shares) determined by multiplying such number of Optional Shares by a fraction, the numerator of which is the maximum number of Optional Shares which such Underwriter is entitled to purchase as set forth opposite the name of such Underwriter in Schedule I hereto and the denominator of which is the maximum number of Optional Shares that all of the Underwriters are entitled to purchase hereunder.

The Company hereby grants to the Underwriters the right to purchase at their election up to ..... Optional Shares, at the purchase price per share set forth 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 only by written notice from you to the Company, given within a period of 30 calendar days after the date of this 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 you but in no event earlier than the First Time of Delivery (as defined in Section 4 hereof) or, unless you and the Company otherwise agree in writing, earlier than two or later than ten business days after the date of such notice.

3. Upon the authorization by you 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.

4. (a) The Shares to be purchased by each Underwriter hereunder, in definitive form, and in such authorized denominations and registered in such names as Goldman, Sachs & Co. may request upon at least forty-eight hours' prior notice to the Company shall be delivered by or on behalf of the Company to Goldman, Sachs & Co., through the facilities of the Depository Trust Company ("DTC"), for the account of such Underwriter, against payment by or on behalf of such Underwriter of the purchase price therefor by wire transfer of Federal (same-day) funds to the account specified by the Company to Goldman, Sachs & Co. at least forty-eight hours in advance. The Company will cause the certificates representing the Shares to be made available for checking and packaging at least twenty-four hours prior to the Time of Delivery (as defined below) with respect thereto at the office of DTC or its designated custodian Goldman, Sachs & Co., 85 Broad Street, New York, New York 10004 (the "Designated Office"). The time and date of such delivery and payment shall be, with respect to the Firm Shares, 9:30 a.m., New York City time, on ....., 2004 or such other time and date as Goldman, Sachs & Co. and the Company may agree upon in writing, and, with respect to the Optional Shares, 9:30 a.m., New York time, on the date specified by Goldman, Sachs & Co. in the written notice given by Goldman, Sachs & Co. of the Underwriters' election to purchase such Optional Shares, or such other time and date as Goldman, Sachs & Co. and the Company may agree upon in writing. Such time and date for delivery of the Firm Shares is herein called the "First Time of Delivery", such time and date for delivery of the Optional Shares, if not the First Time of Delivery, is herein called the "Second Time of Delivery", and each such time and date for delivery is herein called a "Time of Delivery".

(b) The documents to be delivered at each Time of Delivery by or on behalf of the parties hereto pursuant to Section 7 hereof, including the cross receipt for the Shares and any additional documents requested by the Underwriters pursuant to Section 7 hereof, will be delivered at the offices of Hale and Dorr LLP, 60 State Street, Boston, Massachusetts 02109 (the "Closing Location"), and the Shares will be delivered at the Designated Office, all at such Time of Delivery. A meeting will be held at the Closing Location at .....p.m., New York City time, on the New York Business Day next preceding such Time of Delivery, at which meeting the final drafts of the documents to be delivered pursuant to the preceding sentence will be available for review by the parties hereto. For the purposes of this Section 4, "New York Business Day" shall mean each Monday, Tuesday, Wednesday, Thursday and Friday which is not a day on which banking institutions in New York are generally authorized or obligated by law or executive order to close.

5. The Company agrees with each of the Underwriters:

(a) To prepare the Prospectus in a form approved by you 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 this Agreement, or, if applicable, such earlier time as may be required by Rule 430A(a)(3) under the Act; to make no further amendment or any supplement to the Registration Statement or Prospectus which shall be disapproved by you promptly after reasonable notice thereof; to advise you, 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 and to

furnish you with copies thereof; to advise you, promptly after it receives notice thereof, of the issuance by the Commission of any stop order or of any order preventing or suspending the use of any Preliminary Prospectus or prospectus, of the suspension of the qualification of the 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 stop order or of any order preventing or suspending the use of any Preliminary Prospectus or prospectus 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 you may reasonably request to qualify the Shares for offering and sale under the securities laws of such jurisdictions as you 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 the 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 in New York City in such quantities as you may reasonably request, and, if the delivery of a prospectus is required at any time prior to the expiration of nine months after the time of issue of the Prospectus 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 period to amend or supplement the Prospectus in order to comply with the Act, to notify you and upon your request to prepare and furnish without charge to each Underwriter and to any dealer in securities as many written and electronic copies as you 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, and in case any Underwriter is required to deliver a prospectus in connection with sales of any of the Shares at any time nine months or more after the time of issue of the Prospectus, upon your request but at the expense of such Underwriter, to prepare and deliver to such Underwriter as many written and electronic copies as you may request of an amended or supplemented Prospectus complying with Section 10(a)(3) of the Act;

(d) To make generally available to its securityholders 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 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 180 days after the date of the Prospectus, 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 Shares, including but not limited to any securities that are convertible into or exchangeable for, or that represent the right to receive, Stock or any such substantially similar securities (other than pursuant to

employee stock option plans described in the Registration Statement and Prospectus, 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 Goldman, Sachs & Co. on behalf of the Underwriters;

(f) To cause each of the Company's directors, officers, members of senior management, holders of preferred stock and holders of Stock to execute and deliver to you a lock-up agreement in substantially the form of Annex III attached hereto (a "Lock-up Agreement");

(g) To furnish to its stockholders as soon as practicable after the end of each fiscal year an annual report (including a balance sheet and statements of income, stockholders' equity and cash flows of the Company certified by independent public accountants) and, as soon as practicable after the end of each of the first three quarters of each fiscal year (beginning with the fiscal quarter ending after the effective date of the Registration Statement), to make available to its stockholders consolidated summary financial information of the Company for such quarter in reasonable detail;

(h) During a period of five years from the effective date of the Registration Statement, to furnish to you copies of all reports or other communications (financial or other) furnished to stockholders, and to deliver to you (i) as soon as they are available and upon your request, copies of any reports and financial statements furnished to or filed with the Commission or any national securities exchange on which any class of securities of the Company is listed; and (ii) such additional information concerning the business and financial condition of the Company as you may from time to time reasonably request (such financial statements to be on a consolidated basis to the extent the accounts of the Company and its subsidiaries are consolidated in reports furnished to its stockholders generally or to the Commission);

(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 under the caption "Use of Proceeds";

(j) To use its best efforts to list for quotation the Shares on the National Association of Securities Dealers Automated Quotations National Market System ("NASDAQ");

(k) To file with the Commission such information on Form 10-Q or Form 10-K as may be required by Rule 463 under the Act;

(l) 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 to 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; and

(m) 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, the Blue Sky Memorandum, closing documents (including any 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 fees and disbursements of counsel for the Underwriters in connection with such qualification and in connection with the Blue Sky survey; (iv) all fees and expenses in connection with listing the Shares on the NASDAQ; (v) the filing fees incident to, and the fees and disbursements of counsel for the Underwriters in connection with, securing any required review by the National Association of Securities Dealers, Inc. of the terms of the sale of the Shares; (vi) all expenses in connection with conducting the Directed Share Program; (vii) the cost of preparing stock certificates; (viii) the cost and charges of any transfer agent or registrar; and (ix) all other costs and expenses incident to the performance of its obligations hereunder 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, stock transfer taxes on resale of any of the Shares by them, and any advertising expenses connected with any offers they may make.

7. The obligations of the Underwriters hereunder, as to the Shares to be delivered at each Time of Delivery, shall be subject, in their discretion, to the condition that all representations and warranties and other statements of the Company herein are, at and as of such Time of Delivery, 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 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 your reasonable satisfaction;

(b) Hale and Dorr LLP, counsel for the Underwriters, shall have furnished to you such written opinion or opinions, dated such Time of Delivery, with respect to such matters as you 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 you their written opinion (a draft of their opinion is attached as Annex II(a) hereto), dated such Time of Delivery, in form and substance satisfactory to you, to the effect that:

(i) Immediately prior to the Merger, the Company was duly incorporated and validly existing as a corporation in good standing under the laws of the State of Tennessee; and the Company has the corporate power and authority to own its properties and conduct its business as described in the Prospectus;

(ii) The Merger is legal, effective and valid and was consummated in accordance with the laws of the State of Tennessee and the State of Delaware;

(iii) 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;

(iv) The consummation of the Merger, the issue and sale of the Shares being delivered at such Time of Delivery by the Company and the compliance by the Company with all of the provisions of this Agreement and the consummation of the transactions herein 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, 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;

(v) 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, except the registration of the offer and sale of the Shares under the Act, registration of the Shares under the Exchange 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;

(vi) 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;

(vii) The Registration Statement and the Prospectus and any further amendments and supplements thereto made by the Company prior to such Time of Delivery (other than the financial statements and financial 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 described in the Registration Statement or the Prospectus which are not filed or described as required; and

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In the course of the preparation of the Registration Statement and the Prospectus, such counsel has participated in conferences with officers of the Company, representatives of the Company's independent public accountants and representatives of the Underwriters and their counsel during which the contents of the Registration Statement and the Prospectus were discussed, and while 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, such counsel advises you that nothing has come to such counsel's attention that causes such counsel to believe that (A) the Registration Statement (except for the financial statements and financial schedules and other financial data derived therefrom, as to which such counsel expresses no belief) at the time the Registration Statement became effective 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 or (B) the Prospectus (except for the financial statements and financial schedules and other financial data derived therefrom, as to which such counsel expresses no belief) as of its date or as of such Time of Delivery contained or contains an untrue statement of a material fact or omitted or omits 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.

(d) Cooley Godward LLP, counsel for the Company, shall have furnished to you their written opinion (a draft of such opinion is attached as Annex II(b) hereto), dated such Time of Delivery, in form and substance satisfactory to you, 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 corporate power and authority to own its properties and conduct its business as described in the Prospectus;

(ii) The Company has an authorized capitalization as set forth in the Prospectus under the caption "Capitalization" (as of the date set forth therein); all of the outstanding shares of capital stock of the Company have been duly authorized and validly issued and are fully paid and non-assessable and conform in all material respects to the description thereof contained in the Prospectus; and the Shares being delivered at such Time of Delivery have been duly authorized and, when issued and delivered in accordance with the terms of this Agreement, will be validly issued, fully paid and non-assessable;

(iii) The Company has been duly qualified as a foreign corporation to transact business and is in good standing in each jurisdiction in which the conduct of its business or its ownership or leasing of property requires such qualification, except to the extent that the failure to be so qualified or be in good standing would not have a material adverse effect on the general affairs, management, financial position, stockholders' equity or results of operations of the Company (such counsel being entitled to rely in respect of the opinion in this clause upon opinions of local counsel and in respect of matters of fact

upon certificates of officers of the Company, provided that such counsel shall state that they believe that both you and they are justified in relying upon such opinions and certificates);

(iv) To such counsel's knowledge, there are no legal or governmental proceedings pending or overtly threatened to which the Company is a party or to which any of the properties of the Company is the subject that are required to be described in the Registration Statement or Prospectus and are not so described;

(v) This Agreement has been duly authorized, executed and delivered by the Company;

(vi) The Registration Statement and the filing of the Registration Statement have been duly authorized by and on behalf of the Company and the Registration Statement has been duly executed pursuant to authorization by and on behalf of the Company;

(vii) The execution and delivery by the Company of, and the performance by the Company of its obligations under, this Agreement will not contravene any provision of any applicable law (other than applicable state securities or blue sky laws, as to which such counsel need not express an opinion), the Certificate of Incorporation or By-laws of the Company, any agreement or other instrument filed as an Exhibit to the Registration Statement or, to such counsel's knowledge, any judgment, order or decree of any governmental body or agency or court having jurisdiction over the Company;

(viii) No consent, approval, authorization or order of any court, governmental body or agency is required for the performance by the Company of its obligations under this Agreement, except as may be required by (A) the Act, which have been obtained, (B) the rules and regulations of the National Association of Securities Dealers, Inc., as to which such counsel need not express an opinion or (C) the securities or Blue Sky laws of the various states in connection with the offer and sale of the Shares, as to which such counsel need not express an opinion;

(ix) The statements relating to legal matters, documents or proceedings included in the Prospectus under the captions "Description of Capital Stock", "Shares Eligible For Future Sale" and "Underwriting" (only to the extent of a description of the Underwriting Agreement) in each case fairly summarize in all material respects such legal matters, documents or proceedings;

(x) The Company is not and, after giving effect to the offering and sale of the Shares, will not be an "investment company" or a "company" controlled by an "investment company", as such terms are defined in the Investment Company Act, and the rules and regulations promulgated by the Commission thereunder;

(xi) The Registration Statement and the Prospectus and any further amendments and supplements thereto made by the Company prior to such Time of Delivery comply as to form in all material respects with the requirements of the Act and the rules and regulations thereunder; and such counsel does not know of any contracts or other documents of a character required to be filed as an exhibit to the Registration Statement or required to

be described in the Registration Statement or the Prospectus which are not filed or described as required; and

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In the course of the preparation of the Registration Statement and the Prospectus, such counsel has participated in conferences with officers of the Company, representatives of the Company's independent public accountants and representatives of the Underwriters and their counsel during which the contents of the Registration Statement and the Prospectus were discussed, and while 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, except for those portions referred to in the opinion in subsection (ix) of this section 7(d), such counsel advises you that nothing has come to such counsel's attention that causes such counsel to believe that (A) the Registration Statement (except for the financial statements and financial schedules and other financial data derived therefrom, as to which such counsel expresses no belief) at the time the Registration Statement became effective 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 or (B) the Prospectus (except for the financial statements and financial schedules and other financial data derived therefrom, as to which such counsel expresses no belief) as of its date or as of such Time of Delivery contained or contains an untrue statement of a material fact or omitted or omits 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.

(e) Eitan, Pearl, Latzer & Cohen Zedek, LLP, special patent counsel for the Company, shall have furnished to you their written opinion (a draft of such opinion is attached as Annex II(c) hereto), dated such Time of Delivery, in form and substance satisfactory to you, to the effect that:

(i) The Company owns or is the exclusive licensee of the patents and/or patent applications that disclose or claim the Company's product candidates as described in the Prospectus (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; to such counsel's knowledge, no liens or encumbrances against the Company Patents have been recorded; none of the Company Patents are invalid; and to such counsel's knowledge, none of the Company Patents are unenforceable;

(ii) To such counsel's knowledge, the Company does not lack any rights or licenses to use 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 and Company's product candidates described in the Prospectus as being under development; for each U.S. patent application included in the Company Patents, to such counsel's knowledge, 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; the Company has 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 and issued patents 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) The Company Patents disclose subject matter encompassing the Product Candidates, or claim patentable subject matter under the U.S. patent laws encompassing the Product Candidates; to such counsel's knowledge, there is no reason to believe that any of the patent applications included in the Company Patents will not result in issued patents, or that any patents issued in respect of any such patent applications will not be valid 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; and to such counsel's knowledge, there are no third party patents that would dominate the claims of any of the Company Patents;

(vi) To such counsel's knowledge, 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 to such counsel's knowledge, no interference has been threatened, declared or provoked with respect to any of the Company Patents;

(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/or and 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, its licensors as indicated on the Patent Schedule 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. Section 200 et seq) has any right, title or interest in the Company Patents;

(viii) The Company has not received, and to such counsel's knowledge, the Company has 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) To such counsel's knowledge, 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 of third parties by the Company's manufacture, use, sale, offer for sale or importation of any of the Product Candidates; and to such counsel's knowledge, neither the manufacture, use nor sale of any product of any third party is infringing any of the Company Patents;

(x) The statements set forth in the Prospectus under the captions "Risk Factors - [____]" and "Business - [___]", 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 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) the Registration Statement (except for the financial statements and financial schedules and other financial data derived therefrom, as to which such counsel expresses no belief) at the time the Registration Statement became effective 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 or (B) the Prospectus (except for the financial statements and financial schedules and other financial data derived therefrom, as to which such counsel expresses no belief) as of its date or as of such Time of Delivery contained or contains an untrue statement of a material fact or omitted or omits 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.

(f) Hogan & Hartson L.L.P., special regulatory counsel for the Company, shall have furnished to you their written opinion (a draft of such opinion is attached as Annex II(d) hereto), dated such Time of Delivery, in form and substance satisfactory to you, to the effect that:

(i) The statements set forth in the Prospectus under the captions "Risk Factors - [____]" and "Business - [___]" (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, 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, 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 Prospectus at a time prior to the execution of this Agreement, at 9:30 a.m., New York City time, on the effective date of any post-effective amendment to the Registration Statement filed subsequent to the date of this Agreement and also at each Time of Delivery, Ernst & Young LLP shall have furnished to you a letter or letters, dated the respective dates of delivery thereof, in form and substance satisfactory to you, to the effect set forth in Annex I hereto (the executed

copy of the letter delivered prior to the execution of this Agreement is attached as Annex I(a) hereto and a draft of the form of letter to be delivered on the effective date of any post-effective amendment to the Registration Statement and as of each Time of Delivery is attached as Annex I(b) hereto);

(h) (i) The Company shall not have sustained since the date of the latest audited financial statements included in the Prospectus 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, and (ii) since the respective dates as of which information is given in the Prospectus there shall not have been any change in the capital stock (other than as a result of 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, otherwise than as set forth or contemplated in the Prospectus, 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 Shares being delivered at such Time of Delivery on the terms and in the manner contemplated in the Prospectus;

(i) On or after the date hereof (i) no downgrading shall have occurred in the rating accorded the Company's debt securities or preferred stock, if any, 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 hereof 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 Shares being delivered at such Time of Delivery on the terms and in the manner contemplated in the Prospectus;

(k) The Shares to be sold at such Time of Delivery shall have been duly listed for quotation on NASDAQ;

(l) The Company has obtained and delivered to the Underwriters executed copies of the Lock-up Agreement from each of the directors, officers, members of senior management, holders of preferred stock of the Company and holders of Stock in form and substance satisfactory to the Underwriters;

(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 this Agreement; and

(n) The Company shall have furnished or caused to be furnished to you at such Time of Delivery certificates of officers of the Company satisfactory to you 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 you 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, the Registration Statement or the Prospectus, 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, the Registration Statement or the Prospectus or any such amendment or supplement in reliance upon and in conformity with written information furnished to the Company by any Underwriter through Goldman, Sachs & Co. expressly for use therein.

(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, the Registration Statement or the Prospectus, 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, the Registration Statement or the Prospectus or any such amendment or supplement in reliance upon and in conformity with written information furnished to the Company by such Underwriter through Goldman, Sachs & Co. 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 a 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 on the other from the offering of the Shares. 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 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 the Underwriters on the other shall be deemed to be in the same proportion as the total net proceeds from the offering (before deducting expenses) received by the Company bear to the total underwriting discounts and commissions received by the Underwriters, in each case as set forth in the table on the cover page of the Prospectus. 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 the 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 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 Underwriters' obligations in this subsection (d) to contribute are several in proportion to their respective underwriting obligations 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 (including any person who, with his or her consent, is named in the Registration Statement as about to become a 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 Shares which it has agreed to purchase hereunder at a Time of Delivery, you may in your discretion arrange for you or another party or other parties to purchase such Shares on the terms contained herein. If within thirty-six hours after such default by any Underwriter you do not arrange for the purchase of such Shares, 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 you to purchase such Shares on such terms. In the event that, within the respective prescribed periods, you notify the Company that you have so arranged for the purchase of such Shares, or the Company notifies you that it has so arranged for the purchase of such Shares, you or the Company shall have the right to postpone such Time of Delivery 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, or in any other documents or arrangements, and the Company agrees to file promptly any amendments to the Registration Statement or the Prospectus which in your opinion 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 this Agreement with respect to such Shares.

(b) If, after giving effect to any arrangements for the purchase of the Shares of a defaulting Underwriter or Underwriters by you 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 all the Shares to be purchased at such Time of Delivery, then the Company shall have the right to require each non-defaulting Underwriter to purchase the number of shares which such Underwriter agreed to purchase hereunder at such Time of Delivery and, in addition, to require each non-defaulting Underwriter to purchase its pro rata share (based on the number of Shares which such Underwriter agreed to purchase hereunder) of the Shares 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 Shares of a defaulting Underwriter or Underwriters by you and the Company as provided in subsection (a) above, the aggregate number of such Shares which remains unpurchased exceeds one-eleventh of the aggregate number of all the Shares to be purchased at such Time of Delivery, or if the Company shall not exercise the right described in subsection (b) above to require non-defaulting Underwriters to purchase Shares of a defaulting Underwriter or Underwriters, then this Agreement (or, with respect to the Second Time of Delivery, the obligations of the Underwriters to purchase and of the Company to sell the Optional Shares) 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 this Agreement shall be terminated pursuant to Section 9 hereof, the Company shall not then be under any liability to any Underwriter except as provided in Sections 6 and 8 hereof; but, if for any other reason, any Shares are not delivered by or on behalf of the Company as provided herein, the Company will reimburse the Underwriters through you for all out-of-pocket expenses approved in writing by you, including fees and disbursements of counsel, reasonably incurred by the Underwriters in making preparations for the purchase, sale and delivery of the Shares not so delivered, but the Company shall then be under no further liability to any Underwriter except as provided in Sections 6 and 8 hereof.

12. In all dealings hereunder, you shall act on behalf of each of the 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 you jointly or by Goldman, Sachs & Co. on behalf of you as the representatives.

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 you as the representatives in care of Goldman, Sachs & Co., 85 Broad Street, New York, New York 10004, Attention: Registration Department; and if to the Company shall be delivered or sent by mail to the address of the Company set forth in the Registration Statement, Attention: Secretary; 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 you upon request. Any such statements, requests, notices or agreements shall take effect upon receipt thereof.

13. This 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. 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 this 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 SHALL BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF THE STATE OF NEW YORK.

16. This Agreement may be executed by any one or more of the parties hereto in any number of counterparts, each of which shall be deemed to be an original, but all such counterparts shall together constitute one and the same instrument.

17. The Company is authorized, subject to applicable law, to disclose any and all aspects of this potential transaction that are necessary to support any U.S. federal income tax benefits expected to be claimed with respect to such transaction, and all materials of any kind (including tax opinions and other tax analyses) related to those benefits, without the Underwriters imposing any limitation of any kind.

If the foregoing is in accordance with your understanding, please sign and return to us seven counterparts hereof, and upon the acceptance hereof by you, on behalf of each of the Underwriters, this letter and such acceptance hereof 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 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 your part as to the authority of the signers thereof.

Very truly yours,

GTX, INC.

By:.....
Name:
Title:

Accepted as of the date hereof:

Goldman, Sachs & Co.
SG Cowen Securities Corporation
Lazard Freres & Co. LLC

By:.....
(Goldman, Sachs & Co.)

On behalf of each of the Underwriters

SCHEDULE I

UNDERWRITER	TOTAL NUMBER OF FIRM SHARES TO BE PURCHASED	NUMBER OF OPTIONAL SHARES TO BE PURCHASED IF MAXIMUM OPTION EXERCISED
Goldman, Sachs & Co.		
SG Cowen Securities Corporation		
Lazard Freres & Co. LLC		
Total		

ANNEX I

FORM OF COMFORT LETTER IN RELATION TO COMPANY

Pursuant to Section 7(d) 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 in the Prospectus or the Registration Statement comply as to form in all material respects with the applicable accounting requirements of the Act 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 unaudited 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 separately furnished to the representatives of the Underwriters (the "Representatives") and are attached hereto;

(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 as indicated in their reports thereon copies of which have been separately furnished to the Representatives and are attached hereto 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 related published rules and regulations, nothing came to their attention that cause 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 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 agrees with the corresponding amounts (after restatements where applicable) in the audited financial statements for such five fiscal years included in the Prospectus;

(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 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 statements of income, balance sheets and statements of cash flows included in the Prospectus do not comply as to form in all material respects with the applicable accounting requirements of the 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 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 in the Prospectus;

(C) the unaudited financial statements which were not included in the Prospectus but from which were derived any 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 in the Prospectus;

(D) any unaudited pro forma condensed financial statements included 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 two 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 financial statements included in the Prospectus) or any increase in the long-term debt of the Company, 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 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 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 decreases or increases 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 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, or in Part II of, or in exhibits and schedules to, the Registration Statement 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.

ANNEX II(a)

FORM OF OPINION OF BASS, BERRY & SIMS PLC

ANNEX II(b)

FORM OF OPINION OF COOLEY GODWARD LLP

ANNEX II(c)

FORM OF OPINION OF EITAN, PEARL, LATZER & COHEN ZEDEK, LLP

ANNEX II(d)

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

ANNEX III

GTX, INC.

LOCK-UP AGREEMENT

_____, 2003

Goldman, Sachs & Co.
SG Cowen Securities Corporation
Lazard Freres & Co. LLC
c/o Goldman, Sachs & Co.
85 Broad Street
New York, NY 10004

Re: GTx, Inc. - Lock-Up Agreement

Ladies and Gentlemen:

The undersigned understands that you, as representatives (the "Representatives"), propose to enter into an Underwriting Agreement on behalf of the several Underwriters named in Schedule I to such agreement (collectively, the "Underwriters"), with GTx, Inc., a Tennessee corporation ("GTx"), or a newly formed entity with which GTx may enter into a reorganization (GTx and such newly formed entity are collectively referred to herein as the "Company"), providing for a public offering of the Common Stock of the Company (the "Shares") pursuant to a Registration Statement on Form S-1 (the "Registration Statement") to be 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 beginning from the date of the final Prospectus covering the public offering of the Shares and continuing to and including the date 180 days after the date of such final Prospectus, 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 the shares of Common Stock issued upon such exercise shall be 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.

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 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 Goldman, Sachs & Co. 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; provided, however, 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.

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.

This Lock-Up Agreement shall be terminated and the undersigned shall be released from the undersigned's obligations hereunder if (i) if the Company notifies you in writing that it does not intend to proceed with the Offering or (ii) the Registration Statement is not declared effective by the SEC prior to March 31, 2004.

Very truly yours,

_____
Exact Name of Shareholder

_____
Authorized Signature

_____
Title

EXHIBIT 3.1

RESTATED CERTIFICATE OF INCORPORATION
OF
GTX, INC.

GTX, INC., a corporation organized and existing under the General Corporation Law of the State of Delaware (the "Corporation"), does hereby certify as follows:

FIRST: The name of the Corporation is GTx, Inc.

SECOND: The original Certificate of Incorporation of the Corporation was filed with the Secretary of State of the State of Delaware on September 4, 2003.

THIRD: At a meeting of the Board of Directors of the Corporation a resolution was duly adopted pursuant to Sections 242 and 245 of the General Corporation Law of the State of Delaware, setting forth this Amended and Restated Certificate of Incorporation and declaring this Amended and Restated Certificate of Incorporation to be advisable. The stockholders of the Corporation duly approved and adopted this Amended and Restated Certificate of Incorporation by unanimous written consent in accordance with Section 228, 242 and 245 of the General Corporation Law of the State of Delaware.

FOURTH: The Certificate of Incorporation of this Corporation is hereby amended and restated in its entirety to read as follows:

1. Name. The name of the Corporation is GTx, Inc.

2. Authorized Shares. The Corporation is authorized to issue two classes of stock to be designated, respectively, Common Stock (the "Common Stock") and Preferred Stock (the "Preferred Stock"). The total number of shares of capital stock that the Corporation shall have authority to issue is eleven million nine hundred seventy-five thousand (11,975,000) shares, divided as follows: (a) ten million (10,000,000) shares of Common Stock, $.001 par value per share, and (b) one million nine hundred seventy-five thousand (1,975,000) shares of Preferred Stock, $.001 par value per share. The Preferred Stock shall be divided into series. The first series shall consist of two hundred thousand (200,000) shares which shall be designated as 8% Series A Cumulative Convertible Preferred Stock (the "Series A Preferred Stock"). The second series shall consist of one hundred forty thousand (140,000) shares which shall be designated as Series A-2 Convertible Preferred Stock (the "Series A-2 Preferred Stock"). The third series shall consist of two hundred seventy-seven thousand five hundred (277,500) shares which shall be designated as 8% Series B Cumulative Convertible Preferred Stock (the "Series B Preferred Stock"). The fourth series shall consist of one hundred fifty-seven thousand five hundred (157,500) shares which shall be designated as Series B-2 Convertible Preferred Stock (the "Series B-2 Preferred Stock"). The fifth series shall consist of four hundred fifty thousand (450,000) shares which shall be designated as 8% Series C Cumulative Convertible Preferred Stock (the "Series C Preferred Stock"). The sixth series shall consist of three hundred thousand (300,000) shares which shall be designated as 8% Series D Cumulative Convertible Preferred Stock (the "Series D Preferred Stock"). The seventh series shall consist of four hundred fifty thousand (450,000) shares which shall be designated as 8% Series E Cumulative Convertible Preferred Stock (the "Series E Preferred Stock").

3. Registered Office and Agent. The registered office of the Corporation in the State of Delaware is located at 2711 Centerville Road, Suite 400 in the City of Wilmington, County of New Castle, Delaware 19808. Prentice-Hall Corporation System, Inc. is the registered agent of the Corporation at such address.

4. Purpose. The purpose of the Corporation is to engage in any lawful act or activity for which a corporation may be organized under the Delaware General Corporation Law ("DGCL").

5. Limitation of Liability; Indemnification.

5.1 Limitation of Liability. To the fullest extent that the law of the State of Delaware that exists on the date hereof, or as it may hereafter be amended, permits the limitation or elimination of the liability of its directors, no director of the Corporation shall be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director. Any repeal or modification of the foregoing provisions of this Section 5 by the stockholders of the Corporation shall not adversely affect any right or protection of a director of the Corporation in office at the time of such repeal or modification.

5.2 Indemnification by the Corporation. The Corporation shall indemnify and advance expenses to any director, officer, employee or agent of the Corporation or any other person who is serving at the request of the Corporation in any such capacity with another corporation, partnership, joint venture, trust or other enterprise, for the defense of any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative and whether formal or informal, including counsel fees actually incurred as a result of such action, suit or proceeding or any appeal thereof, and against all fines (including any excise tax assessed with respect to an employee benefit plan), judgments and amounts paid in settlement thereof, provided that such action, suit or proceeding be instituted by reason of the fact that such person is or was a director, officer, employee or agent of the Corporation or is or was serving at the request of the Corporation in any such capacity with another corporation, partnership, joint venture, trust or other enterprise, to the fullest extent permitted by the DGCL, as it exists on the date hereof or as it may hereafter be amended, and such indemnification may continue as to any person who has ceased to be a director, employee or agent and may inure to the benefit of the heirs, executors and administrators of such a person.

5.3 Nature of Indemnification. The rights to indemnification and advancement of expenses set forth in this Section 5 are intended to be greater than those which are otherwise provided for under the DGCL, are contractual between the Corporation and the person being indemnified, his heirs, executors and administrators, and are mandatory. The rights to indemnification and advancement of expenses set forth in this Section 5 are nonexclusive of other similar rights which may be granted by law, the Corporation's Bylaws, vote of the stockholders or disinterested directors or an agreement with the Corporation, which means of indemnification and advancement of expenses are hereby specifically authorized.

5.4 Effect of Repeal or Modification. Any repeal or modification of the provisions of this Section 5, either directly or by the adoption of an inconsistent provision of this Restated Certificate of Incorporation, shall not adversely affect any right or protection set forth

herein existing in favor of a particular individual at the time of such repeal or modification. In addition, if an amendment to the DGCL limits or restricts in any way the indemnification rights permitted by law as of the date hereof, such amendment shall apply only to the extent mandated by law and only to activities of persons subject to indemnification under this Section 5 which occur subsequent to the effective date of such amendment.

6. Removal of Directors. Except as otherwise provided in Section 8.6.5 and Section 8.6.6 hereof, any or all of the directors of the Corporation may be removed, with or without cause, by a proper vote of the stockholders. The term "cause" shall include, but not be limited to, a director willfully being absent from any regular or special meeting for the purpose of obstructing or hindering the business of the Corporation.

7. Common Stock.

7.1 Voting Rights of Common Stock. Each share of Common Stock shall entitle the holder thereof to one vote, in person or by proxy, upon each question or matter submitted generally to the holders of the Common Stock of the Corporation.

7.2 Liquidation. Upon any dissolution, liquidation or winding up of the Corporation, whether voluntary or involuntary, and after payment to the holders of shares of Preferred Stock as provided below, the remaining assets and funds of the Corporation, if any, shall be distributed and paid over to the holders of Common Stock, pro rata according to their respective shares.

7.3 No Preemptive Rights. No holder of shares of Common Stock shall, as such holder, have any right to purchase or subscribe for any part of the unissued shares of the Corporation of any class or series, now or hereafter authorized, or of any bond, debenture, obligation or instrument which the Corporation may issue or sell that shall be convertible into or exchangeable for or entitle the holders thereof to purchase or subscribe for any shares of the Corporation of any class or series, now or hereafter authorized, other than such right, if any, as the Board of Directors of the Corporation in its discretion may determine.

8. Preferred Stock.

8.1 Definitions.

8.1.1 "Accrued PIK Dividend Shares" means, at any given time, the unissued PIK Dividend Shares that represent the then accrued but unpaid dividends on the Designated Preferred Stock, as expressly contemplated in Section 8.3 below.

8.1.2 "Approved Stock Option Plan" means (i) any stock option plan of the Predecessor Corporation in existence before the Merger Effective Date, and (ii) any stock option plan which is approved by the Board of Directors and holders of a majority of the then outstanding shares of Designated Preferred Stock, voting together as a single class.

8.1.3 "Common Stock Deemed Outstanding" means, at any given time, the total number of shares of Common Stock actually outstanding at such time, plus the total number of shares of Common Stock issuable on conversion of outstanding Convertible Securities

and outstanding Options, plus the total number of shares of Common Stock that would be issuable on conversion of the Accrued PIK Dividend Shares if such shares were then issued and outstanding.

8.1.4 "Convertible Securities" means any evidence of indebtedness, shares or other securities, directly or indirectly convertible into or exchangeable for shares of Common Stock.

8.1.5 "Designated Preferred Stock" means the Series A Preferred Stock, the Series A-2 Preferred Stock, the Series B Preferred Stock, the Series B-2 Preferred Stock, the Series C Preferred Stock, the Series D Preferred Stock and the Series E Preferred Stock, whether collectively or individually as the context requires.

8.1.6 "Fair Value" means, with respect to any share of Common Stock, the closing sales prices of the Common Stock on all securities exchanges or automated quotation systems on which such shares may at the time be listed or included, or, if there has been no sale on any such exchange or reported on such quotation system on any day, the average of the highest bid and lowest asked prices on all such exchanges or reported on such quotation systems at the end of such day, or, if on any day such share is not so listed or included in any such quotation system, the average of the highest bid or lowest asked prices on such day in the domestic over-the-counter market as reported by the National Quotation Bureau, Incorporated, or any similar successor organization, in each such case averaged over a period of 21 business days consisting of the third business day immediately prior to the date as of which the Fair Value is being determined and the 20 consecutive business days prior to such date; provided, however, that if the Common Stock is not listed on any securities exchange or quoted in any such quotation system or over-the-counter market, then "Fair Value" means the fair value of a share of Common Stock as determined by the Board of Directors in good faith and approved by the holders of a majority of the then outstanding shares of each series of Designated Preferred Stock, each series voting as a separate class, or, if such approval is not obtained, Fair Value shall be determined by an independent investment bank of nationally recognized standing experienced in valuing securities, which investment bank shall be jointly selected by the Corporation and the holders of a majority of the then outstanding shares of each series of Designated Preferred Stock, each series voting as a separate class, valued on the basis of a sale of the Corporation as a whole (without consideration of any control premium) in an arms-length transaction between a willing buyer and the Corporation as a willing seller, neither acting under compulsion; and provided, further, that for purposes of Section 8.7.1(B) (Automatic Conversion), "Fair Value" means the offering price in the Qualified Public Offering. The determination of the independent investment bank (as contemplated in the preceding sentence) shall be final and binding upon all parties, and the Corporation shall pay the fees and expenses of such investment bank.

8.1.7 "Junior Securities" means the Common Stock and any other Stock of the Corporation, except for the Designated Preferred Stock, that by the terms of the instrument creating and designating such Stock is stated to be junior to Designated Preferred Stock as to dividends or rights on liquidation, dissolution or winding up of the Corporation, whether voluntary or involuntary.

8.1.8 "Liquidation Value" means (i) with respect to the Series A Preferred Stock, $7.275 per share, (ii) with respect to the Series A-2 Preferred Stock, $7.275 per share, (iii) with respect to the Series B Preferred Stock, $18.018 per share, (iv) with respect to the Series B-2 Preferred Stock, $18.018 per share, (v) with respect to the Series C Preferred Stock, $57.658 per share, (vi) with respect to the Series D Preferred Stock, $66.762 per share, and (vii) with respect to the Series E Preferred Stock, $60.69 per share, subject in each case to appropriate adjustment for any stock combinations, stock splits, recapitalizations and other similar transactions.

8.1.9 "Material Event" means the occurrence of a merger, consolidation, share exchange or similar transaction involving the Corporation or any of its Subsidiaries and one or more Persons (other than a merger of a Subsidiary with and into another Subsidiary or, if the Corporation is the surviving corporation, the Corporation, provided that the holders of shares of Designated Preferred Stock have received prior written notice thereof) or a disposition (by sale, assignment, conveyance, transfer, lease, exchange or otherwise), in one or more related transactions, of all or a substantial portion of the assets, business or revenue, or income generating operations of the Corporation and its Subsidiaries taken as a whole or any substantial change in the type of business conducted by the Company and its Subsidiaries taken as a whole.

8.1.10 "Merger" means the merger of the Predecessor Corporation with and into the Corporation, whereupon the separate existence of the Predecessor Corporation ceased and the Corporation was the surviving corporation.

8.1.11 "Merger Effective Date" means the time and date the Merger became effective.

8.1.12 "Options" means rights, options or warrants to subscribe for, purchase or otherwise acquire Common Stock or Convertible Securities.

8.1.13 "Original Series A Date of Issuance" means the original date of issuance of each share of the Predecessor Series A Preferred Stock.

8.1.14 "Original Series B Date of Issuance" means the original date of issuance of each share of the Predecessor Series B Preferred Stock.

8.1.15 "Original Series C Date of Issuance" means the original date of issuance of each share of the Predecessor Series C Preferred Stock.

8.1.16 "Original Series D Date of Issuance" means the original date of issuance of each share of the Predecessor Series D Preferred Stock.

8.1.17 "Original Series E Date of Issuance" means the original date of issuance of each share of the Predecessor Series E Preferred Stock.

8.1.18 "Person" means any individual, sole proprietorship, partnership (including a limited partnership), joint venture, trust, unincorporated organization, association, corporation, institution, public benefit corporation, limited liability company, joint stock corporation, entity or government (whether federal, state, county, city, municipal or otherwise,

including, without limitation, any instrumentality, division, agency, body or department thereof) or any other business entity.

8.1.19 "PIK Dividend Shares" means the shares of Designated Preferred Stock issuable in payment of accrued dividends on outstanding shares of Designated Preferred Stock, as expressly contemplated in Section 8.3 hereof. Notwithstanding any provision herein to the contrary, the PIK Dividend Shares shall have only such rights, privileges and priorities as are set forth in Section 8.4, Section 8.5, and Section 8.7 hereof.

8.1.20 "Predecessor Corporation" means GTx, Inc., a corporation incorporated under the laws of the State of Tennessee.

8.1.21 "Predecessor Series A Liquidation Value" means $7.275 per share of Predecessor Series A Preferred Stock.

8.1.22 "Predecessor Series A Preferred Stock" means the Predecessor Corporation's 8% Series A Cumulative Convertible Preferred Stock, each issued and outstanding share of which converted into one share of the Series A Preferred Stock on the Merger Effective Date.

8.1.23 "Predecessor Series B Liquidation Value" means $18.018 per share of Predecessor Series B Preferred Stock.

8.1.24 "Predecessor Series B Preferred Stock" means the Predecessor Corporation's 8% Series B Cumulative Convertible Preferred Stock, each issued and outstanding share of which converted into one share of the Series B Preferred Stock on the Merger Effective Date.

8.1.25 "Predecessor Series C Liquidation Value" means $57.658 per share of Predecessor Series C Preferred Stock.

8.1.26 "Predecessor Series C Preferred Stock" means the Predecessor Corporation's 8% Series C Cumulative Convertible Preferred Stock, each issued and outstanding share of which converted into one share of the Series C Preferred Stock on the Merger Effective Date.

8.1.27 "Predecessor Series D Liquidation Value" means $66.762 per share of Predecessor Series D Preferred Stock.

8.1.28 "Predecessor Series D Preferred Stock" means the Predecessor Corporation's 8% Series D Cumulative Convertible Preferred Stock, each issued and outstanding share of which converted into one share of the Series D Preferred Stock on the Merger Effective Date.

8.1.29 "Predecessor Series E Liquidation Value" means $60.69 per share of Predecessor Series E Preferred Stock.

8.1.30 "Predecessor Series E Preferred Stock" means the Predecessor Corporation's 8% Series E Cumulative Convertible Preferred Stock, each issued and outstanding share of which converted into one share of the Series E Preferred Stock on the Merger Effective Date.

8.1.31 "Qualified Public Offering" means an offering to the public, pursuant to Section 5 of the Securities Act of 1933, as amended, of registered shares of Common Stock or Convertible Securities, in which (i) the proceeds to the Corporation, net of underwriters' commissions and all other expenses of the offering (including, without limitation, accountants' and attorneys' fees, filing fees and other expenses of the offering), are not less than $25,000,000, and (ii) the price per share of Common Stock (or, if Convertible Securities are offered, the price per Common Stock equivalent) is not less than $115.316 (adjusted for stock splits, stock dividends and other similar changes to the Common Stock).

8.1.32 "Redemption Date" means, as to any share of Designated Preferred Stock, the applicable date specified herein in the case of any redemption; provided, that no such date will be a Redemption Date unless the applicable Redemption Price is actually paid in cash, and if not so paid, the Redemption Date will be the date on which such Redemption Price is fully paid in cash.

8.1.33 "Redemption Price" means the redemption price specified in Section 8.5.1 or Section 8.5.2, as applicable.

8.1.34 "Series AB Director" means the member of the Board of Directors chosen or to be chosen by the holders of the Series A Preferred Stock and the Series B Preferred Stock as provided in Section 8.6.5 below.

8.1.35 "Series C Director" means the member of the Board of Directors chosen or to be chosen by the holders of the Series C Preferred Stock as provided in Section 8.6.6 below.

8.1.36 "Stock" means all shares, options, warrants, general or limited partnership interests, participations or other equivalents (regardless of how designated) of or in a Person, whether voting or nonvoting, including, without limitation, common stock, preferred stock or any other "equity security" (as such term is defined in Rule 3a11-1 of the General Rules and Regulations promulgated by the Securities and Exchange Commission under the Securities Exchange Act of 1934, as amended), including, without limitation, any securities with profit participation features, and any rights, warrants, options or other securities convertible into or exercisable or exchangeable for any such shares, equity or profits interests, participations or other equivalents.

8.1.37 "Subsidiary" means, with respect to any Person, (i) any company of which an aggregate of more than 50% of the outstanding Stock having ordinary voting power for the election of directors, managers or trustees of such company (irrespective of whether, at the time, Stock of any other class or classes of such company shall have or might have voting power by reason of the happening of any contingency) is at the time, directly or indirectly, owned legally or beneficially or controlled, directly or indirectly, by such Person and/or one or

more Subsidiaries of such Person, or any combination thereof, or with respect to which any such Person has the right to vote or designate the vote of more than 50% of such Stock whether by proxy, agreement, operation of law or otherwise, (ii) any partnership, limited liability company, association or other business entity, in which such Person and/or one or more Subsidiaries of such Person shall have more than 50% of the partnership or other similar ownership interests thereof (whether in the form of voting or participation in profits or capital contribution), and (iii) all other Persons from time to time included in the consolidated financial statements of such Person. For purposes hereof, a Person or Persons shall be deemed to have more than 50% ownership interest in a limited liability company, partnership, association or other business entity if such Person or Persons shall be allocated more than 50% of limited liability company, partnership, association or other business entity gains or losses or shall be or control any managing director or general partner of such limited liability company, partnership, association or other business entity.

8.2 Rank. Each series of Designated Preferred Stock shall, with respect to dividend rights and rights upon liquidation, dissolution, winding up of the Corporation, whether voluntary or involuntary, rank (a) senior to all Junior Securities; (b) on a parity with each other series of Designated Preferred Stock (except that the PIK Dividend Shares shall have no dividend rights); (c) junior to all equity securities issued by the Corporation in accordance with Section 8.6.2(B) and/or Section 8.6.3.(B), as applicable, the terms of which specifically provide that such equity securities rank senior to such series of Designated Preferred Stock with respect to dividend rights or rights upon liquidation, dissolution or winding up of the Corporation, whether voluntary or involuntary; and (d) junior to all existing and future indebtedness of the Corporation.

8.3 Dividends.

8.3.1 Series A Preferred Stock.

(A) From the Original Series A Date of Issuance until October 4, 2001, the holders of shares of the Predecessor Series A Preferred Stock were entitled to receive, when, as and if declared by the Board of Directors of the Predecessor Corporation out of funds of the Predecessor Corporation legally available for payment, cumulative cash dividends payable at the annual rate of 8% of the Predecessor Series A Liquidation Value for each share of the Predecessor Series A Preferred Stock ("Predecessor Series A Non-Compounded Dividends"). As of the Merger Effective Date, no such Predecessor Series A Non-Compounded Dividends had been paid. Such accrued but unpaid Predecessor Series A Non-Compounded Dividends, without compounding of interest thereon (either prior to or following the Merger Effective Date), shall become payable on the Series A Preferred Stock in the same manner and at the same time as dividends accruing on the Series A Preferred Stock after the Merger Effective Date become payable.

(B) From October 5, 2001 until the Merger Effective Date, dividends on the Predecessor Series A Preferred Stock accrued and were cumulative at the annual rate of 8% of the Predecessor Series A Liquidation Value and compounded annually (the "Predecessor Series A Compounded Dividends"). As of the Merger Effective Date, no such Predecessor Series A Compounded Dividends had been paid. Such accrued but

unpaid Predecessor Series A Compounded Dividends shall become payable with respect to the Series A Preferred Stock as provided below in paragraph (C) below.

(C) Dividends on the Series A Preferred Stock shall accrue and be cumulative from the Merger Effective Date at the annual rate of 8% of the Liquidation Value for the Series A Preferred Stock. Such accrued but unpaid dividends from the Merger Effective Date shall be added with the Predecessor Series A Compounded Dividends, the total of which shall thereafter compound annually and be payable only at such time as such shares of the Series A Preferred Stock are converted or redeemed (including in case of liquidation) as hereinafter provided. Dividends on the Series A Preferred Stock, including dividends accrued on the Predecessor Series A Preferred Stock prior to the Merger Effective Date, shall be payable, solely in shares of Series A-2 Preferred Stock, to holders of record as they appear on the stock records of the Corporation at the time of conversion or redemption, with the number of shares of Series A-2 Preferred Stock issued as dividends to be determined by dividing the amount of accrued but unpaid dividends by the Liquidation Value of the Series A Preferred Stock.

8.3.2 Series B Preferred Stock.

(A) From the Original Series B Date of Issuance until October 4, 2001, the holders of shares of the Predecessor Series B Preferred Stock were entitled to receive, when, as and if declared by the Board of Directors of the Predecessor Corporation out of funds of the Predecessor Corporation legally available for payment, cumulative cash dividends payable at the annual rate of 8% of the Predecessor Series B Liquidation Value for each share of the Predecessor Series B Preferred Stock ("Predecessor Series B Non-Compounded Dividends"). As of the Merger Effective Date, no such Predecessor Series B Non-Compounded Dividends had been paid. Such accrued but unpaid Predecessor Series B Non-Compounded Dividends, without compounding of interest thereon (either prior to or following the Merger Effective Date), shall become payable on the Series B Preferred Stock in the same manner and at the same time as dividends accruing on the Series B Preferred Stock after the Merger Effective Date become payable.

(B) From October 5, 2001 until the Merger Effective Date, dividends on the Predecessor Series B Preferred Stock accrued and were cumulative at the annual rate of 8% of the Predecessor Series B Liquidation Value and compounded annually (the "Predecessor Series B Compounded Dividends"). As of the Merger Effective Date, no such Predecessor Series B Compounded Dividends had been paid. Such accrued but unpaid Predecessor Series B Compounded Dividends shall become payable with respect to the Series B Preferred Stock as provided below in paragraph (C) below.

(C) Dividends on the Series B Preferred Stock shall accrue and be cumulative from the Merger Effective Date at the annual rate of 8% of the Liquidation Value for the Series B Preferred Stock. Such accrued but unpaid dividends from the Merger Effective Date shall be added with the Predecessor Series B Compounded

Dividends, the total of which shall thereafter compound annually and be payable only at such time as such shares of the Series B Preferred Stock are converted or redeemed (including in case of liquidation) as hereinafter provided. Dividends on the Series B Preferred Stock, including dividends accrued on the Predecessor Series B Preferred Stock prior to the Merger Effective Date, shall be payable, solely in shares of Series B-2 Preferred Stock, to holders of record as they appear on the stock records of the Corporation at the time of conversion or redemption, with the number of shares of Series B-2 Preferred Stock issued as dividends to be determined by dividing the amount of accrued but unpaid dividends by the Liquidation Value of the Series B Preferred Stock.

8.3.3 Series C Preferred Stock.

(A) From the Original Series C Date of Issuance until the Merger Effective Date, dividends on the Predecessor Series C Preferred Stock accrued and were cumulative at the annual rate of 8% of the Predecessor Series C Liquidation Value and compounded annually (the "Predecessor Series C Dividends"). As of the Merger Effective Date, no such Predecessor Series C Dividends had been paid. Such accrued but unpaid Predecessor Series C Dividends shall become payable with respect to the Series C Preferred Stock as provided in paragraph (B) below.

(B) Dividends on the Series C Preferred Stock shall accrue and be cumulative from the Merger Effective Date at the annual rate of 8% of the Liquidation Value for the Series C Preferred Stock. Such accrued but unpaid dividends from the Merger Effective Date shall be added with the Predecessor Series C Dividends, the total of which shall thereafter compound annually and be payable only at such time as such shares of the Series C Preferred Stock are converted or redeemed (including in case of liquidation) as hereinafter provided. Dividends on the Series C Preferred Stock, including the Predecessor Series C Dividends, shall be payable, solely in shares of Series C Preferred Stock, to holders of record as they appear on the stock records of the Corporation at the time of conversion or redemption, with the number of shares of Series C Preferred Stock issued as dividends to be determined by dividing the amount of accrued but unpaid dividends by the Liquidation Value of the Series C Preferred Stock.

8.3.4 Series D Preferred Stock.

(A) From the Original Series D Date of Issuance until the Merger Effective Date, dividends on the Predecessor Series D Preferred Stock accrued and were cumulative at the annual rate of 8% of the Predecessor Series D Liquidation Value and compounded annually (the "Predecessor Series D Dividends"). As of the Merger Effective Date, no such Predecessor Series D Dividends had been paid. Such accrued but unpaid Predecessor Series D Dividends shall become payable with respect to the Series D Preferred Stock as provided in paragraph (B) below.

(B) Dividends on the Series D Preferred Stock shall accrue and be cumulative from the Merger Effective Date at the annual rate of 8% of the Liquidation Value for the Series D Preferred Stock. Such accrued but unpaid dividends from the Merger Effective Date shall be added with the Predecessor Series D Dividends, the total

of which shall thereafter compound annually and be payable only at such time as such shares of the Series D Preferred Stock are converted or redeemed (including in case of liquidation) as hereinafter provided. Dividends on the Series D Preferred Stock, including the Predecessor Series D Dividends, shall be payable, solely in shares of Series D Preferred Stock, to holders of record as they appear on the stock records of the Corporation at the time of conversion or redemption, with the number of shares of Series D Preferred Stock issued as dividends to be determined by dividing the amount of accrued but unpaid dividends by the Liquidation Value of the Series D Preferred Stock.

8.3.5 Series E Preferred Stock.

(A) From the Original Series E Date of Issuance until the Merger Effective Date, dividends on the Predecessor Series E Preferred Stock accrued and were cumulative at the annual rate of 8% of the Predecessor Series E Liquidation Value and compounded annually (the "Predecessor Series E Dividends"). As of the Merger Effective Date, no such Predecessor Series E Dividends had been paid. Such accrued but unpaid Predecessor Series E Dividends shall become payable with respect to the Series E Preferred Stock as provided in paragraph (B) below.

(B) Dividends on the Series E Preferred Stock shall accrue and be cumulative from the Merger Effective Date at the annual rate of 8% of the Liquidation Value for the Series E Preferred Stock. Such accrued but unpaid dividends from the Merger Effective Date shall be added with the Predecessor Series E Dividends, the total of which shall thereafter compound annually and be payable only at such time as such shares of the Series E Preferred Stock are converted or redeemed (including in case of liquidation) as hereinafter provided. Dividends on the Series E Preferred Stock, including the Predecessor Series E Dividends, shall be payable, solely in shares of Series E Preferred Stock, to holders of record as they appear on the stock records of the Corporation at the time of conversion or redemption, with the number of shares of Series E Preferred Stock issued as dividends to be determined by dividing the amount of accrued but unpaid dividends by the Liquidation Value of the Series E Preferred Stock.

8.3.6 PIK Dividend Shares. Notwithstanding any provision herein to the contrary, the PIK Dividend Shares, when issued, shall not accrue dividends under any circumstances.

8.3.7 Basis for Accrual. Dividends accruing on any Designated Preferred Stock for any period greater or less than a full dividend period will be computed on the basis of a 360-day year consisting of twelve 30-day months.

8.3.8 Restriction on Payment. No dividends on shares of any Designated Preferred Stock shall be declared by the Board of Directors or paid or set apart for payment by the Corporation at such time as the terms and provisions of any agreement of the Corporation, including any agreement relating to its indebtedness, prohibits such declaration, payment or setting apart for payment or provides that such declaration, payment or setting apart for payment would constitute a breach thereof or a default thereunder, or if such declaration or payment shall be restricted or prohibited by law; provided, however, that the terms of any agreements which

contain a prohibition on payments of dividends on any series of Designated Preferred Stock shall have been consented to by the holders of a majority of the then outstanding shares of such series.

8.4 Liquidation. Upon any dissolution, liquidation or winding up of the Corporation, whether voluntary or involuntary, the holders of outstanding shares of each series of Designated Preferred Stock shall be entitled to be paid out of the funds legally available therefor for distribution to shareholders, before any distribution or payment is made upon any of the Junior Securities, an amount in cash equal to (a) the aggregate Liquidation Value of all shares of such series of Designated Preferred Stock then outstanding plus (b) the aggregate Liquidation Value of the PIK Dividend Shares thereon, and the holders of outstanding shares of such Designated Preferred Stock will not be entitled to any further payment (whether on such outstanding shares of Designated Preferred Stock or such PIK Dividend Shares). No such payment shall be made if payment with respect to the other series of Designated Preferred Stock is not being made simultaneously, except with respect to any holder of shares of Designated Preferred Stock who is not exercising its Liquidation Option (as defined below). If upon any such dissolution, liquidation or winding up of the Corporation, the Corporation's assets to be distributed among the holders of Designated Preferred Stock are insufficient to permit payment to such holders of the aggregate amounts to which they are entitled to be paid, then the entire assets to be distributed shall be distributed ratably among such holders based upon the aggregate Liquidation Value of the shares held by each such holder (plus the aggregate Liquidation Value of the PIK Dividend Shares). Immediately prior to the time of any dissolution, liquidation or winding up of the Corporation, to the extent permitted by applicable law, the Corporation shall declare for payment all accrued and unpaid dividends with respect to the Designated Preferred Stock in the form of the PIK Dividend Shares. The Corporation will mail written notice of such dissolution, liquidation or winding up not less than 10 days prior to the payment date stated therein to each record holder of Designated Preferred Stock. A sale of all or substantially all of its assets by the Corporation or a merger, consolidation or reorganization of the Corporation (other than one in which the holders of the shares of Stock of the Corporation immediately prior to such transaction will own more than a majority of the outstanding voting Stock of the Corporation or its successor entity after the transaction) shall, at the option ("Liquidation Option") of holders of a majority of the then outstanding shares of any one or more series of Designated Preferred Stock, be deemed a liquidation. The conversion of the Designated Preferred Stock into shares of Common Stock of the Corporation shall be permitted for a period of fifteen (15) days following written notice by the Corporation to the record holder of shares of Designated Preferred Stock of any such proposed transaction following its approval by the shareholders of the Corporation.

8.5 Redemptions.

8.5.1 Mandatory Redemption. Shares of outstanding Designated Preferred Stock shall be redeemed at the election of the respective holders thereof at any time on or after August 31, 2006. The redemption price per share shall equal the greater of (i) the applicable Liquidation Value thereof, or (ii) the Fair Value thereof calculated as if such shares had been converted into Common Stock pursuant to Section 8.7 hereof. Any redemption of outstanding shares of Designated Preferred Stock shall automatically and simultaneously include the redemption of any PIK Dividend Shares thereon, at the redemption price per share set forth in the preceding sentence. Shares to be redeemed by the Corporation pursuant to this Section

8.5.1 shall be delivered by the holder thereof free and clear of all liens and encumbrances. The Corporation shall not have the right to require the redemption of the Designated Preferred Stock.

8.5.2 Redemption in Certain Circumstances. Upon the occurrence of a Material Event and written notice from any one or more holders of outstanding shares of any Designated Preferred Stock, the Corporation shall repurchase from such holders all or the portion of the Designated Preferred Stock designated in such notices for an amount determined by multiplying (i) the number of shares of Common Stock into which the shares of Designated Preferred Stock to be repurchased are then convertible pursuant to Section 8.7 hereof by (ii) the Fair Value of Common Stock as of the date of such notice. A redemption of any outstanding shares of Designated Preferred Stock shall automatically and simultaneously include the redemption of any PIK Dividend Shares thereon, at the redemption price per share set forth in the preceding sentence. Nothing herein shall preclude the conversion by any holder of any shares of Designated Preferred Stock at any time prior to such repurchase. Shares to be redeemed by the Corporation pursuant to this Section 8.5.2 shall be delivered by the holder thereof free and clear of all liens and encumbrances.

8.5.3 Redemption Price. For each share of Designated Preferred Stock (including any PIK Dividend Share) which is to be redeemed, the Corporation will be obligated on the Redemption Date to pay to the holder thereof an amount in immediately available funds equal to the Redemption Price thereof; provided, however, that the Corporation shall not be obligated to pay the Redemption Price unless and until the holder surrenders the certificate representing such share of Designated Preferred Stock, other than any PIK Dividend Share, to the Corporation at the Corporation's principal office, free and clear of all liens and encumbrances. If the Corporation's funds which are legally available for redemption of shares of Designated Preferred Stock on any Redemption Date are insufficient to redeem the total number of shares to be redeemed on such date, those funds which are legally available will be used to redeem shares of Designated Preferred Stock ratably among the holders of the shares tendered for redemption. At any time thereafter when additional funds of the Corporation are legally available for the redemption of shares of Designated Preferred Stock, such funds will immediately be used to redeem the balance of the shares which the Corporation has become obligated to redeem on any Redemption Date but which it has not redeemed. Without limiting any rights of the holders of any shares of Designated Preferred Stock which are set forth in this Fifth Amended and Restated Charter or are otherwise available under law, the balance of the outstanding shares of Designated Preferred Stock which the Corporation has become obligated to redeem on any Redemption Date but which it has not redeemed shall continue to have all of the powers, designations, preferences and relative participating, optional, and other special rights (including, without limitation, the rights to accrue dividends) which such shares had prior to such Redemption Date, until the aggregate Redemption Price of such shares of Designated Preferred Stock has been paid in full; provided, however, that dividends shall thereafter accrue on outstanding shares of Designated Preferred Stock which the Corporation has become obligated to redeem on any Redemption Date but which it has not redeemed, at the annual rate of (a) 8% or (b) the prime rate plus 4%, whichever is greater (the "Default Rate"), based on the liquidation value of such shares. The "prime rate" referred to in the preceding sentence shall be the rate, denoted as such, published as the base rate on corporate loans at large U.S. money center commercial banks in the Wall Street Journal under "Money Rates" on the applicable date and, for purposes of adjustment thereafter, on the second Tuesday of each month.

8.5.4 Redemption Procedures.

(A) A holder ("Electing Holder") may elect to have his/her/its outstanding shares of Designated Preferred Stock redeemed by giving written notice thereof not less than 60 days prior to the date on which such redemption is to be made, by certified mail, return receipt requested, or by reputable overnight courier, to the Secretary of the Corporation at the Corporation's principal office (the "Notice of Redemption"). The Notice of Redemption shall set forth:

(i) the name and current address of the Electing Holder;

(ii) if the Electing Holder is not the holder of record of the shares of Designated Preferred Stock to be redeemed, the complete name of the holder of record as indicated on the certificate(s) evidencing the shares of Designated Preferred Stock to be redeemed, and a brief explanation of the Electing Holder's source of title to the shares of Designated Preferred Stock to be redeemed; and

(iii) the number of outstanding shares of Designated Preferred Stock to be redeemed (the Notice of Redemption need not specify the number of PIK Dividend Shares that will be redeemed).

(B) Within three (3) business days following receipt of the Notice of Redemption, the Corporation shall mail a written notice (the "Redemption Acknowledgment") by certified mail, return receipt requested, or reputable overnight courier, to the Electing Holder at the address set forth in the Notice of Redemption, specifying the address to which the Electing Holder shall deliver certificates evidencing the outstanding shares of Designated Preferred Stock to be redeemed and indicating whether or not there are any defects or deficiencies in the Notice of Redemption (which defects and deficiencies, if any, if not so identified, shall be deemed waived). Further, the Corporation shall specify a Redemption Date which shall be no later than 60 days following the Notice of Redemption. Upon the Corporation's receipt, prior to the Redemption Date, of certificates evidencing the outstanding shares of Designated Preferred Stock to be redeemed, the Corporation shall promptly pay the amount due upon redemption to the Electing Holder on the Redemption Date. Upon such payment, the rights of the Electing Holder as a holder of the shares of Designated Preferred Stock so redeemed shall cease and be of no further force or effect.

(C) In case fewer than the total number of shares represented by any certificate are redeemed, a new certificate representing the number of unredeemed shares will be issued to the holder thereof without cost to such holder within 3 business days after surrender of the certificate to the Corporation as provided above.

8.5.5 Dividends After Redemption Date; Rights of Shareholder. No share of Designated Preferred Stock is entitled to any dividends accruing after the Redemption Date on which the Redemption Price of such share is paid in full. On such Redemption Date, all

rights of the holder of such share of Designated Preferred Stock as a holder of such share will cease, and such share of Designated Preferred Stock will not be deemed to be outstanding.

8.5.6 Redeemed or Otherwise Acquired Shares. Any shares of Designated Preferred Stock which are redeemed or otherwise acquired by the Corporation will be canceled and will not be reissued, sold or transferred.

8.6 Voting Rights.

8.6.1 General. The holders of Designated Preferred Stock shall be entitled to vote on all matters submitted to a vote of holders of Common Stock of the Corporation as if such holders of Designated Preferred Stock held that number of shares of Common Stock into which such outstanding shares of Designated Preferred Stock are then convertible, including any Accrued PIK Dividend Shares. The holders of Designated Preferred Stock shall be entitled to receive all notices of regular and special meetings of stockholders at which corporate action is to be taken and to notice of corporate action to be taken by written consent, and to inspect and copy the Corporation's stock books, as if such holders were holders of Common Stock of the Corporation. At any meeting of stockholders of the Corporation, the number of shares of Common Stock into which the Designated Preferred Stock then outstanding is convertible, shall be counted for the purposes of determining whether a quorum is present. The PIK Dividend Shares shall have no voting rights except to the extent provided in the first sentence of this Section 8.6.1.

8.6.2 Corporate Action Requiring Affirmative Vote of Holders of Series A Preferred Stock and Series B Preferred Stock. So long as any shares of the Series A Preferred Stock or the Series B Preferred Stock are outstanding, the Corporation shall not, without first obtaining the consent, given in person or by proxy, either in writing or at any meeting called for the purpose of obtaining the approval herein required, of the holders of at least a majority of the then outstanding shares of each of the Series A Preferred Stock and the Series B Preferred Stock:

(A) amend, alter, change, or repeal any of the express terms and provisions of the Series A Preferred Stock or the Series B Preferred Stock, in a manner which would adversely affect the rights or preferences of the Series A Preferred Stock or the Series B Preferred Stock, respectively, including any increase in the authorized number of shares of any such series;

(B) authorize, create or issue any shares of stock of any other class or series, or authorize an increase in the authorized amount of any class or series of shares, which shall rank in any respect on a parity with or senior to the Series A Preferred Stock or the Series B Preferred Stock, as the case may be, or authorize, create or issue any obligations, bonds, notes, debentures, stock or other securities by their terms convertible into shares of stock of any other class or series which rank in any respect on a parity with or senior to shares of the Series A Preferred Stock or the Series B Preferred Stock. as the case may be; or

(C) authorize any repurchase or redemption of Stock of the Corporation, except as provided in Section 8.5 or Section 8.6.4(G).

For the purpose of this Section 8.6.2, the holders of shares of Series A Preferred Stock shall vote as one class, and each holder of Series A Preferred Stock shall be entitled to one vote for each share held; the holders of shares of Series B Preferred Stock shall vote as one class, and each holder of Series B Preferred Stock shall be entitled to one vote for each share held.

8.6.3 Corporate Action Requiring Affirmative Vote of Holders of Series C Preferred Stock, Series D Preferred Stock and Series E Preferred Stock. So long as any shares of Series C Preferred Stock, Series D Preferred Stock or Series E Preferred Stock are outstanding, the Corporation shall not, without first obtaining the consent, given in person or by proxy, either in writing or at any meeting called for the purpose of obtaining the approval herein required, of the holders of at least a majority of the then outstanding shares of each of the Series C Preferred Stock, Series D Preferred Stock and Series E Preferred Stock:

(A) amend, alter, change, or repeal any of the express terms and provisions of the Series C Preferred Stock, the Series D Preferred Stock or the Series E Preferred Stock, as the case may be, in a manner which would adversely affect the rights or preferences of the Series C Preferred Stock, the Series D Preferred Stock or the Series E Preferred Stock, respectively, including any increase in the authorized number of shares of such series;

(B) authorize, create or issue any shares of stock of any other class or series, or authorize an increase in the authorized amount of any class or series of shares, which shall rank in any respect on a parity with or senior to the Series C Preferred Stock, the Series D Preferred Stock or the Series E Preferred Stock, as the case may be, or authorize, create or issue any obligations, bonds, notes, debentures, stock or other securities by their terms convertible into shares of stock of any other class or series which rank in any respect on a parity with or senior to shares of the Series C Preferred Stock, the Series D Preferred Stock or the Series E Preferred Stock, as the case may be; or

(C) authorize any repurchase or redemption of Stock of the Corporation, except as provided in Section 8.5 or Section 8.6.4(G), sell shares of Series C Preferred Stock in excess of 260,154 shares, or sell shares of Series D Preferred Stock in excess of 164,765 shares.

For the purpose of this Section 8.6.3, the holders of Series C Preferred Stock shall vote as one class, and each holder of Series C Preferred Stock shall be entitled to one vote for each share held; the holders of Series D Preferred Stock shall vote as one class, and each holder of Series D Preferred Stock shall be entitled to one vote for each share held; the holders of Series E Preferred Stock shall vote as one class, and each holder of Series E Preferred Stock shall be entitled to one vote for each share held.

8.6.4 Corporate Action Requiring Affirmative Vote of Holders of Designated Preferred Stock. So long as any shares of Designated Preferred Stock are outstanding, the Corporation shall not, without first obtaining the consent, given in person or by proxy, either in writing or at any meeting called for the purpose of obtaining the approval herein

required, of the holders of an absolute majority of the then outstanding shares of Designated Preferred Stock, voting together as a single class, and with respect only to items (A), (B), (C), (E), (G), (H), (J), (N) and (V) below, of the holders of a majority of the outstanding shares of Series C Preferred Stock and Series D Preferred Stock, each voting as a separate class:

(A) amend or repeal any provision of the Corporation's Certificate of Incorporation or Bylaws;

(B) increase or decrease (other than, as to any decrease, pursuant to conversion, redemption or repurchase as authorized by the Corporation's Certificate of Incorporation) the number of authorized shares of any series of Preferred Stock;

(C) reclassify any Preferred Stock;

(D) issue any shares of Common Stock or Preferred Stock other than (i) pursuant to the conversion of Designated Preferred Stock, (ii) as contemplated in Section 8.3 hereof, or (iii) Common Stock issuable upon the exercise of Options pursuant to Approved Stock Option Plans;

(E) pay a dividend on or repurchase any shares of Common Stock, except pursuant to the liquidation, conversion or redemption provisions hereof with respect to the Designated Preferred Stock or as otherwise allowable pursuant to paragraph (G) below;

(F) pay or declare any dividend or make any distribution (either in cash or property) upon any Junior Securities (other than dividends payable solely in the securities in respect of which such dividends are paid);

(G) directly or through a Subsidiary redeem, retire, purchase or otherwise acquire any Junior Securities provided that upon approval of the Corporation's Board of Directors, the Corporation may redeem Options (or Common Stock previously issued upon exercise of Options) issued to a Corporation employee as long as the redemption price thereof during any fiscal year of the Corporation does not exceed $100,000 for such employee;

(H) except as set forth in subparagraph (G) above, pay into, set apart, or make available any moneys or property for the purchase or redemption of any Junior Securities;

(I) pay a dividend on or repurchase any shares of Preferred Stock, other than the Designated Preferred Stock in accordance with the terms hereof, without amendment hereafter;

(J) recapitalize, reorganize, liquidate, file for bankruptcy, sell material assets, or merge (except transactions in which the Corporation's shareholders own a majority of the securities of the surviving entity) or sell substantially all of the Corporation's assets where proceeds are less than 200% of the aggregate Liquidation

Value and all accrued dividends (including required interest thereon) of the then outstanding Designated Preferred Stock;

(K) increase or decrease the size of the Board of Directors;

(L) adopt any new stock option plan or employee stock ownership plan;

(M) grant any stock options except Options issued under the 1999, 2000, 2001 and 2002 Stock Option Plans previously adopted by the Predecessor Corporation and assumed by the Corporation pursuant to the Merger;

(N) enter into any transaction with a related party;

(O) enter into any bank or non-trade indebtedness for borrowed money or issue any debt securities;

(P) loan money (provided that the advancement of expenses as contemplated in Section 5 hereof (and other similar arrangements) is expressly not a loan of money);

(Q) terminate officers;

(R) increase compensation of officer employees more than 10% in any year;

(S) make (i) any single capital expenditure (including through purchase, capital lease or otherwise) in excess of $200,000 or (ii) capital expenditures in any calendar year in excess of an aggregate of $1,000,000;

(T) approve any legal settlement in excess of $25,000;

(U) alter the method of keeping the Corporation's books or accounting practices; or

(V) adopt a strategic or operating plan that changes the business of the Corporation.

In any voting as required by this Section 8.6.4, each share of Designated Preferred Stock shall have the number of votes equal to the number of shares of Common Stock into which such shares of Designated Preferred Stock are then convertible.

8.6.5 Election of Series AB Director. Notwithstanding any contrary or inconsistent provision of this Restated Certificate of Incorporation or the Bylaws of the Corporation:

(A) So long as any shares of Series A Preferred Stock or Series B Preferred Stock are outstanding, the Board of Directors of the Corporation shall include one director (the "Series AB Director") who is elected or appointed by the holders of a

majority of the Series A Preferred Stock and the Series B Preferred Stock, voting as a single class, with each share of the Series A Preferred Stock and the Series B Preferred Stock having one vote. Any vacancy in the office of the Series AB Director shall be filled only by the holders of the Series A Preferred Stock and the Series B Preferred Stock. Except as herein provided, the authority, rights, privileges, duties and obligations of the Series AB Director shall be no different than any other director.

(B) The Series AB Director may not be removed by any stockholders other than by a majority vote (or majority written consent) of the holders of the Series A Preferred Stock and the Series B Preferred Stock, voting (or acting by written consent) as a single class, and such removal may be with or without cause.

(C) The term of the Series AB Director shall not expire until his/her successor has been elected and qualified.

8.6.6 Election of Series C Director. Notwithstanding any contrary or inconsistent provision of this Restated Certificate of Incorporation or Bylaws of the Corporation:

(A) So long as any shares of Series C Preferred Stock are outstanding, the Board of Directors of the Corporation shall include one director (the "Series C Director") who is elected or appointed exclusively by the holders of a majority of the Series C Preferred Stock, with each share of Series C Preferred Stock having one vote. Any vacancy in the office of the Series C Director shall be filled only by the holders of the Series C Preferred Stock. Except as herein provided, the authority, rights, privileges, duties and obligations of the Series C Director shall be no different than any other director.

(B) The Series C Director may not be removed by any shareholders other than by a majority vote (or majority written consent) of the holders of the Series C Preferred Stock, voting (or acting by written consent) as a separate class, and such removal may be with or without cause.

(C) The term of the Series C Director shall not expire until his/her successor has been elected and qualified.

8.7 Conversion.

8.7.1 Optional Conversion; Automatic Conversion; Procedures.

(A) Optional Right to Convert. A holder of any outstanding share or shares of Designated Preferred Stock shall have the right at any time, at such holder's option, to convert all or a portion of such shares into such number of fully paid and nonassessable shares of Common Stock as is determined by dividing (i) the applicable, aggregate Liquidation Value of the shares of such Designated Preferred Stock to be converted by (ii) the applicable Conversion Price (as hereinafter defined) then in effect for such Designated Preferred Stock. The conversion of any outstanding shares of Designated Preferred Stock shall automatically and simultaneously include the conversion of any PIK Dividend Shares thereon, as described in the preceding sentence.

(B) Automatic Conversion. All outstanding shares of Designated Preferred Stock, together with all PIK Dividend Shares thereon, shall be automatically converted into Common Stock upon the closing of a Qualified Public Offering. The number of shares of Common Stock into which the outstanding shares of Designated Preferred Stock (and all PIK Dividend Shares thereon) shall be converted shall be determined on the same basis as provided in the preceding paragraph. At the time of the closing of a Qualified Public Offering, the certificates which theretofore evidenced shares of the Designated Preferred Stock shall thereupon evidence only the right to receive the shares of Common Stock and such other property, money or other thing of value into which the Designated Preferred Stock (including the PIK Dividend Shares) is then convertible.

(C) Except as otherwise provided herein with respect to automatic conversion upon closing of a Qualified Public Offering, each conversion of shares of Designated Preferred Stock shall be deemed to have been effected as of the close of business on the date on which the certificate or certificates representing the shares of Designated Preferred Stock to be converted (other than PIK Dividend Shares) have been surrendered for conversion at the principal office of the Corporation. At the time any such conversion has been effected, the rights of the holder of the shares of Designated Preferred Stock converted (including the PIK Dividend Shares thereon) as a holder of Designated Preferred Stock shall cease and the Person or Persons in whose name or names any certificate or certificates for shares of Common Stock are to be issued upon such conversion shall be deemed to have become the holder or holders of record of the shares of Common Stock represented thereby.

(D) The conversion rights of any share of Designated Preferred Stock subject to redemption hereunder shall terminate on the Redemption Date for such share of Designated Preferred Stock unless the Corporation has failed to pay to the holder thereof the Redemption Price thereof.

(E) Notwithstanding any other provision hereof, if a conversion of shares of Designated Preferred Stock is to be made in connection with a Material Event, the conversion of any shares of Designated Preferred Stock may, at the election of the holder thereof, be conditioned upon the consummation of such transaction, in which case such conversion shall not be deemed to be effective until such transaction has been consummated.

(F) As soon as possible after a conversion has been effected the Corporation shall deliver to the converting holder:

(i) a certificate or certificates representing the number of shares of Common Stock issuable by reason of such conversion in such name or names and such denomination or denominations as the converting holder has specified; and

(ii) a certificate representing any shares of Designated Preferred Stock which were represented by the certificate or certificates delivered

to the Corporation in connection with such conversion but which were not converted.

(G) The issuance of certificates for shares of Common Stock upon conversion of shares of Designated Preferred Stock shall be made without charge to the holders of such Designated Preferred Stock for any issuance tax in respect thereof or other cost incurred by the Corporation in connection with such conversion and the related issuance of shares of Common Stock. Upon conversion of each share of Designated Preferred Stock, the Corporation shall take all such actions as are necessary in order to insure that the Common Stock issuable with respect to such conversion shall be validly issued, fully paid and nonassessable, and free and clear of all taxes, liens, charges and encumbrances of the Corporation with respect to the issuance thereof.

(H) The Corporation shall not close its books against the transfer of any Designated Preferred Stock or Common Stock issued or issuable upon conversion of Designated Preferred Stock in any manner which interferes with the timely conversion of such Designated Preferred Stock. The Corporation shall assist and cooperate with any holder of shares of Designated Preferred Stock required to make any governmental filings or obtain any governmental approval prior to or in connection with any conversion of shares of Designated Preferred Stock hereunder (including, without limitation, making any filings required to be made by the Corporation).

(I) The Corporation shall at all times reserve and keep available out of its authorized but unissued shares of Common Stock, solely for the purpose of issuance upon the conversion of shares of the Designated Preferred Stock, such number of shares of Common Stock as are issuable upon the conversion of all outstanding Designated Preferred Stock (and all Accrued PIK Dividend Shares thereon). The Corporation shall take all such actions as may be necessary to assure that all such shares of Common Stock may be so issued without violation of any applicable law or governmental regulation or any requirements of any domestic securities exchange or the Nasdaq National Market upon which shares of Common Stock may be listed (except for official notice of issuance which shall be immediately delivered by the Corporation upon each such issuance). The Corporation shall not take any action which would cause the number of authorized but unissued shares of Common Stock to be less than the number of such shares required to be reserved hereunder for issuance upon conversion of the Designated Preferred Stock.

(J) No fractional shares or scrip representing fractional shares shall be issued upon the conversion of any Designated Preferred Stock. With respect to any fraction of a share of Common Stock called for upon any conversion, the Corporation shall pay to the holder an amount in cash equal to such fraction multiplied by the then Fair Value per share.

8.7.2 Conversion Price.

(A) The initial "Conversion Price" for (i) the Series A Preferred Stock shall be $7.275 per share, (ii) the Series A-2 Preferred Stock shall be $57.658 per share, (iii) the Series B Preferred Stock shall be $18.018 per share, (iv) the Series B-2 Preferred

Stock shall be $57.658 per share, (v) the Series C Preferred Stock shall be $57.658 per share, (vi) the Series D Preferred Stock shall be $65.890 per share, and (vii) the Series E Preferred Stock shall be $60.69 per share. In order to prevent dilution of the conversion rights granted under this Section 8.7, the Conversion Price shall be subject to adjustment from time to time pursuant to this Section 8.7.2.

(B) If and whenever after the Merger Effective Date, the Corporation issues or sells, or in accordance with Section 8.7.3 is deemed to have issued or sold, any shares of its Common Stock for a consideration per share less than the Fair Value per share immediately prior to the time of such issue or sale, then immediately upon such issue or sale, or deemed issue or sale, the Conversion Price shall be reduced to the Conversion Price determined by dividing (i) the sum of (a) the product derived by multiplying the Fair Value per share in effect immediately prior to such issue or sale by the number of shares of Common Stock Deemed Outstanding immediately prior to such issue or sale, plus (b) the consideration, if any, received by the Corporation upon such issue or sale, by (ii) the number of shares of Common Stock Deemed Outstanding immediately after such issue or sale.

(C) If and whenever on or after the Merger Effective Date, the Corporation issues or sells, or in accordance with Section 8.7.3 is deemed to have issued or sold, any shares of its Common Stock for a consideration per share less than the Conversion Price with respect to any series of the Designated Preferred Stock, then immediately upon such issue or sale, or deemed issue or sale, the Conversion Price for such series (but only such series) shall be reduced to the Conversion Price determined by multiplying the Conversion Price in effect immediately prior to such issuance or sale by a fraction:

(i) the numerator of which shall be (a) the number of shares of Common Stock Deemed Outstanding immediately prior to such issue or sale, plus (b) the number of shares of Common Stock which the consideration received by the Corporation for the total number of additional shares of Common Stock so issued would purchase at the Conversion Price in effect immediately prior to such issuance or sale, and

(ii) the denominator of which shall be (a) the number of shares of Common Stock Deemed Outstanding immediately prior to such issue or sale plus the total number of additional shares of Common Stock so issued.

(D) In the event that both subsections (B) and (C) above shall apply to the sale or issuance or deemed sale or issuance by the Corporation, then the provisions resulting in the lower Conversion Price shall control.

8.7.3 Effect on Conversion Price of Certain Events. For purposes of determining the adjusted Conversion Price under Section 8.7.2, the following shall be applicable:

(A) Issuance of Rights or Options. Except when pursuant to an Approved Stock Option Plan, if the Corporation in any manner grants or sells any

Options and the price per share for which Common Stock is issuable upon the exercise of such Options, or upon conversion or exchange of any Convertible Securities issuable upon exercise of such Options, is less than the applicable Conversion Price or the Fair Value per share immediately prior to the time of the granting or sale of such Options, then the total maximum number of shares of Common Stock issuable upon the exercise of such Options or upon conversion or exchange of the total maximum amount of such Convertible Securities issuable upon the exercise of such Options shall be deemed to be outstanding and to have been issued and sold by the Corporation at the time of the granting or sale of such Options. For purposes of this subsection, the "price per share for which Common Stock is issuable" shall be determined by dividing (i) the total amount, if any, received or receivable by the Corporation as consideration for the granting or sale of such Options, plus the minimum aggregate amount of additional consideration payable to the Corporation upon exercise of all such Options, plus in the case of such Options which relate to Convertible Securities, the minimum aggregate amount of additional consideration, if any, payable to the Corporation upon the issuance or sale of such Convertible Securities and the conversion or exchange thereof, by (ii) the total maximum number of shares of Common Stock issuable upon the exercise of such Options or upon the conversion or exchange of all such Convertible Securities issuable upon the exercise of such Options. No further adjustment of the Conversion Price shall be made when Convertible Securities are actually issued upon the exercise of such Options or when Common Stock is actually issued upon the exercise of such Options or the conversion or exchange of such Convertible Securities.

(B) Issuance of Convertible Securities. If the Corporation in any manner issues or sells any Convertible Securities and the price per share for which Common Stock is issuable upon conversion or exchange thereof is less than the applicable Conversion Price or the Fair Value per share immediately prior to the time of the issue or sale of such Convertible Securities, then the maximum number of shares of Common Stock issuable upon conversion or exchange of such Convertible Securities shall be deemed to be outstanding and to have been issued and sold by the Corporation at the time of the issuance or sale of such Convertible Securities. For the purposes of this subsection, the "price per share for which Common Stock is issuable" shall be determined by dividing (i) the total amount received or receivable by the Corporation as consideration for the issue or sale of such Convertible Securities, plus the minimum aggregate amount of additional consideration, if any, payable to the Corporation upon the conversion or exchange thereof, by (ii) the total maximum number of shares of Common Stock issuable upon the conversion or exchange of all such Convertible Securities. No further adjustment of the Conversion Price shall be made when Common Stock is actually issued upon the conversion or exchange of such Convertible Securities. Notwithstanding the foregoing to the contrary, if any such issue or sale of such Convertible Securities is made upon exercise of any Options, the provisions of the preceding paragraph (A), and not this paragraph (B), will apply.

(C) Change in Option Price or Conversion Rate. If the exercise price of Options granted other than pursuant to an Approved Stock Option Plan, the additional consideration, if any, payable upon the conversion or exchange of any Convertible Securities, or the rate at which any Convertible Securities are convertible into or

exchangeable for Common Stock changes at any time, the applicable Conversion Price in effect at the time of such change shall be immediately adjusted to the Conversion Price which would have been in effect at such time had such Options or Convertible Securities still outstanding provided for such changed exercise price, additional consideration or conversion rate, as the case may be, at the time initially granted, issued or sold. For purposes of determining the adjusted Conversion Price of the Series A Preferred Stock, if the terms of any Option (other than any Option granted pursuant to an Approved Stock Option Plan) or Convertible Security which was outstanding as of the Original Series A Date of Issuance are changed in the manner described in the first sentence of this paragraph (C), then such Option or Convertible Security and the Common Stock deemed issuable upon exercise, conversion or exchange thereof shall be deemed to have been issued as of the date of such change; provided that no such change shall at any time cause the Conversion Price hereunder to be increased. For purposes of determining the adjusted Conversion Price of the Series B Preferred Stock, if the terms of any Option (other than any Option granted pursuant to an Approved Stock Option Plan) or Convertible Security which was outstanding as of the Original Series B Date of Issuance are changed in the manner described in the first sentence of this paragraph (C), then such Option or Convertible Security and the Common Stock deemed issuable upon exercise, conversion or exchange thereof shall be deemed to have been issued as of the date of such change; provided that no such change shall at any time cause the Conversion Price hereunder to be increased. For purposes of determining the adjusted Conversion Price of the Series C Preferred Stock, if the terms of any Option (other than any Option granted pursuant to an Approved Stock Option Plan) or Convertible Security which was outstanding as of the Original Series C Date of Issuance are changed in the manner described in the first sentence of this paragraph (C), then such Option or Convertible Security and the Common Stock deemed issuable upon exercise, conversion or exchange thereof shall be deemed to have been issued as of the date of such change; provided that no such change shall at any time cause the Conversion Price hereunder to be increased. For purposes of determining the adjusted Conversion Price of the Series D Preferred Stock, if the terms of any Option (other than any Option granted pursuant to an Approved Stock Option Plan) or Convertible Security which was outstanding as of the Original Series D Date of Issuance are changed in the manner described in the first sentence of this paragraph (C), then such Option or Convertible Security and the Common Stock deemed issuable upon exercise, conversion or exchange thereof shall be deemed to have been issued as of the date of such change; provided that no such change shall at any time cause the Conversion Price hereunder to be increased. For purposes of determining the adjusted Conversion Price of the Series E Preferred Stock, if the terms of any Option (other than any Option granted pursuant to an Approved Stock Option Plan) or Convertible Security which was outstanding as of the Original Series E Date of Issuance are changed in the manner described in the first sentence of this paragraph (C), then such Option or Convertible Security and the Common Stock deemed issuable upon exercise, conversion or exchange thereof shall be deemed to have been issued as of the date of such change; provided that no such change shall at any time cause the Conversion Price hereunder to be increased.

(D) Treatment of Expired Options and Unexercised Convertible Securities. Upon the expiration of any Option (other than any Option granted pursuant to an Approved Stock Option Plan) or the termination of any right to convert or exchange

any Convertible Security without the exercise of any such Option or right, the Conversion Price then in effect hereunder shall be adjusted immediately to the Conversion Price which would have been in effect at the time of such expiration or termination had such Option or Convertible Security, to the extent outstanding immediately prior to such expiration or termination, never been issued. For purposes of this Section 8.7.3, the expiration or termination of any Option (other than any Option granted pursuant to an Approved Stock Option Plan) or Convertible Security which was outstanding as of the Original Series A Date of Issuance, the Original Series B Date of Issuance, the Original Series C Date of Issuance, the Original Series D Date of Issuance, or the Original Series E Date of Issuance, as applicable, shall not cause the Conversion Price hereunder to be adjusted unless, and only to the extent that, a change in the terms of such Option or Convertible Security caused it to be deemed to have been issued after the Original Series A Date of Issuance, the Original Series B Date of Issuance, the Original Series C Date of Issuance, the Original Series D Date of Issuance or the Original Series E Date of Issuance, as applicable.

(E) Calculation of Consideration Received. If any Common Stock, Option or Convertible Security is issued or sold or deemed to have been issued or sold for cash, the consideration received therefor shall be deemed to be the amount received by the Corporation therefor (net of discounts, commissions and related expenses). If any Common Stock, Option or Convertible Security is issued or sold for a consideration other than cash, the amount of the consideration other than cash received by the Corporation shall be the fair value of such consideration, except where such consideration consists of securities, in which case the amount of consideration received by the Corporation shall be determined as of the date of receipt in the manner set forth in the definition of the term "Fair Value." If any Common Stock, Option or Convertible Security is issued to the owners of the non-surviving entity in connection with any merger in which the Corporation is the surviving company, the amount of consideration therefor shall be deemed to be the fair value of such portion of the net assets and business of the non-surviving entity as is attributable to such Common Stock, Option or Convertible Security, as the case may be. The fair value of any consideration other than cash and securities shall be determined jointly by the Corporation and the holders of a majority of the then outstanding shares of each series of the Designated Preferred Stock, voting as separate classes. If such parties are unable to reach agreement within a reasonable period of time, the fair value of such consideration shall be determined by an independent appraiser experienced in valuing such type of consideration jointly selected by the Corporation and the holders of a majority of the then outstanding shares of each series of the Designated Preferred Stock, voting as separate classes. The determination of such appraiser shall be final and binding upon the parties, and the fees and expenses of such appraiser shall be borne by the Corporation.

(F) Integrated Transactions. In case any Option is issued in connection with the issue or sale of other securities of the Corporation, together comprising one integrated transaction in which no specific consideration is allocated to such Option by the parties thereto, consideration shall be allocated to such Option by the Board of Directors of the Corporation on a reasonable basis.

(G) Treasury Shares. The number of shares of Common Stock outstanding at any given time shall not include shares owned or held by or for the account of the Corporation or any Subsidiary, and the disposition of any shares so owned or held shall be considered an issue or sale of Common Stock.

(H) Record Date. If the Corporation takes a record of the holders of Common Stock for the purpose of entitling them (i) to receive a dividend or other distribution payable in Common Stock, Options or in Convertible Securities or (ii) to subscribe for or purchase Common Stock, Options or Convertible Securities, then such record date shall be deemed to be the date of the issue or sale of the shares of Common Stock deemed to have been issued or sold upon the declaration of such dividend or upon the making of such other distribution or the date of the granting of such right of subscription or purchase, as the case may be.

8.7.4 Subdivision or Combination of Common Stock. Notwithstanding any provision of this Section 8.7 to the contrary, if the Corporation at any time subdivides (by any stock split, stock dividend, recapitalization or otherwise) one or more series of its outstanding shares of Common Stock into a greater number of shares, the applicable Conversion Price for each series of the Designated Preferred Stock in effect immediately prior to such subdivision shall be proportionately reduced, and if the Corporation at any time combines (by reverse stock split or otherwise) one or more series of its outstanding shares of Common Stock into a smaller number of shares, the applicable Conversion Price for each series of the Designated Preferred Stock in effect immediately prior to such combination shall be proportionately increased.

8.7.5 Reorganization, Reclassification, Consolidation, Merger or Sale. Any recapitalization, reorganization, reclassification, consolidation, merger, sale of all or substantially all of the Corporation's assets or other transaction, which is effected in such a manner that the holders of Common Stock are entitled to receive (either directly or upon subsequent liquidation) stock, securities or assets with respect to or in exchange for Common Stock, is referred to herein as an "Organic Change." Prior to the consummation of any Organic Change, the Corporation shall make appropriate provisions (in form and substance satisfactory to the holders of a majority of the then outstanding shares of each series of the Designated Preferred Stock, voting as separate classes with one vote per share) to insure that each holder of shares of Designated Preferred Stock shall thereafter have the right to acquire and receive, in lieu of or in addition to (as the case may be) the shares of Common Stock immediately theretofore acquirable and receivable upon the conversion of such holder's shares of Designated Preferred Stock, such shares of stock, securities or assets as such holder would have received in connection with such Organic Change if such holder had converted his/her/its Designated Preferred Stock immediately prior to such Organic Change. In each such case, the Corporation shall also make appropriate provisions (in form and substance satisfactory to the holders of a majority of the then outstanding shares of each series of the Designated Preferred Stock, voting as separate classes with one vote per share) to insure that the provisions of this Section 8.7 shall thereafter be applicable to the Designated Preferred Stock (including, in the case of any such consolidation, merger or sale in which the successor entity or purchasing entity is other than the Corporation, an immediate adjustment of the Conversion Price to the value for the Common Stock reflected by the terms of such consolidation, merger or sale, and a corresponding immediate adjustment in the number of

shares of Common Stock acquirable and receivable upon conversion of Designated Preferred Stock, if the value so reflected is less than the Fair Value per share immediately prior to such consolidation, merger or sale). The Corporation shall not effect any such consolidation, merger or sale, unless prior to the consummation thereof, the successor entity (if other than the Corporation) resulting from consolidation or merger or the entity purchasing such assets assumes by written instrument (in form and substance reasonably satisfactory to the holders of a majority of the then outstanding shares of each series of the Designated Preferred Stock, voting as separate classes with one vote per share), the obligation to deliver to each such holder such shares of stock, securities or assets as, in accordance with the foregoing provisions, such holder may be entitled to acquire.

8.7.6 Certain Events. If any event occurs of the type contemplated by the provisions of this Section 8.7 but not expressly provided for by such provisions (including, without limitation, the granting of stock appreciation rights, phantom stock rights or other rights with equity features), then the Corporation's Board of Directors shall make an appropriate adjustment in the applicable Conversion Price so as to protect the rights of the holders of Designated Preferred Stock; provided that no adjustment shall be made in connection with any stock appreciation rights or phantom stock rights granted to employees pursuant to employee benefit plans approved by the Corporation's Board of Directors; and provided further that no such adjustment shall increase the applicable Conversion Price as otherwise determined pursuant to this Section 8.7 or decrease the number of shares of Common Stock issuable upon conversion of each share of Designated Preferred Stock.

8.7.7 Notices. Upon reasonable written request from a holder of shares of any series of Designated Preferred Stock, the Corporation shall give written notice to all holders of such series, setting forth in reasonable detail and certifying the calculation of any adjustment of the applicable Conversion Price for such series of Designated Preferred Stock.

8.8 Registration of Transfer. The Corporation will keep at its principal office a register for the registration of shares of Preferred Stock. Upon the surrender of any certificate representing shares of Preferred Stock at such place, the Corporation will, at the request of the record holder of such certificate, execute and deliver (at the Corporation's expense) a new certificate or certificates in exchange therefor representing in the aggregate the number of shares represented by the surrendered certificate. Each such new certificate will be registered in the name of such transferee and will represent such number of shares as is requested by the holder of the surrendered certificate and will be substantially identical in form to the surrendered certificate, and dividends will accrue on the shares of Preferred Stock represented by such new certificate from the date to which dividends have been fully paid on such shares of Preferred Stock represented by the surrendered certificate.

8.9 Replacement. Upon receipt of evidence reasonably satisfactory to the Corporation (an affidavit of the registered holder will be satisfactory) of the ownership and the loss, theft, destruction or mutilation of any certificate evidencing shares of Preferred Stock, and in the case of any such loss, theft or destruction, upon receipt of indemnity reasonably satisfactory to the Corporation, or, in the case of any such mutilation upon surrender of such certificate, the Corporation will (at its expense) execute and deliver in lieu of such certificate a new certificate of like kind representing the number of shares of Preferred Stock of such series

represented by such lost, stolen, destroyed or mutilated certificate and dated the date of such lost, stolen, destroyed or mutilated certificate, and dividends will accrue on the Preferred Stock represented by such new certificate from the date to which dividends have been fully paid on such lost, stolen, destroyed or mutilated certificate.

8.10 Amendment and Waiver. Subject to the additional provisions of Sections 8.6.2, 8.6.3 and 8.6.4 hereof, no amendment, modification or waiver will be binding or effective with respect to any of the provisions of this Amended and Restated Certificate of Incorporation stating the number, designation, relative rights, preferences and limitations of any series of the Preferred Stock, without the prior written consent of the holders of a majority of the shares of such series then outstanding.

8.11 Notices. Except as otherwise expressly provided herein, all notices referred to herein will be in writing and will be delivered by registered or certified mail, return receipt requested, postage prepaid and will be deemed to have been given four business days after being deposited in the mail (A) to the Corporation, at its principal executive offices and (B) to any shareholder, at such holder's address as it appears in the stock records of the Corporation (unless otherwise indicated in writing by any such holder).

IN WITNESS WHEREOF, GTx, Inc. has caused this Amended and Restated Certificate of Incorporation to be signed on its behalf by the undersigned officers, thereunto duly authorized, this 26th day of November, 2003.

GTx, Inc.

By:/s/ Henry P. Doggrell

Henry P. Doggrell
Secretary

CERTIFICATE OF AMENDMENT
TO THE CERTIFICATE OF INCORPORATION

OF

GTx, INC.

GTx, Inc. (hereinafter called the "Corporation"), a corporation organized and existing under the General Corporation Law of the State of Delaware, does hereby certify:

1. The name of the Corporation is GTx, Inc.

2. The certificate of incorporation of the Corporation is hereby amended by striking out Section 2 thereof and by substituting in lieu of said Section 2 the following new Section 2:

"2. Authorized Shares. The Corporation is authorized to issue two classes of stock to be designated, respectively, Common Stock (the "Common Stock") and Preferred Stock (the "Preferred Stock"). The total number of shares of capital stock that the Corporation shall have authority to issue is twenty six million nine hundred seventy-five thousand (26,975,000) shares, divided as follows: (a) twenty-five million (25,000,000) shares of Common Stock, $.001 par value per share, and (b) one million nine hundred seventy-five thousand (1,975,000) shares of Preferred Stock, $.001 par value per share. The Preferred Stock shall be divided into series. The first series shall consist of two hundred thousand (200,000) shares which shall be designated as 8% Series A Cumulative Convertible Preferred Stock (the "Series A Preferred Stock"). The second series shall consist of one hundred forty thousand (140,000) shares, which shall be designated as Series A-2 Convertible Preferred Stock (the "Series A-2 Preferred Stock"). The third series shall consist of two hundred seventy-seven thousand five hundred (277,500) shares which shall be designated as 8% Series B Cumulative Convertible Preferred Stock (the "Series B Preferred Stock"). The fourth series shall consist of one hundred fifty-seven thousand five hundred (157,500) shares which shall be designated as Series B-2 Convertible Preferred Stock (the "Series B-2 Preferred Stock"). The fifth series shall consist of four hundred fifty thousand (450,000) shares which shall be designated as 8% Series C Cumulative Convertible Preferred Stock (the "Series C Preferred Stock"). The sixth series shall consist of three hundred thousand (300,000) shares which shall be designated as 8% Series D Cumulative Convertible Preferred Stock (the "Series D Preferred Stock"). The seventh series shall consist of four hundred fifty thousand (450,000) shares which shall be designated as 8% Series E Cumulative Convertible Preferred Stock (the "Series E Preferred Stock")."

3. The amendment of the certificate of incorporation herein certified has been duly adopted in accordance with the provisions of Sections 228 and 242 of the General Corporation Law of the State of Delaware.

Executed on this 13th day of January, 2004.

/s/ Henry P. Doggrell

_____

Henry P. Doggrell
Secretary

Exhibit 5.1

[COOLEY GODWARD LLP LETTERHEAD]

January 14, 2004

GTx, Inc.
3 N. Dunlap Street, 3rd Floor
Ven Vleet Building

Memphis, TN 38163

Ladies and Gentlemen:

You have requested our opinion with respect to certain matters in connection with the filing by GTx, Inc. (the "Company") of a Registration Statement on Form S-1 (the "Registration Statement") with the Securities and Exchange Commission (the "Commission") covering an underwritten public offering of up to 6,210,000 shares of common stock (the "Shares").

In connection with this opinion, we have examined and relied upon the Registration Statement and related Prospectus, the Company's Amended and Restated Certificate of Incorporation and Bylaws, as currently in effect, and the originals or copies certified to our satisfaction of such records, documents, certificates, memoranda and other instruments as in our judgment are necessary or appropriate to enable us to render the opinion expressed below. Our opinion is expressed only with respect to the laws of the State of Delaware.

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

We consent to the reference to our firm under the caption "Legal Matters" in the Prospectus included on 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

EXHIBIT 10.5

GTx, INC.

2004 EQUITY INCENTIVE PLAN

ADOPTED JANUARY 14, 2004
APPROVED BY STOCKHOLDERS JANUARY 14, 2004

1. PURPOSES.

(a) ELIGIBLE STOCK AWARD RECIPIENTS. The persons eligible to receive Stock Awards are the Employees, Directors and Consultants of the Company and its Affiliates.

(b) AVAILABLE STOCK AWARDS. The purpose of the Plan is to provide a means by which eligible recipients of Stock Awards may be given an opportunity to benefit from increases in value of the Common Stock through the granting of the following Stock Awards: (i) Options, (ii) Restricted Stock Awards, (iii) Stock Appreciation Rights, (iv) Phantom Stock and (v) Other Stock Awards.

(c) GENERAL PURPOSE. The Company, by means of the Plan, seeks to retain the services of the group of persons eligible to receive Stock Awards, to secure and retain the services of new members of this group and to provide incentives for such persons to exert maximum efforts for the success of the Company and its Affiliates.

2. DEFINITIONS.

(a) "AFFILIATE" means any parent corporation or subsidiary corporation of the Company, whether now or hereafter existing, as those terms are defined in Sections 424(e) and (f), respectively, of the Code.

(b) "BOARD" means the Board of Directors of the Company.

(c) "CAPITALIZATION ADJUSTMENT" has the meaning ascribed to that term in Section 11(a).

(d) "CHANGE IN CONTROL" means the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events:

(i) any Exchange Act Person becomes the Owner, directly or indirectly, of securities of the Company representing more than fifty percent (50%) of the combined voting power of the Company's then outstanding securities other than by virtue of a merger, consolidation or similar transaction. Notwithstanding the foregoing, a Change in Control shall not be deemed to occur solely because the level of Ownership held by any Exchange Act Person (the "Subject Person") exceeds the designated percentage threshold of the outstanding voting securities as a result of a repurchase or other acquisition of voting securities by the Company reducing the number of shares outstanding, provided that if a Change in Control would occur (but for the operation of this sentence) as a result of the acquisition of voting securities by the Company, and after such share acquisition, the Subject Person becomes the Owner of any

additional voting securities that, assuming the repurchase or other acquisition had not occurred, increases the percentage of the then outstanding voting securities Owned by the Subject Person over the designated percentage threshold, then a Change in Control shall be deemed to occur;

(ii) there is consummated a merger, consolidation or similar transaction involving (directly or indirectly) the Company and, immediately after the consummation of such merger, consolidation or similar transaction, the stockholders of the Company immediately prior thereto do not Own, directly or indirectly, outstanding voting securities representing more than fifty percent (50%) of the combined outstanding voting power of the surviving Entity in such merger, consolidation or similar transaction or more than fifty percent (50%) of the combined outstanding voting power of the parent of the surviving Entity in such merger, consolidation or similar transaction;

(iii) the stockholders of the Company approve or the Board approves a plan of complete dissolution or liquidation of the Company, or a complete dissolution or liquidation of the Company shall otherwise occur;

(iv) there is consummated a sale, lease, license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries, other than a sale, lease, license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries to an Entity, more than fifty percent (50%) of the combined voting power of the voting securities of which are Owned by stockholders of the Company in substantially the same proportions as their Ownership of the Company immediately prior to such sale, lease, license or other disposition; or

(v) individuals who, on the date this Plan is adopted by the Board, are members of the Board (the "Incumbent Board") cease for any reason to constitute at least a majority of the members of the Board; provided, however, that if the appointment or election (or nomination for election) of any new Board member was approved or recommended by a majority vote of the members of the Incumbent Board then still in office, such new member shall, for purposes of this Plan, be considered as a member of the Incumbent Board.

Notwithstanding the foregoing or any other provision of this Plan, the definition of Change in Control (or any analogous term) in an individual written agreement between the Company or any Affiliate and the Participant shall supersede the foregoing definition with respect to Stock Awards subject to such agreement (it being understood, however, that if no definition of Change in Control or any analogous term is set forth in such an individual written agreement, the foregoing definition shall apply).

(e) "CODE" means the Internal Revenue Code of 1986, as amended.

(f) "COMMITTEE" means a committee of one or more members of the Board appointed by the Board in accordance with Section 3(c).

(g) "COMMON STOCK" means the common stock of the Company.

(h) "COMPANY" means GTx, Inc., a Delaware corporation.

(i) "CONSULTANT" means any person, including an advisor, (i) engaged by the Company or an Affiliate to render consulting or advisory services and who is compensated for such services or (ii) serving as a member of the Board of Directors of an Affiliate and who is compensated for such services. However, the term "Consultant" shall not include Directors who are not compensated by the Company for their services as Directors, and the payment of a director's fee by the Company for services as a Director shall not cause a Director to be considered a "Consultant" for purposes of the Plan.

(j) "CONTINUOUS SERVICE" means that the Participant's service with the Company or an Affiliate, whether as an Employee, Director or Consultant, is not interrupted or terminated. A change in the capacity in which the Participant renders service to the Company or an Affiliate as an Employee, Consultant or Director or a change in the entity for which the Participant renders such service, provided that there is no interruption or termination of the Participant's service with the Company or an Affiliate, shall not terminate a Participant's Continuous Service. For example, a change in status from an Employee of the Company to a Consultant of an Affiliate or a Director shall not constitute an interruption of Continuous Service. The Board or the chief executive officer of the Company, in that party's sole discretion, may determine whether Continuous Service shall be considered interrupted in the case of any leave of absence approved by that party, including sick leave, military leave or any other personal leave. Notwithstanding the foregoing, a leave of absence shall be treated as Continuous Service for purposes of vesting in a Stock Award only to such extent as may be provided in the Company's leave of absence policy or in the written terms of the Participant's leave of absence.

(k) "CORPORATE TRANSACTION" means the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events:

(i) a sale or other disposition of all or substantially all, as determined by the Board in its discretion, of the consolidated assets of the Company and its Subsidiaries;

(ii) a sale or other disposition of at least ninety percent (90%) of the outstanding securities of the Company;

(iii) a merger, consolidation or similar transaction following which the Company is not the surviving corporation; or

(iv) a merger, consolidation or similar transaction following which the Company is the surviving corporation but the shares of Common Stock outstanding immediately preceding the merger, consolidation or similar transaction are converted or exchanged by virtue of the merger, consolidation or similar transaction into other property, whether in the form of securities, cash or otherwise.

(l) "COVERED EMPLOYEE" means the chief executive officer and the four (4) other highest compensated officers of the Company for whom total compensation is required to be reported to stockholders under the Exchange Act, as determined for purposes of Section 162(m) of the Code.

(m) "DIRECTOR" means a member of the Board of Directors of the Company.

(n) "DISABILITY" means the permanent and total disability of a person within the meaning of Section 22(e)(3) of the Code.

(o) "EMPLOYEE" means any person employed by the Company or an Affiliate. Service as a Director or payment of a director's fee by the Company or an Affiliate shall not be sufficient to constitute "employment" by the Company or an Affiliate.

(p) "ENTITY" means a corporation, partnership or other entity.

(q) "EXCHANGE ACT" means the Securities Exchange Act of 1934, as amended.

(r) "EXCHANGE ACT PERSON" means any natural person, Entity or "group" (within the meaning of Section 13(d) or 14(d) of the Exchange Act), except that "Exchange Act Person" shall not include (A) the Company or any Subsidiary of the Company, (B) any employee benefit plan of the Company or any Subsidiary of the Company or any trustee or other fiduciary holding securities under an employee benefit plan of the Company or any Subsidiary of the Company, (C) an underwriter temporarily holding securities pursuant to an offering of such securities, or (D) an Entity Owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their Ownership of stock of the Company.

(s) "FAIR MARKET VALUE" means, as of any date, the value of the Common Stock determined as follows:

(i) If the Common Stock is listed on any established stock exchange or traded on the Nasdaq National Market or the Nasdaq SmallCap Market, the Fair Market Value of a share of Common Stock shall be the closing sales price for such stock (or the closing bid, if no sales were reported) as quoted on such exchange or market (or the exchange or market with the greatest volume of trading in the Common Stock) on the last market trading day prior to the day of determination, as reported in The Wall Street Journal or such other source as the Board deems reliable.

(ii) In the absence of such markets for the Common Stock, the Fair Market Value shall be determined in good faith by the Board.

(t) "NON-EMPLOYEE DIRECTOR" means a Director who either (i) is not a current Employee or Officer of the Company or its parent or a subsidiary, does not receive compensation (directly or indirectly) from the Company or its parent or a subsidiary for services rendered as a consultant or in any capacity other than as a Director (except for an amount as to which disclosure would not be required under Item 404(a) of Regulation S-K promulgated pursuant to the Securities Act ("Regulation S-K")), does not possess an interest in any other transaction as to which disclosure would be required under Item 404(a) of Regulation S-K and is not engaged in a business relationship as to which disclosure would be required under Item 404(b) of Regulation S-K; or (ii) is otherwise considered a "non-employee director" for purposes of Rule 16b-3.

(u) "OFFICER" means a person who is an officer of the Company within the meaning of Section 16 of the Exchange Act and the rules and regulations promulgated thereunder.

(v) "OPTION" means a nonstatutory stock option granted pursuant to the Plan that is not intended to qualify as an incentive stock option under Section 422 of the Code and the regulations promulgated thereunder.

(w) "OPTION AGREEMENT" means a written agreement between the Company and an Optionholder evidencing the terms and conditions of an individual Option grant. Each Option Agreement shall be subject to the terms and conditions of the Plan.

(x) "OPTIONHOLDER" means a person to whom an Option is granted pursuant to the Plan or, if applicable, such other person who holds an outstanding Option.

(y) "OTHER STOCK AWARD" means an award based in whole or in part by reference to the Common Stock that is granted pursuant to the terms and conditions of Section 7(d).

(z) "OUTSIDE DIRECTOR" means a Director who either (i) is not a current employee of the Company or an "affiliated corporation" (within the meaning of Treasury Regulations promulgated under Section 162(m) of the Code), is not a former employee of the Company or an "affiliated corporation" receiving compensation for prior services (other than benefits under a tax-qualified pension plan), was not an officer of the Company or an "affiliated corporation" at any time and is not currently receiving direct or indirect remuneration from the Company or an "affiliated corporation" for services in any capacity other than as a Director; or (ii) is otherwise considered an "outside director" for purposes of Section 162(m) of the Code.

(aa) "OWN," "OWNED," "OWNER," "OWNERSHIP" A person or Entity shall be deemed to "Own," to have "Owned," to be the "Owner" of, or to have acquired "Ownership" of securities if such person or Entity, directly or indirectly, through any contract, arrangement, understanding, relationship or otherwise, has or shares voting power, which includes the power to vote or to direct the voting, with respect to such securities.

(bb) "PARTICIPANT" means a person to whom a Stock Award is granted pursuant to the Plan or, if applicable, such other person who holds an outstanding Stock Award.

(cc) "PHANTOM STOCK" means a right to receive shares of Common Stock that is granted pursuant to the terms and conditions of Section 7(b).

(dd) "RESTRICTED STOCK AWARD" means an award of shares of Common Stock which is granted pursuant to the terms and conditions of Section 7(a).

(ee) "RETIREMENT" means a Participant's voluntary termination of Continuous Service with the Company either (i) after age sixty-five and after having been employed by the Company for at least ten (10) years or (ii) after age fifty-five, after having been employed by the Company for at least ten (10) years and with the written authorization of the chief executive officer or the Board.

(ff) "PLAN" means this GTx, Inc. 2004 Equity Incentive Plan.

(gg) "RULE 16b-3" means Rule 16b-3 promulgated under the Exchange Act or any successor to Rule 16b-3, as in effect from time to time.

(hh) "SECURITIES ACT" means the Securities Act of 1933, as amended.

(ii) "STOCK APPRECIATION RIGHT" means a right to receive the appreciation of Common Stock that is granted pursuant to the terms and conditions of Section 7(c).

(jj) "STOCK AWARD" means any right granted under the Plan, including an Option, a Restricted Stock Award, Phantom Stock, a Stock Appreciation Right and an Other Stock Award.

(kk) "STOCK AWARD AGREEMENT" means a written agreement between the Company and a holder of a Stock Award evidencing the terms and conditions of an individual Stock Award grant. Each Stock Award Agreement shall be subject to the terms and conditions of the Plan.

(ll) "SUBSIDIARY" means, with respect to the Company, (i) any corporation of which more than fifty percent (50%) of the outstanding capital stock having ordinary voting power to elect a majority of the board of directors of such corporation (irrespective of whether, at the time, stock of any other class or classes of such corporation shall have or might have voting power by reason of the happening of any contingency) is at the time, directly or indirectly, Owned by the Company, and (ii) any partnership in which the Company has a direct or indirect interest (whether in the form of voting or participation in profits or capital contribution) of more than fifty percent (50%).

3. ADMINISTRATION.

(a) ADMINISTRATION BY BOARD. The Board shall administer the Plan unless and until the Board delegates administration to a Committee, as provided in Section 3(c).

(b) POWERS OF BOARD. The Board shall have the power, subject to, and within the limitations of, the express provisions of the Plan:

(i) To determine from time to time which of the persons eligible under the Plan shall be granted Stock Awards; when and how each Stock Award shall be granted; what type or combination of types of Stock Award shall be granted; the provisions of each Stock Award granted (which need not be identical), including the time or times when a person shall be permitted to receive Common Stock pursuant to a Stock Award; and the number of shares of Common Stock with respect to which a Stock Award shall be granted to each such person.

(ii) To construe and interpret the Plan and Stock Awards granted under it, and to establish, amend and revoke rules and regulations for its administration. The Board, in the exercise of this power, may correct any defect, omission or inconsistency in the Plan or in any Stock Award Agreement, in a manner and to the extent it shall deem necessary or expedient to make the Plan fully effective.

(iii) To effect, at any time and from time to time, with the consent of any adversely affected Optionholder, (1) the reduction of the exercise price of any outstanding Option under the Plan, (2) the cancellation of any outstanding Option under the Plan and the

grant in substitution therefor of (A) a new Option under the Plan or another equity plan of the Company covering the same or a different number of shares of Common Stock, (B) a Restricted Stock Award (including a stock bonus), (C) a Stock Appreciation Right, (D) Phantom Stock, (E) an Other Stock Award, (F) cash and/or (G) other valuable consideration (as determined by the Board, in its sole discretion), or (3) any other action that is treated as a repricing under Generally Accepted Accounting Principles.

(iv) To amend the Plan or a Stock Award as provided in Section 12.

(v) To terminate or suspend the Plan as provided in Section 13.

(vi) Generally, to exercise such powers and to perform such acts as the Board deems necessary or expedient to promote the best interests of the Company and that are not in conflict with the provisions of the Plan.

(c) DELEGATION TO COMMITTEE.

(i) GENERAL. The Board may delegate administration of the Plan to a Committee or Committees of one (1) or more members of the Board, and the term "Committee" shall apply to any person or persons to whom such authority has been delegated. If administration is delegated to a Committee, the Committee shall have, in connection with the administration of the Plan, the powers theretofore possessed by the Board, including the power to delegate to a subcommittee any of the administrative powers the Committee is authorized to exercise (and references in this Plan to the Board shall thereafter be to the Committee or subcommittee), subject, however, to such resolutions, not inconsistent with the provisions of the Plan, as may be adopted from time to time by the Board. The Board may abolish the Committee at any time and revest in the Board the administration of the Plan.

(ii) SECTION 162(m) AND RULE 16b-3 COMPLIANCE. In the discretion of the Board, the Committee may consist solely of two or more Outside Directors, in accordance with Section 162(m) of the Code, and/or solely of two or more Non-Employee Directors, in accordance with Rule 16b-3. Within the scope of such authority, the Board or the Committee may (1) delegate to a committee of one or more members of the Board who are not Outside Directors the authority to grant Stock Awards to eligible persons who are either (a) not then Covered Employees and are not expected to be Covered Employees at the time of recognition of income resulting from such Stock Award or (b) not persons with respect to whom the Company wishes to comply with Section 162(m) of the Code and/or (2) delegate to a committee of one or more members of the Board who are not Non-Employee Directors the authority to grant Stock Awards to eligible persons who are not then subject to Section 16 of the Exchange Act.

(d) DELEGATION TO AN OFFICER. The Board may delegate to one or more Officers of the Company the authority to do one or both of the following (i) designate Officers and Employees of the Company or any of its Subsidiaries to be recipients of Stock Awards and (ii) determine the number of shares of Common Stock to be subject to such Stock Awards granted to such Officers and Employees of the Company; provided, however, that the Board resolutions regarding such delegation shall specify the total number of shares of Common Stock that may be subject to the Stock Awards granted by such Officer and that such Officer may not grant a Stock Award to

himself or herself. Notwithstanding the foregoing, the Board may not delegate authority to an Officer to determine the Fair Market Value of the Common Stock

(e) EFFECT OF BOARD'S DECISION. All determinations, interpretations and constructions made by the Board in good faith shall not be subject to review by any person and shall be final, binding and conclusive on all persons.

4. SHARES SUBJECT TO THE PLAN.

(a) SHARE RESERVE. Subject to the provisions of Section 11(a) relating to Capitalization Adjustments, the shares of Common Stock that may be issued pursuant to Stock Awards shall not exceed in the aggregate one million five hundred thousand (1,500,000) shares of Common Stock, plus an annual increase to be added on January 1st of each year, commencing on January 1, 2005 and ending on January 1, 2013 (each such day, a "Calculation Date"), equal to five percent (5%) of the shares of Common Stock outstanding on each Calculation Date (rounded down to the nearest whole share). Notwithstanding the foregoing, the Board may act, prior to the first day of any fiscal year of the Company, to increase the share reserve by such number of shares of Common Stock as the Board shall determine, which number shall be less than the amount described in the foregoing sentence.

(b) REVERSION OF SHARES TO THE SHARE RESERVE. If any Stock Award shall for any reason expire or otherwise terminate, in whole or in part, without having been exercised in full, or if any shares of Common Stock issued to a Participant pursuant to a Stock Award are forfeited back to or repurchased by the Company, including, but not limited to, any repurchase or forfeiture caused by the failure to meet a contingency or condition required for the vesting of such shares, then the shares of Common Stock not acquired under such Stock Award shall revert to and again become available for issuance under the Plan. If any shares subject to a Stock Award are not delivered to a Participant because such shares are withheld for the payment of taxes or the Stock Award is exercised through a reduction of shares subject to the Stock Award (i.e., "net exercised"), the number of shares that are not delivered shall revert to and again become available for issuance under the Plan. If the exercise price of any Stock Award is satisfied by tendering shares of Common Stock held by the Participant (either by actual delivery or attestation), then the number of such tendered shares shall revert to and again become available for issuance under the Plan.

(c) SOURCE OF SHARES. The shares of Common Stock subject to the Plan may be unissued shares or reacquired shares, bought on the market or otherwise.

5. ELIGIBILITY.

(a) ELIGIBILITY FOR SPECIFIC STOCK AWARDS. Stock Awards may be granted to Employees, Directors and Consultants.

(b) CONSULTANTS. A Consultant shall not be eligible for the grant of a Stock Award if, at the time of grant, a Form S-8 Registration Statement under the Securities Act ("Form S-8") is not available to register either the offer or the sale of the Company's securities to such Consultant because of the nature of the services that the Consultant is providing to the Company,

because the Consultant is not a natural person, or because of any other rule governing the use of Form S-8.

6. OPTION PROVISIONS.

Each Option shall be in such form and shall contain such terms and conditions as the Board shall deem appropriate. All Options shall be designated as nonstatutory stock options at the time of grant. The provisions of separate Options need not be identical, but each Option shall include (through incorporation of the provisions hereof by reference in the Option or otherwise) the substance of each of the following provisions:

(a) TERM. The Board shall determine the term of an Option.

(b) EXERCISE PRICE OF AN OPTION. The Board, in its discretion, shall determine the exercise price of each Option.

(c) CONSIDERATION. The purchase price of Common Stock acquired pursuant to an Option shall be paid, to the extent permitted by applicable law, either (i) in cash at the time the Option is exercised or (ii) at the discretion of the Board, (1) by delivery to the Company of other Common Stock, (2) by a "net exercise" of the Option (as further described below) or (3) pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board that, prior to the issuance of Common Stock, results in either the receipt of cash (or check) by the Company or the receipt of irrevocable instructions to pay the aggregate exercise price to the Company from the sales proceeds. Unless otherwise specifically provided in the Option, the purchase price of Common Stock acquired pursuant to an Option that is paid by delivery to the Company of other Common Stock acquired, directly or indirectly, from the Company, shall be paid only by shares of the Common Stock of the Company that have been held for more than six (6) months (or such longer or shorter period of time required to avoid a charge to earnings for financial accounting purposes). At any time that the Company is incorporated in Delaware, payment of the Common Stock's "par value," as defined in the Delaware General Corporation Law, shall not be made by deferred payment.

In the case of any deferred payment arrangement, interest shall be compounded at least annually and shall be charged at the minimum rate of interest necessary to avoid (1) the treatment as interest, under any applicable provisions of the Code, of any amounts other than amounts stated to be interest under the deferred payment arrangement and (2) the treatment of the Option as a variable award for financial accounting purposes.

In the case of a "net exercise" of an Option, the Company will not require a payment of the exercise price of the Option from the Participant but will reduce the number of shares of Common Stock issued upon the exercise by the largest number of whole shares that has a Fair Market Value that does not exceed the aggregate exercise price. With respect to any remaining balance of the aggregate exercise price, the Company shall accept a cash payment from the Participant. The shares of Common Stock so used to pay the exercise price of an Option under a "net exercise" will be considered to have resulted from the exercise of the Option, and accordingly, the Option will not again be exercisable with respect to such shares, the shares actually delivered to the Participant, and any shares withheld for purposes of tax withholding.

(d) TRANSFERABILITY OF AN OPTION. An Option shall be transferable to the extent provided in the Option Agreement. If the Option does not provide for transferability, then the Option shall not be transferable except by will or by the laws of descent and distribution and shall be exercisable during the lifetime of the Optionholder only by the Optionholder. Notwithstanding the foregoing, the Optionholder may, by delivering written notice to the Company, in a form provided by or otherwise satisfactory to the Company, designate a third party who, in the event of the death of the Optionholder, shall thereafter be entitled to exercise the Option.

(e) VESTING GENERALLY. The total number of shares of Common Stock subject to an Option may, but need not, vest and therefore become exercisable in periodic installments that may, but need not, be equal. The Option may be subject to such other terms and conditions on the time or times when it may be exercised (which may be based on performance or other criteria) as the Board may deem appropriate. The vesting provisions of individual Options may vary. The provisions of this Section 6(e) are subject to any Option provisions governing the minimum number of shares of Common Stock as to which an Option may be exercised.

(f) TERMINATION OF CONTINUOUS SERVICE. In the event that an Optionholder's Continuous Service terminates (other than upon the Optionholder's death or Disability), the Optionholder may exercise his or her Option (to the extent that the Optionholder was entitled to exercise such Option as of the date of termination) but only within such period of time ending on the earlier of (i) the date three (3) months following the termination of the Optionholder's Continuous Service (or such longer or shorter period specified in the Option Agreement) or (ii) the expiration of the term of the Option as set forth in the Option Agreement. If, after termination, the Optionholder does not exercise his or her Option within the time specified in the Option Agreement, the Option shall terminate.

(g) EXTENSION OF TERMINATION DATE. An Optionholder's Option Agreement may also provide that if the exercise of the Option following the termination of the Optionholder's Continuous Service (other than upon the Optionholder's death or Disability) would be prohibited at any time solely because the issuance of shares of Common Stock would violate the registration requirements under the Securities Act, then the Option shall terminate on the earlier of (i) the expiration of the term of the Option set forth in the Option Agreement or (ii) the expiration of a period of three (3) months after the termination of the Optionholder's Continuous Service during which the exercise of the Option would not be in violation of such registration requirements.

(h) DISABILITY OF OPTIONHOLDER. In the event that an Optionholder's Continuous Service terminates as a result of the Optionholder's Disability, the Optionholder may exercise his or her Option (to the extent that the Optionholder was entitled to exercise such Option as of the date of termination), but only within such period of time ending on the earlier of (i) the date twelve (12) months following such termination (or such longer or shorter period specified in the Option Agreement or (ii) the expiration of the term of the Option as set forth in the Option Agreement. If, after termination, the Optionholder does not exercise his or her Option within the time specified herein, the Option shall terminate.

(i) DEATH OF OPTIONHOLDER. In the event that (i) an Optionholder's Continuous Service terminates as a result of the Optionholder's death or (ii) the Optionholder dies within the period (if any) specified in the Option Agreement after the termination of the Optionholder's Continuous Service for a reason other than death, then the Option may be exercised (to the extent the Optionholder was entitled to exercise such Option as of the date of death) by the Optionholder's estate, by a person who acquired the right to exercise the Option by bequest or inheritance or by a person designated to exercise the option upon the Optionholder's death pursuant to Section 6(d), but only within the period ending on the earlier of (1) the date eighteen (18) months following the date of death (or such longer or shorter period specified in the Option Agreement, or (2) the expiration of the term of such Option as set forth in the Option Agreement. If, after death, the Option is not exercised within the time specified herein, the Option shall terminate.

(j) RETIREMENT OF AN OPTIONHOLDER. In the event that an Optionholder's Continuous Service terminates as a result of the Optionholder's Retirement, the Optionholder may exercise his or her Option (to the extent that the Optionholder was entitled to exercise such Option as of the date of termination of employment due to Retirement), but only within such period of time ending on the earlier of (i) the date twenty-four (24) months following such termination (or such longer or shorter period specified in the Option Agreement or (ii) the expiration of the term of the Option as set forth in the Option Agreement. If, after termination, the Optionholder does not exercise his or her Option within the time specified herein, the Option shall terminate.

(k) EARLY EXERCISE. The Option may, but need not, include a provision whereby the Optionholder may elect at any time before the Optionholder's Continuous Service terminates to exercise the Option as to any part or all of the shares of Common Stock subject to the Option prior to the full vesting of the Option. Any unvested shares of Common Stock so purchased may be subject to a repurchase option in favor of the Company or to any other restriction the Board determines to be appropriate. The Company will not exercise its repurchase option until at least six (6) months (or such longer or shorter period of time required to avoid a charge to earnings for financial accounting purposes) have elapsed following exercise of the Option unless the Board otherwise specifically provides in the Option.

7. PROVISIONS OF STOCK AWARDS OTHER THAN OPTIONS.

(a) RESTRICTED STOCK AWARDS. Each Restricted Stock Award agreement shall be in such form and shall contain such terms and conditions as the Board shall deem appropriate. The terms and conditions of Restricted Stock Award agreements may change from time to time, and the terms and conditions of separate Restricted Stock Award agreements need not be identical; provided, however, that each Restricted Stock Award agreement shall include (through incorporation of the provisions hereof by reference in the agreement or otherwise) the substance of each of the following provisions:

(i) PURCHASE PRICE. At the time of the grant of a Restricted Stock Award, the Board will determine the price to be paid by the Participant for each share subject to the Restricted Stock Award. To the extent required by applicable law, the price to be paid by the Participant for each share of the Restricted Stock Award will not be less than the par value of a

share of Common Stock. A Restricted Stock Award may be awarded as a stock bonus (i.e., with no cash purchase price to be paid) to the extent permissible under applicable law.

(ii) CONSIDERATION. At the time of the grant of a Restricted Stock Award, the Board will determine the consideration permissible for the payment of the purchase price of the Restricted Stock Award. The purchase price of Common Stock acquired pursuant to the Restricted Stock Award shall be paid in one of the following ways: (i) in cash at the time of purchase; or (ii) by services rendered or to be rendered to the Company; provided, however, that at any time that the Company is incorporated in Delaware, the Common Stock's "par value," as defined in the Delaware General Corporation Law, must be paid in a form of consideration that is permissible under the Delaware General Corporation Law.

(iii) VESTING. Shares of Common Stock acquired under a Restricted Stock Award may, but need not, be subject to a share repurchase option in favor of the Company in accordance with a vesting schedule to be determined by the Board.

(iv) TERMINATION OF PARTICIPANT'S CONTINUOUS SERVICE. In the event that a Participant's Continuous Service terminates, the Company may repurchase or otherwise reacquire any or all of the shares of Common Stock held by the Participant that have not vested as of the date of termination under the terms of the Restricted Stock Award agreement. The Company will not exercise its repurchase option until at least six (6) months (or such longer or shorter period of time required to avoid a charge to earnings for financial accounting purposes) have elapsed following the purchase of the restricted stock unless otherwise determined by the Board or provided in the Restricted Stock Award agreement.

(v) TRANSFERABILITY. Rights to purchase or receive shares of Common Stock granted under a Restricted Stock Award shall be transferable by the Participant only upon such terms and conditions as are set forth in the Restricted Stock Award agreement, as the Board shall determine in its discretion, and so long as Common Stock awarded under the Restricted Stock Award remains subject to the terms of the Restricted Stock Award agreement.

(b) PHANTOM STOCK. Each Phantom Stock agreement shall be in such form and shall contain such terms and conditions as the Board shall determine. The terms and conditions of Phantom Stock agreements may change from time to time, and the terms and conditions of separate Phantom Stock agreements need not be identical; provided, however, that each Phantom Stock agreement shall include (through incorporation of the provisions hereof by reference in the agreement or otherwise) the substance of each of the following provisions:

(i) CONSIDERATION. At the time of grant of a Phantom Stock award, the Board will determine the consideration, if any, to be paid by the Participant upon delivery of each share of Common Stock subject to the Phantom Stock award. To the extent required by applicable law, the consideration to be paid by the Participant for each share of Common Stock subject to a Phantom Stock award will not be less than the par value of a share of Common Stock. Such consideration may be paid in any form permitted under applicable law.

(ii) VESTING. At the time of the grant of a Phantom Stock award, the Board may impose such restrictions or conditions to the vesting of the shares Phantom Stock as it deems appropriate.

(iii) PAYMENT. A Phantom Stock award may be settled by the delivery of shares of Common Stock, their cash equivalent, or any combination of the two, as the Board deems appropriate.

(iv) ADDITIONAL RESTRICTIONS. At the time of the grant of a Phantom Stock award, the Board, as it deems appropriate, may impose such restrictions or conditions that delay the delivery of the shares of Common Stock (or their cash equivalent) subject to a Phantom Stock award after the vesting of such Award.

(v) DIVIDEND EQUIVALENTS. Dividend equivalents may be credited in respect of shares of Phantom Stock, as the Board deems appropriate. Such dividend equivalents may be converted into additional shares of Phantom Stock by dividing (1) the aggregate amount or value of the dividends paid with respect to that number of shares of Common Stock equal to the number of shares of Phantom Stock then credited by (2) the Fair Market Value per share of Common Stock on the payment date for such dividend. The additional shares of Phantom Stock credited by reason of such dividend equivalents will be subject to all the terms and conditions of the underlying Phantom Stock award to which they relate.

(vi) TERMINATION OF PARTICIPANT'S CONTINUOUS SERVICE. Except as otherwise provided in the applicable Stock Award Agreement, shares of Phantom Stock that have not vested will be forfeited upon the Participant's termination of Continuous Service for any reason.

(c) STOCK APPRECIATION RIGHTS. Each Stock Appreciation Rights agreement shall be in such form and shall contain such terms and conditions as the Board shall deem appropriate. The terms and conditions of Stock Appreciation Rights agreements may change from time to time, and the terms and conditions of separate Stock Appreciation Rights agreements need not be identical, but each Stock Appreciation Rights agreement shall include (through incorporation of the provisions hereof by reference in the agreement or otherwise) the substance of each of the following provisions:

(i) STRIKE PRICE AND CALCULATION OF APPRECIATION. Each Stock Appreciation Right will be denominated in share of Common Stock equivalents. The appreciation distribution payable on the exercise of a Stock Appreciation Right will be not greater than an amount equal to the excess of (A) the aggregate Fair Market Value (on the date of the exercise of the Stock Appreciation Right) of a number of shares of Common Stock equal to the number of share of Common Stock equivalents in which the Participant is vested under such Stock Appreciation Right and with respect to which the Participant is exercising the Stock Appreciation Right on such date, over (B) an amount that will be determined by the Committee at the time of grant of the Stock Appreciation Right.

(ii) VESTING. At the time of the grant of a Stock Appreciation Right, the Board may impose such restrictions or conditions to the vesting of such Right as it deems appropriate.

(iii) EXERCISE. To exercise any outstanding Stock Appreciation Right, the Participant must provide written notice of exercise to the Company in compliance with the provisions of the Stock Appreciation Rights agreement evidencing such Right.

(iv) PAYMENT. The appreciation distribution in respect of a Stock Appreciation Right may be paid in Common Stock, in cash, or any combination of the two, as the Board deems appropriate.

(v) TERMINATION OF CONTINUOUS SERVICE. In the event that a Participant's Continuous Service terminates, the Participant may exercise his or her Stock Appreciation Right (to the extent that the Participant was entitled to exercise such Stock Appreciation Right as of the date of termination) but only within such period of time ending on the earlier of (i) the date three (3) months following the termination of the Participant's Continuous Service (or such longer or shorter period specified in the Stock Appreciation Rights agreement) or (ii) the expiration of the term of the Stock Appreciation Right as set forth in the Stock Appreciation Rights agreement. If, after such termination, the Participant does not exercise his or her Stock Appreciation Right within the time specified in the Stock Appreciation Rights agreement, the Stock Appreciation Right shall terminate.

(d) OTHER STOCK AWARDS. Other forms of Stock Awards valued in whole or in part by reference to, or otherwise based on, Common Stock may be granted either alone or in addition to Stock Awards provided for under Section 6 and the preceding provisions of this Section 7. Subject to the provisions of the Plan, the Board shall have sole and complete authority to determine the persons to whom and the time or times at which such Other Stock Awards will be granted, the number of shares of Common Stock (or the cash equivalent thereof) to be granted pursuant to such Awards and all other terms and conditions of such Awards.

8. SECURITIES LAW COMPLIANCE.

The Company shall seek to obtain from each regulatory commission or agency having jurisdiction over the Plan such authority as may be required to grant Stock Awards and to issue and sell shares of Common Stock upon exercise of the Stock Awards; provided, however, that this undertaking shall not require the Company to register under the Securities Act the Plan, any Stock Award or any Common Stock issued or issuable pursuant to any such Stock Award. If, after reasonable efforts, the Company is unable to obtain from any such regulatory commission or agency the authority which counsel for the Company deems necessary for the lawful issuance and sale of Common Stock under the Plan, the Company shall be relieved from any liability for failure to issue and sell Common Stock upon exercise of such Stock Awards unless and until such authority is obtained.

9. USE OF PROCEEDS FROM STOCK.

Proceeds from the sale of Common Stock pursuant to Stock Awards shall constitute general funds of the Company.

10. MISCELLANEOUS.

(a) ACCELERATION OF EXERCISABILITY AND VESTING. The Board shall have the power to accelerate the time at which a Stock Award may first be exercised or the time during which a Stock Award or any part thereof will vest in accordance with the Plan, notwithstanding the provisions in the Stock Award stating the time at which it may first be exercised or the time during which it will vest.

(b) STOCKHOLDER RIGHTS. Subject to the further limitations of Section 7(b)(iv) hereof, no Participant shall be deemed to be the holder of, or to have any of the rights of a holder with respect to, any shares of Common Stock subject to such Stock Award unless and until such Participant has satisfied all requirements for exercise of the Stock Award pursuant to its terms.

(c) NO EMPLOYMENT OR OTHER SERVICE RIGHTS. Nothing in the Plan or any instrument executed or Stock Award granted pursuant thereto shall confer upon any Participant any right to continue to serve the Company or an Affiliate in the capacity in effect at the time the Stock Award was granted or shall affect the right of the Company or an Affiliate to terminate (i) the employment of an Employee with or without notice and with or without cause, (ii) the service of a Consultant pursuant to the terms of such Consultant's agreement with the Company or an Affiliate or (iii) the service of a Director pursuant to the Bylaws of the Company or an Affiliate, and any applicable provisions of the corporate law of the state in which the Company or the Affiliate is incorporated, as the case may be.

(d) INVESTMENT ASSURANCES. The Company may require a Participant, as a condition of exercising or acquiring Common Stock under any Stock Award, (i) to give written assurances satisfactory to the Company as to the Participant's knowledge and experience in financial and business matters and/or to employ a purchaser representative reasonably satisfactory to the Company who is knowledgeable and experienced in financial and business matters and that he or she is capable of evaluating, alone or together with the purchaser representative, the merits and risks of exercising the Stock Award; and (ii) to give written assurances satisfactory to the Company stating that the Participant is acquiring Common Stock subject to the Stock Award for the Participant's own account and not with any present intention of selling or otherwise distributing the Common Stock. The foregoing requirements, and any assurances given pursuant to such requirements, shall be inoperative if (1) the issuance of the shares of Common Stock upon the exercise or acquisition of Common Stock under the Stock Award has been registered under a then currently effective registration statement under the Securities Act or (2) as to any particular requirement, a determination is made by counsel for the Company that such requirement need not be met in the circumstances under the then applicable securities laws. The Company may, upon advice of counsel to the Company, place legends on stock certificates issued under the Plan as such counsel deems necessary or appropriate in order to comply with applicable securities laws, including, but not limited to, legends restricting the transfer of the Common Stock.

(e) WITHHOLDING OBLIGATIONS. To the extent provided by the terms of a Stock Award Agreement, the Participant may satisfy any federal, state or local tax withholding obligation relating to the exercise or acquisition of Common Stock under a Stock Award by any of the following means (in addition to the Company's right to withhold from any compensation paid to

the Participant by the Company) or by a combination of such means: (i) tendering a cash payment; (ii) authorizing the Company to withhold shares of Common Stock from the shares of Common Stock otherwise issuable to the Participant as a result of the exercise or acquisition of Common Stock under the Stock Award; provided, however, that no shares of Common Stock are withheld with a value exceeding the minimum amount of tax required to be withheld by law (or such lesser amount as may be necessary to avoid variable award accounting); or (iii) delivering to the Company owned and unencumbered shares of Common Stock.

11. ADJUSTMENTS UPON CHANGES IN STOCK.

(a) CAPITALIZATION ADJUSTMENTS. If any change is made in, or other event occurs with respect to, the Common Stock subject to the Plan or subject to any Stock Award without the receipt of consideration by the Company (through merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, stock split, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or other transaction not involving the receipt of consideration by the Company (each a "Capitalization Adjustment"), the Plan will be appropriately adjusted in the class(es) and maximum number of securities subject to the Plan pursuant to Sections 4(a) and 4(b), and the outstanding Stock Awards will be appropriately adjusted in the class(es) and number of securities and price per share of Common Stock subject to such outstanding Stock Awards. The Board shall make such adjustments, and its determination shall be final, binding and conclusive. (The conversion of any convertible securities of the Company shall not be treated as a transaction "without receipt of consideration" by the Company.)

(b) DISSOLUTION OR LIQUIDATION. In the event of a dissolution or liquidation of the Company, then all outstanding Stock Awards shall terminate immediately prior to the completion of such dissolution or liquidation.

(c) CORPORATE TRANSACTION. In the event of a Corporate Transaction, any surviving corporation or acquiring corporation may assume or continue any or all Stock Awards outstanding under the Plan or may substitute similar stock awards for Stock Awards outstanding under the Plan (it being understood that similar stock awards include, but are not limited to, awards to acquire the same consideration paid to the stockholders or the Company, as the case may be, pursuant to the Corporate Transaction), and any reacquisition or repurchase rights held by the Company in respect of Common Stock issued pursuant to Stock Awards may be assigned by the Company to the successor of the Company (or the successor's parent company), if any, in connection with such Corporate Transaction. In the event that any surviving corporation or acquiring corporation does not assume or continue any or all such outstanding Stock Awards or substitute similar stock awards for such outstanding Stock Awards, then with respect to Stock Awards that have been not assumed, continued or substituted and that are held by Participants whose Continuous Service has not terminated prior to the effective time of the Corporate Transaction, the vesting of such Stock Awards (and, if applicable, the time at which such Stock Awards may be exercised) shall (contingent upon the effectiveness of the Corporate Transaction) be accelerated in full to a date prior to the effective time of such Corporate Transaction as the Board shall determine (or, if the Board shall not determine such a date, to the date that is five (5) days prior to the effective time of the Corporate Transaction), the Stock Awards shall terminate if not exercised (if applicable) at or prior to such effective time, and any reacquisition or

repurchase rights held by the Company with respect to such Stock Awards held by Participants whose Continuous Service has not terminated shall (contingent upon the effectiveness of the Corporate Transaction) lapse. With respect to any other Stock Awards outstanding under the Plan that have not been assumed, continued or substituted, the vesting of such Stock Awards (and, if applicable, the time at which such Stock Award may be exercised) shall not be accelerated, unless otherwise provided in a written agreement between the Company or any Affiliate and the holder of such Stock Award, and such Stock Awards shall terminate if not exercised (if applicable) prior to the effective time of the Corporate Transaction.

(d) CHANGE IN CONTROL. A Stock Award held by any Participant whose Continuous Service has not terminated prior to the effective time of a Change in Control may be subject to additional acceleration of vesting and exercisability upon or after such event as may be provided in the Stock Award Agreement for such Stock Award or as may be provided in any other written agreement between the Company or any Affiliate and the Participant, but in the absence of such provision, no such acceleration shall occur.

12. AMENDMENT OF THE PLAN AND STOCK AWARDS.

(a) AMENDMENT OF PLAN. The Board at any time, and from time to time, may amend the Plan. However, except as provided in Section 11(a) relating to Capitalization Adjustments, no amendment shall be effective unless approved by the stockholders of the Company to the extent stockholder approval is necessary to satisfy applicable law.

(b) STOCKHOLDER APPROVAL. The Board, in its sole discretion, may submit any other amendment to the Plan for stockholder approval, including, but not limited to, amendments to the Plan intended to satisfy the requirements of Section 162(m) of the Code and the regulations thereunder regarding the exclusion of performance-based compensation from the limit on corporate deductibility of compensation paid to Covered Employees.

(c) NO IMPAIRMENT OF RIGHTS. Rights under any Stock Award granted before amendment of the Plan shall not be impaired by any amendment of the Plan unless (i) the Company requests the consent of the Participant and (ii) the Participant consents in writing.

(d) AMENDMENT OF STOCK AWARDS. The Board at any time, and from time to time, may amend the terms of any one or more Stock Awards; provided, however, that the rights under any Stock Award shall not be impaired by any such amendment unless (i) the Company requests the consent of the Participant and (ii) the Participant consents in writing.

13. TERMINATION OR SUSPENSION OF THE PLAN.

(a) PLAN TERM. The Board may suspend or terminate the Plan at any time. No Stock Awards may be granted under the Plan while the Plan is suspended or after it is terminated.

(b) NO IMPAIRMENT OF RIGHTS. Suspension or termination of the Plan shall not impair rights and obligations under any Stock Award granted while the Plan is in effect except with the written consent of the Participant.

14. EFFECTIVE DATE OF PLAN.

The Plan shall become effective as determined by the Board, but no Stock Award shall be exercised (or, in the case of a stock bonus, shall be granted) unless and until the Plan has been approved by the stockholders of the Company, which approval shall be within twelve (12) months before or after the date the Plan is adopted by the Board.

15. CHOICE OF LAW.

The law of the State of Delaware shall govern all questions concerning the construction, validity and interpretation of this Plan, without regard to such state's conflict of laws rules.

GTx, INC.
2004 EQUITY INCENTIVE PLAN

STOCK OPTION AGREEMENT
(NONSTATUTORY STOCK OPTION)

Pursuant to your Stock Option Grant Notice ("Grant Notice") and this Stock Option Agreement, GTx, Inc. (the "Company") has granted you an option under its 2004 Equity Incentive Plan (the "Plan") to purchase the number of shares of the Company's Common Stock indicated in your Grant Notice at the exercise price indicated in your Grant Notice. Defined terms not explicitly defined in this Stock Option Agreement but defined in the Plan shall have the same definitions as in the Plan.

The details of your option are as follows:

1. VESTING. Subject to the limitations contained herein, your option will vest as provided in your Grant Notice, provided that vesting will cease upon the termination of your Continuous Service and that your vesting may be accelerated as provided in the Plan and in Section 9 below.

2. NUMBER OF SHARES AND EXERCISE PRICE. The number of shares of Common Stock subject to your option and your exercise price per share referenced in your Grant Notice may be adjusted from time to time for Capitalization Adjustments.

3. EXERCISE PRIOR TO VESTING ("EARLY EXERCISE"). If permitted in your Grant Notice (i.e., the "Exercise Schedule" indicates that "Early Exercise" of your option is permitted) and subject to the provisions of your option, you may elect at any time that is both (i) during the period of your Continuous Service and (ii) during the term of your option, to exercise all or part of your option, including the nonvested portion of your option; provided, however, that:

(i) a partial exercise of your option shall be deemed to cover first vested shares of Common Stock and then the earliest vesting installment of unvested shares of Common Stock;

(ii) any shares of Common Stock so purchased from installments that have not vested as of the date of exercise shall be subject to the purchase option in favor of the Company as described in the Company's form of Early Exercise Stock Purchase Agreement;

(iii) you shall enter into the Company's form of Early Exercise Stock Purchase Agreement with a vesting schedule that will result in the same vesting as if no early exercise had occurred; and

4. METHOD OF PAYMENT. Payment of the exercise price is due in full upon exercise of all or any part of your option. You may elect to make payment of the exercise price in cash or by check or in any other manner PERMITTED BY YOUR GRANT NOTICE, which may include one or more of the following:

(i) In the Company's sole discretion at the time your option is exercised and provided that at the time of exercise the Common Stock is publicly traded and quoted regularly in The Wall Street Journal, pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board that, prior to the issuance of Common Stock, results in either the receipt of cash (or check) by the Company or the receipt of irrevocable instructions to pay the aggregate exercise price to the Company from the sales proceeds.

(ii) Provided that at the time of exercise the Common Stock is publicly traded and quoted regularly in The Wall Street Journal, by delivery of already-owned shares of Common Stock either that you have held for the period required to avoid a charge to the Company's reported earnings (generally six (6) months) or that you did not acquire, directly or indirectly from the Company, that are owned free and clear of any liens, claims, encumbrances or security interests, and that are valued at Fair Market Value on the date of exercise. "Delivery" for these purposes, in the sole discretion of the Company at the time you exercise your option, shall include delivery to the Company of your attestation of ownership of such shares of Common Stock in a form approved by the Company. Notwithstanding the foregoing, you may not exercise your option by tender to the Company of Common Stock to the extent such tender would violate the provisions of any law, regulation or agreement restricting the redemption of the Company's stock.

5. WHOLE SHARES. You may exercise your option only for whole shares of Common Stock.

6. SECURITIES LAW COMPLIANCE. Notwithstanding anything to the contrary contained herein, you may not exercise your option unless the shares of Common Stock issuable upon such exercise are then registered under the Securities Act or, if such shares of Common Stock are not then so registered, the Company has determined that such exercise and issuance would be exempt from the registration requirements of the Securities Act. The exercise of your option also must comply with other applicable laws and regulations governing your option, and you may not exercise your option if the Company determines that such exercise would not be in material compliance with such laws and regulations.

7. TERM. You may not exercise your option before the commencement or after the expiration of its term. The term of your option commences on the Date of Grant and expires upon the earliest of the following:

(i) three (3) months after the termination of your Continuous Service for any reason other than your Disability or death, provided that if during any part of such three (3) month period your option is not exercisable solely because of the condition set forth in Section 6, your option shall not expire until the earlier of the Expiration Date or until it shall have been exercisable for an aggregate period of three (3) months after the termination of your Continuous Service;

(ii) twelve (12) months after the termination of your Continuous Service due to your Disability;

(iii) eighteen (18) months after your death if you die either during your Continuous Service or within three (3) months after your Continuous Service terminates;

(iv) twenty-four (24) months after the termination of your Continuous Service due to your Retirement;

(v) twelve (12) months after the termination of your Continuous Service due to a termination by the Company or its successor without Cause or a Constructive Termination where such termination occurs within twelve months after a Change in Control;

(vi) the Expiration Date indicated in your Grant Notice; or

(vii) the day before the tenth (10th) anniversary of the Date of Grant.

8. EXERCISE.

(i) You may exercise the vested portion of your option (and the unvested portion of your option if your Grant Notice so permits) during its term by delivering a Notice of Exercise (in a form designated by the Company) together with the exercise price to the Secretary of the Company, or to such other person as the Company may designate, during regular business hours, together with such additional documents as the Company may then require.

(ii) By exercising your option you agree that, as a condition to any exercise of your option, the Company may require you to enter into an arrangement providing for the payment by you to the Company of any tax withholding obligation of the Company arising by reason of (1) the exercise of your option, (2) the lapse of any substantial risk of forfeiture to which the shares of Common Stock are subject at the time of exercise, or (3) the disposition of shares of Common Stock acquired upon such exercise.

9. VESTING ACCELERATION AFTER A CHANGE IN CONTROL

(a) DOUBLE TRIGGER ACCELERATION. If a Change in Control occurs and either (i) your Continuous Service with the Company or its successor or the successor's parent (together, the "Successor Company") is terminated by the Successor Company without Cause or (ii) your Continuous Service with the Successor Company is terminated as a result of a Constructive Termination, in either case, within [twelve] months after the effective time of the Change in Control, then, immediately prior to such termination, your option shall become fully vested and, if applicable, fully exercisable. In the event that you are required to resign your position with the Company as a condition of a Change in Control, (for example, if you, as an officer of the Company, must resign your position as a condition of the Change of Control transaction), then your option shall become fully vested and exercisable immediately prior to the effectiveness of such resignation.

(b) "CAUSE" means that, in the reasonable determination of the Company or its successor, (i) you have committed an act that materially injures the business of the Company; (ii) [you have refused or failed to follow lawful and reasonable

directions of the Board or the appropriate individual to whom you report]; (iii) you have willfully or habitually neglected your duties with the Company; (iv) you have been convicted of a felony that is likely to inflict or has inflicted material injury on the business of the Company; or (v) you have committed a material fraud, misappropriation, embezzlement or other act of gross dishonesty that resulted in material loss, damage or injury to the Company. [Notwithstanding the foregoing, Cause based on the conduct described in clause (ii) or clause (iii) shall not exist unless the conduct described in such clause has not been cured within fifteen (15) days following receipt by you of written notice from the Company or the Board, as the case may be, specifying the particulars of your conduct constituting Cause.]

(c) "CONSTRUCTIVE TERMINATION" means that you voluntarily terminate employment with the Company or its successor within [twelve (12)] months following a Change in Control after any of the following are undertaken without your express written consent:

(i) the assignment to you of any duties or responsibilities which results in a significant diminution in your function as in effect immediately prior to the effective date of the Change in Control; provided, however, that a mere change in your title or reporting relationships shall not constitute a Constructive Termination;

(ii) a [material/five percent (5%) or greater] reduction by the Company in your annual base salary, as in effect on the effective date of the Change in Control;

(iii) [any failure by the Company to continue in effect any benefit plan or program, including fringe benefits, incentive plans and plans with respect to the receipt of securities of the Company, in which you are participating immediately prior to the effective date of the Change in Control (hereinafter referred to as "Benefit Plans"); or the taking of any action by the Company that would adversely affect your participation in or reduce your benefits under the Benefit Plans; provided, however, that a "Constructive Termination" shall not exist under this paragraph following a Change in Control if the Company offers a range of benefit plans and programs which, taken as a whole, are comparable to the Benefit Plans];

(iv) a relocation of your business office to a location more than fifty (50) miles from the location at which you performed duties as of the effective date of the Change in Control, except for required travel by you on the Company's business to an extent substantially consistent with your business travel obligations prior to the Change in Control; or

(v) a material breach by the Company of any provision of the this Stock Option Agreement.

10. TRANSFERABILITY. Your option is not transferable, except by will or by the laws of descent and distribution, and is exercisable during your life only by you. Notwithstanding the foregoing, by delivering written notice to the Company, in a form satisfactory to the Company, you may designate a third party who, in the event of your death, shall thereafter be entitled to exercise your option.

11. OPTION NOT A SERVICE CONTRACT. Your option is not an employment or service contract, and nothing in your option shall be deemed to create in any way whatsoever any obligation on your part to continue in the employ of the Company or an Affiliate, or of the Company or an Affiliate to continue your employment. In addition, nothing in your option shall obligate the Company or an Affiliate, their respective stockholders, Boards of Directors, Officers or Employees to continue any relationship that you might have as a Director or Consultant for the Company or an Affiliate.

12. WITHHOLDING OBLIGATIONS.

(i) At the time you exercise your option, in whole or in part, or at any time thereafter as requested by the Company, you hereby authorize withholding from payroll and any other amounts payable to you, and otherwise agree to make adequate provision for (including by means of a "cashless exercise" pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board to the extent permitted by the Company), any sums required to satisfy the federal, state, local and foreign tax withholding obligations of the Company or an Affiliate, if any, which arise in connection with the exercise of your option.

(ii) Upon your request and subject to approval by the Company, in its sole discretion, and compliance with any applicable legal conditions or restrictions, the Company may withhold from fully vested shares of Common Stock otherwise issuable to you upon the exercise of your option a number of whole shares of Common Stock having a Fair Market Value, determined by the Company as of the date of exercise, not in excess of the minimum amount of tax required to be withheld by law (or such lower amount as may be necessary to avoid variable award accounting). If the date of determination of any tax withholding obligation is deferred to a date later than the date of exercise of your option, share withholding pursuant to the preceding sentence shall not be permitted unless you make a proper and timely election under Section 83(b) of the Code, covering the aggregate number of shares of Common Stock acquired upon such exercise with respect to which such determination is otherwise deferred, to accelerate the determination of such tax withholding obligation to the date of exercise of your option. Notwithstanding the filing of such election, shares of Common Stock shall be withheld solely from fully vested shares of Common Stock determined as of the date of exercise of your option that are otherwise issuable to you upon such exercise. Any adverse consequences to you arising in connection with such share withholding procedure shall be your sole responsibility.

(iii) You may not exercise your option unless the tax withholding obligations of the Company and/or any Affiliate are satisfied. Accordingly, you may not be able to exercise your option when desired even though your option is vested, and the Company shall have no obligation to issue a certificate for such shares of Common Stock or release such shares of Common Stock from any escrow provided for herein unless such obligations are satisfied.

13. NOTICES. Any notices provided for in your option or the Plan shall be given in writing and shall be deemed effectively given upon receipt or, in the case of notices delivered by mail by the Company to you, five (5) days after deposit in the United States mail, postage prepaid, addressed to you at the last address you provided to the Company.

14. GOVERNING PLAN DOCUMENT. Your option is subject to all the provisions of the Plan, the provisions of which are hereby made a part of your option, and is further subject to all interpretations, amendments, rules and regulations, which may from time to time be promulgated and adopted pursuant to the Plan. In the event of any conflict between the provisions of your option and those of the Plan, the provisions of the Plan shall control.

EXHIBIT 10.6

GTX, INC.

2004 NON-EMPLOYEE DIRECTORS' STOCK OPTION PLAN

ADOPTED JANUARY 14, 2004
APPROVED BY STOCKHOLDERS JANUARY 14, 2004

1. PURPOSES.

(a) ELIGIBLE OPTION RECIPIENTS. The persons eligible to receive Options are the Non-Employee Directors of the Company.

(b) AVAILABLE OPTIONS. The purpose of the Plan is to provide a means by which Non-Employee Directors may be given an opportunity to benefit from increases in value of the Common Stock through the granting of Nonstatutory Stock Options.

(c) GENERAL PURPOSE. The Company, by means of the Plan, seeks to retain the services of its Non-Employee Directors, to secure and retain the services of new Non-Employee Directors and to provide incentives for such persons to exert maximum efforts for the success of the Company and its Affiliates.

2. DEFINITIONS.

(a) "ACCOUNTANT" means the independent public accountants of the Company.

(b) "AFFILIATE" means any parent corporation or subsidiary corporation of the Company, whether now or hereafter existing, as those terms are defined in Sections 424(e) and (f), respectively, of the Code.

(c) "ANNUAL GRANT" means an Option granted annually to all Non-Employee Directors who meet the specified criteria pursuant to Section 6(b).

(d) "ANNUAL MEETING" means the annual meeting of the stockholders of the Company.

(e) "BOARD" means the Board of Directors of the Company.

(f) "CAPITALIZATION ADJUSTMENT" has the meaning ascribed to that term in Section 11(a).

(g) "CHANGE IN CONTROL" means the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events:

(i) any Exchange Act Person becomes the Owner, directly or indirectly, of securities of the Company representing more than fifty percent (50%) of the combined voting power of the Company's then outstanding securities other than by virtue of a merger, consolidation or similar transaction. Notwithstanding the foregoing, a Change in Control shall

not be deemed to occur solely because the level of Ownership held by any Exchange Act Person (the "Subject Person") exceeds the designated percentage threshold of the outstanding voting securities as a result of a repurchase or other acquisition of voting securities by the Company reducing the number of shares outstanding, provided that if a Change in Control would occur (but for the operation of this sentence) as a result of the acquisition of voting securities by the Company, and after such share acquisition, the Subject Person becomes the Owner of any additional voting securities that, assuming the repurchase or other acquisition had not occurred, increases the percentage of the then outstanding voting securities Owned by the Subject Person over the designated percentage threshold, then a Change in Control shall be deemed to occur;

(ii) there is consummated a merger, consolidation or similar transaction involving (directly or indirectly) the Company and, immediately after the consummation of such merger, consolidation or similar transaction, the stockholders of the Company immediately prior thereto do not Own, directly or indirectly, outstanding voting securities representing more than fifty percent (50%) of the combined outstanding voting power of the surviving Entity in such merger, consolidation or similar transaction or more than fifty percent (50%) of the combined outstanding voting power of the parent of the surviving Entity in such merger, consolidation or similar transaction;

(iii) the stockholders of the Company approve or the Board approves a plan of complete dissolution or liquidation of the Company, or a complete dissolution or liquidation of the Company shall otherwise occur;

(iv) there is consummated a sale, lease, license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries, other than a sale, lease, license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries to an Entity, more than fifty percent (50%) of the combined voting power of the voting securities of which are Owned by stockholders of the Company in substantially the same proportions as their Ownership of the Company immediately prior to such sale, lease, license or other disposition; or

(v) individuals who, on the date this Plan is adopted by the Board, are members of the Board (the "Incumbent Board") cease for any reason to constitute at least a majority of the members of the Board; (provided, however, that if the appointment or election (or nomination for election) of any new Board member was approved or recommended by a majority vote of the members of the Incumbent Board then still in office, such new member shall, for purposes of this Plan, be considered as a member of the Incumbent Board).

(h) "CODE" means the Internal Revenue Code of 1986, as amended.

(i) "COMMITTEE GRANT" means an Option granted annually to all Non-Employee Directors who meet the specified criteria pursuant to Section 6(c).

(j) "COMMON STOCK" means the common stock of the Company.

(k) "COMPANY" means GTx, Inc., a Delaware corporation.

(l) "CONSULTANT" means any person, including an advisor, (i) engaged by the Company or an Affiliate to render consulting or advisory services and who is compensated for such services or (ii) serving as a member of the Board of Directors of an Affiliate. However, the term "Consultant" shall not include either Directors of the Company who are not compensated by the Company for their services as Directors or Directors of the Company who are merely paid a director's fee by the Company for their services as Directors.

(m) "CONTINUOUS SERVICE" means that the Optionholder's service with the Company or an Affiliate, whether as an Employee, Director or Consultant, is not interrupted or terminated. The Optionholder's Continuous Service shall not be deemed to have terminated merely because of a change in the capacity in which the Optionholder renders service to the Company or an Affiliate as an Employee, Consultant or Director or a change in the entity for which the Optionholder renders such service, provided that there is no interruption or termination of the Optionholder's Continuous Service. For example, a change in status from a Non-Employee Director of the Company to a Consultant of an Affiliate or an Employee of the Company will not constitute an interruption of Continuous Service. The Board or the chief executive officer of the Company, in that party's sole discretion, may determine whether Continuous Service shall be considered interrupted in the case of any leave of absence approved by that party, including sick leave, military leave or any other personal leave.

(n) "CORPORATE TRANSACTION" means the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events:

(i) a sale or other disposition of all or substantially all, as determined by the Board in its discretion, of the consolidated assets of the Company and its Subsidiaries;

(ii) a sale or other disposition of at least ninety percent (90%) of the outstanding securities of the Company;

(iii) a merger, consolidation or similar transaction following which the Company is not the surviving corporation; or

(iv) a merger, consolidation or similar transaction following which the Company is the surviving corporation but the shares of Common Stock outstanding immediately preceding the merger, consolidation or similar transaction are converted or exchanged by virtue of the merger, consolidation or similar transaction into other property, whether in the form of securities, cash or otherwise.

(o) "DIRECTOR" means a member of the Board of Directors of the Company.

(p) "DISABILITY" means the inability of a person, in the opinion of a qualified physician acceptable to the Company, to perform the major duties of that person's position with the Company or an Affiliate of the Company because of the sickness or injury of the person.

(q) "EMPLOYEE" means any person employed by the Company or an Affiliate. Service as a Director or payment of a director's fee by the Company or an Affiliate shall not be sufficient to constitute "employment" by the Company or an Affiliate.

(r) "ENTITY" means a corporation, partnership or other entity.

(s) "EXCHANGE ACT" means the Securities Exchange Act of 1934, as amended.

(t) "EXCHANGE ACT PERSON" means any natural person, Entity or "group" (within the meaning of Section 13(d) or 14(d) of the Exchange Act), except that "Exchange Act Person" shall not include (A) the Company or any Subsidiary of the Company, (B) any employee benefit plan of the Company or any Subsidiary of the Company or any trustee or other fiduciary holding securities under an employee benefit plan of the Company or any Subsidiary of the Company, (C) an underwriter temporarily holding securities pursuant to an offering of such securities, or (D) an Entity Owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their Ownership of stock of the Company.

(u) "FAIR MARKET VALUE" means, as of any date, the value of the Common Stock determined as follows:

(i) If the Common Stock is listed on any established stock exchange or traded on the Nasdaq National Market or the Nasdaq SmallCap Market, the Fair Market Value of a share of Common Stock shall be the closing sales price for such stock (or the closing bid, if no sales were reported) as quoted on such exchange or market (or the exchange or market with the greatest volume of trading in the Common Stock) on the last market trading day prior to the day of determination, as reported in The Wall Street Journal or such other source as the Board deems reliable.

(ii) In the absence of such markets for the Common Stock, the Fair Market Value shall be determined in good faith by the Board.

(v) "INITIAL GRANT" means an Option granted to a Non-Employee Director who meets the specified criteria pursuant to Section 6(a).

(w) "IPO DATE" means the means the first day that the Common Stock is publicly traded after the initial public offering of the Common Stock.

(x) "NON-EMPLOYEE DIRECTOR" means a Director who is not an Employee.

(y) "NONSTATUTORY STOCK OPTION" means an Option not intended to qualify as an incentive stock option within the meaning of Section 422 of the Code and the regulations promulgated thereunder.

(z) "OFFICER" means a person who is an officer of the Company within the meaning of Section 16 of the Exchange Act and the rules and regulations promulgated thereunder.

(aa) "OPTION" means a Nonstatutory Stock Option granted pursuant to the Plan.

(bb) "OPTION AGREEMENT" means a written agreement between the Company and an Optionholder evidencing the terms and conditions of an individual Option grant. Each Option Agreement shall be subject to the terms and conditions of the Plan.

(cc) "OPTIONHOLDER" means a person to whom an Option is granted pursuant to the Plan or, if applicable, such other person who holds an outstanding Option.

(dd) "OWN," "OWNED," "OWNER," "OWNERSHIP" A person or Entity shall be deemed to "Own," to have "Owned," to be the "Owner" of, or to have acquired "Ownership" of securities if such person or Entity, directly or indirectly, through any contract, arrangement, understanding, relationship or otherwise, has or shares voting power, which includes the power to vote or to direct the voting, with respect to such securities.

(ee) "PLAN" means this GTx, Inc. 2004 Non-Employee Directors' Stock Option Plan.

(ff) "RULE 16B-3" means Rule 16b-3 promulgated under the Exchange Act or any successor to Rule 16b-3, as in effect from time to time.

(gg) "SECURITIES ACT" means the Securities Act of 1933, as amended.

(hh) "SUBSIDIARY" means, with respect to the Company, (i) any corporation of which more than fifty percent (50%) of the outstanding capital stock having ordinary voting power to elect a majority of the board of directors of such corporation (irrespective of whether, at the time, stock of any other class or classes of such corporation shall have or might have voting power by reason of the happening of any contingency) is at the time, directly or indirectly, Owned by the Company, and (ii) any partnership in which the Company has a direct or indirect interest (whether in the form of voting or participation in profits or capital contribution) of more than fifty percent (50%).

3. ADMINISTRATION.

(a) ADMINISTRATION BY BOARD. The Board shall administer the Plan. The Board may not delegate administration of the Plan to a committee.

(b) POWERS OF BOARD. The Board shall have the power, subject to, and within the limitations of, the express provisions of the Plan:

(i) To determine the provisions of each Option to the extent not specified in the Plan.

(ii) To construe and interpret the Plan and Options granted under it, and to establish, amend and revoke rules and regulations for its administration. The Board, in the exercise of this power, may correct any defect, omission or inconsistency in the Plan or in any Option Agreement, in a manner and to the extent it shall deem necessary or expedient to make the Plan fully effective.

(iii) To amend the Plan or an Option as provided in Section 12.

(iv) Generally, to exercise such powers and to perform such acts as the Board deems necessary or expedient to promote the best interests of the Company and that are not in conflict with the provisions of the Plan.

(c) EFFECT OF BOARD'S DECISION. All determinations, interpretations and constructions made by the Board in good faith shall not be subject to review by any person and shall be final, binding and conclusive on all persons.

4. SHARES SUBJECT TO THE PLAN.

(a) SHARE RESERVE. Subject to the provisions of Section 11 relating to adjustments upon changes in the Common Stock, the Common Stock that may be issued pursuant to Options shall not exceed in the aggregate Two Hundred Thousand (200,000) shares of Common Stock (on a post split basis), plus an annual increase for ten years beginning on January 1, 2005 and ending on (and including) January 1, 2013 equal to the number of shares subject to Options granted during the prior calendar year. Notwithstanding the foregoing, the Board may act, prior to the first day of any fiscal year of the Company, to increase the share reserve by such number of shares of Common Stock as the Board shall determine, which number shall be less than the amount described in the foregoing sentence.

(b) REVERSION OF SHARES TO THE SHARE RESERVE. If any Option shall for any reason expire or otherwise terminate, in whole or in part, without having been exercised in full, the shares of Common Stock not acquired under such Option shall revert to and again become available for issuance under the Plan.

(c) SOURCE OF SHARES. The shares of Common Stock subject to the Plan may be unissued shares or reacquired shares, bought on the market or otherwise.

5. ELIGIBILITY.

The Options, as set forth in Section 6, automatically shall be granted under the Plan to all Non-Employee Directors who meet the criteria specified in Section 6. Notwithstanding the foregoing, a Non-Employee Director shall not be eligible for the grant of an Option under the Plan if the Non-Employee Director is the Owner, directly or indirectly, of securities of the Company representing more than ten percent (10%) of the combined voting power of the Company's then outstanding securities.

6. NON-DISCRETIONARY GRANTS.

(a) INITIAL GRANTS. Without any further action of the Board, each person who is serving as a Non-Employee Director on the IPO Date automatically shall, on the IPO Date, be granted an Initial Grant to purchase ten thousand (10,000) shares of Common Stock on the terms and conditions set forth herein. Additionally, without any further action of the Board, each person who after the IPO Date is elected or appointed for the first time to be a Non-Employee Director automatically shall, upon the date of his or her initial election or appointment to be a Non-Employee Director, be granted an Initial Grant to purchase ten thousand (10,000) shares of Common Stock (after

adjustment for the 8.5 to 1 stock split of January 14, 2004) on the terms and conditions set forth herein.

(b) ANNUAL GRANTS. Without any further action of the Board, on the day following each Annual Meeting, commencing with the Annual Meeting in 2005, each person who is then a Non-Employee Director automatically shall be granted an Annual Grant to purchase two thousand (2,000) shares of Common Stock on the terms and conditions set forth herein; provided, however, that a Non-Employee Director shall not receive an Annual Grant within one year of an Initial Grant.

7. OPTION PROVISIONS.

Each Option shall be in such form and shall contain such terms and conditions as required by the Plan. Each Option shall contain such additional terms and conditions, not inconsistent with the Plan, as the Board shall deem appropriate. Each Option shall include (through incorporation of provisions hereof by reference in the Option or otherwise) the substance of each of the following provisions:

(a) TERM. No Option shall be exercisable after the expiration of ten (10) years from the date it was granted.

(b) EXERCISE PRICE. The exercise price of each Option shall be one hundred percent (100%) of the Fair Market Value of the stock subject to the Option on the date the Option is granted; provided however, that for Initial Grants granted on or within three (3) months after the IPO Date, the exercise price of such Initial Grants shall be the price at which the Common Stock was first sold to the public in the initial public offering of the Common Stock.

(c) CONSIDERATION. The purchase price of stock acquired pursuant to an Option may be paid, to the extent permitted by applicable law, in any combination of (i) cash or check, (ii) delivery to the Company of other Common Stock or (iii) pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board that, prior to the issuance of Common Stock, results in either the receipt of cash (or check) by the Company or the receipt of irrevocable instructions to pay the aggregate exercise price to the Company from the sales proceeds. The purchase price of Common Stock acquired pursuant to an Option that is paid by delivery to the Company of other Common Stock acquired, directly or indirectly from the Company, shall be paid only by shares of the Common Stock of the Company that have been held for more than six (6) months (or such longer or shorter period of time required to avoid a charge to earnings for financial accounting purposes).

(d) TRANSFERABILITY. An Option is transferable by will or by the laws of descent and distribution. An Option also may be transferable upon written consent of the Company if, at the time of transfer, a Form S-8 registration statement under the Securities Act is available for the exercise of the Option and the subsequent resale of the underlying securities. In addition, an Optionholder may, by delivering written notice to the Company, in a form provided by or otherwise satisfactory to the Company, designate a third party who, in the event of the death of the Optionholder, shall thereafter be entitled to exercise the Option.

(e) VESTING. Options shall vest as follows:

(i) Initial Grants: 1/3rd of the shares shall vest annually on the anniversary of the date of grant, so that the Initial Grant is fully vested after 3 years.

(ii) Annual Grants: 1/3rd of the shares shall vest annually on the anniversary of the date of grant, so that the Annual Grant is fully vested after 3 years.

(f) EARLY EXERCISE. The Option may, but need not, include a provision whereby the Optionholder may elect at any time before the Optionholder's Continuous Service terminates to exercise the Option as to any part or all of the shares of Common Stock subject to the Option prior to the full vesting of the Option. Any unvested shared of Common Stock so purchased may be subject to a repurchase option in favor of the Company or to any other restriction the Board determines to be appropriate. The Company will not exercise its repurchase option until at least six (6) months (or such longer or shorter period of time required to avoid a charge to earnings for financial accounting purposes) have elapsed following exercise of the Option unless the Board otherwise specifically provides in the Option.

(g) TERMINATION OF CONTINUOUS SERVICE. In the event an Optionholder's Continuous Service terminates (other than upon the Optionholder's death or Disability), the Optionholder may exercise his or her Option (to the extent that the Optionholder was entitled to exercise it as of the date of termination) but only within such period of time ending on the earlier of (i) the date three (3) months following the termination of the Optionholder's Continuous Service, or (ii) the expiration of the term of the Option as set forth in the Option Agreement. If the Optionholder's Continuous Service terminates either as a condition of a Change in Control or upon the effectiveness of a Change in Control then the Optionholder may exercise the outstanding vested portion his or her Option within such period of time ending on the earlier of (i) the date twelve (12) months following the termination of the Optionholder's Continuous Service, or (ii) the expiration of the term of the Option as set forth in the Option Agreement. If, after termination, the Optionholder does not exercise his or her Option within the time specified in the Option Agreement, the Option shall terminate.

(h) EXTENSION OF TERMINATION DATE. If the exercise of the Option following the termination of the Optionholder's Continuous Service (other than upon the Optionholder's death or Disability) would be prohibited at any time solely because the issuance of shares would violate the registration requirements under the Securities Act, then the Option shall terminate on the earlier of (i) the expiration of the term of the Option as set forth in the Option Agreement or (ii) the expiration of a period of three (3) months after the termination of the Optionholder's Continuous Service during which the exercise of the Option would not be in violation of such registration requirements.

(i) DISABILITY OF OPTIONHOLDER. In the event an Optionholder's Continuous Service terminates as a result of the Optionholder's Disability, the Optionholder may exercise his or her Option (to the extent that the Optionholder was entitled to exercise it as of the date of termination), but only within such period of time ending on the earlier of (i) the date twelve (12) months following such termination or (ii) the expiration of the term of the Option as set forth in

the Option Agreement. If, after termination, the Optionholder does not exercise his or her Option within the time specified herein, the Option shall terminate.

(j) DEATH OF OPTIONHOLDER. In the event (i) an Optionholder's Continuous Service terminates as a result of the Optionholder's death or (ii) the Optionholder dies within the three-month period after the termination of the Optionholder's Continuous Service for a reason other than death, then the Option may be exercised (to the extent the Optionholder was entitled to exercise the Option as of the date of death) by the Optionholder's estate, by a person who acquired the right to exercise the Option by bequest or inheritance or by a person designated to exercise the Option upon the Optionholder's death, but only within the period ending on the earlier of (1) the date eighteen (18) months following the date of death or (2) the expiration of the term of such Option as set forth in the Option Agreement. If, after death, the Option is not exercised within the time specified herein, the Option shall terminate.

8. SECURITIES LAW COMPLIANCE.

The Company shall seek to obtain from each regulatory commission or agency having jurisdiction over the Plan such authority as may be required to grant Options and to issue and sell shares of Common Stock upon exercise of the Options; provided, however, that this undertaking shall not require the Company to register under the Securities Act the Plan, any Option or any stock issued or issuable pursuant to any such Option. If, after reasonable efforts, the Company is unable to obtain from any such regulatory commission or agency the authority which counsel for the Company deems necessary for the lawful issuance and sale of stock under the Plan, the Company shall be relieved from any liability for failure to issue and sell stock upon exercise of such Options unless and until such authority is obtained.

9. USE OF PROCEEDS FROM STOCK.

Proceeds from the sale of stock pursuant to Options shall constitute general funds of the Company.

10. MISCELLANEOUS.

(a) STOCKHOLDER RIGHTS. No Optionholder shall be deemed to be the holder of, or to have any of the rights of a holder with respect to, any shares subject to such Option unless and until such Optionholder has satisfied all requirements for exercise of the Option pursuant to its terms.

(b) NO SERVICE RIGHTS. Nothing in the Plan or any instrument executed or Option granted pursuant thereto shall confer upon any Optionholder any right to continue to serve the Company as a Non-Employee Director or shall affect the right of the Company or an Affiliate to terminate (i) the employment of an Employee with or without notice and with or without cause, (ii) the service of a Consultant pursuant to the terms of such Consultant's agreement with the Company or an Affiliate or (iii) the service of a Director pursuant to the Bylaws of the Company or an Affiliate, and any applicable provisions of the corporate law of the state in which the Company or the Affiliate is incorporated, as the case may be.

(c) INVESTMENT ASSURANCES. The Company may require an Optionholder, as a condition of exercising or acquiring stock under any Option, (i) to give written assurances satisfactory to the Company as to the Optionholder's knowledge and experience in financial and business matters and/or to employ a purchaser representative reasonably satisfactory to the Company who is knowledgeable and experienced in financial and business matters and that he or she is capable of evaluating, alone or together with the purchaser representative, the merits and risks of exercising the Option; and (ii) to give written assurances satisfactory to the Company stating that the Optionholder is acquiring the stock subject to the Option for the Optionholder's own account and not with any present intention of selling or otherwise distributing the stock. The foregoing requirements, and any assurances given pursuant to such requirements, shall be inoperative if (1) the issuance of the shares upon the exercise or acquisition of stock under the Option has been registered under a then currently effective registration statement under the Securities Act or (2) as to any particular requirement, a determination is made by counsel for the Company that such requirement need not be met in the circumstances under the then applicable securities laws. The Company may, upon advice of counsel to the Company, place legends on stock certificates issued under the Plan as such counsel deems necessary or appropriate in order to comply with applicable securities laws, including, but not limited to, legends restricting the transfer of the stock.

(d) WITHHOLDING OBLIGATIONS. The Optionholder may satisfy any federal, state or local tax withholding obligation relating to the exercise or acquisition of stock under an Option by any of the following means (in addition to the Company's right to withhold from any compensation paid to the Optionholder by the Company) or by a combination of such means: (i) tendering a cash payment; (ii) authorizing the Company to withhold shares from the shares of the Common Stock otherwise issuable to the Optionholder as a result of the exercise or acquisition of stock under the Option; provided, however, that no shares of Common Stock are withheld with a value exceeding the minimum amount of tax required to be withheld by law; or (iii) delivering to the Company owned and unencumbered shares of the Common Stock.

11. ADJUSTMENTS UPON CHANGES IN COMMON STOCK.

(a) CAPITALIZATION ADJUSTMENTS. If any change is made in, or other events occur with respect to, the stock subject to the Plan, or subject to any Option, without the receipt of consideration by the Company (through merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, stock split, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or other transaction not involving the receipt of consideration by the Company (each a "Capitalization Adjustment")), the Plan will be appropriately adjusted in the class(es) and maximum number of securities subject both to the Plan pursuant to Section 4 and to the nondiscretionary Options specified in Section 6, and the outstanding Options will be appropriately adjusted in the class(es) and number of securities and price per share of stock subject to such outstanding Options. The Board shall make such adjustments, and its determination shall be final, binding and conclusive. (The conversion of any convertible securities of the Company shall not be treated as a transaction "without receipt of consideration" by the Company.)

(b) DISSOLUTION OR LIQUIDATION. In the event of a dissolution or liquidation of the Company, then all outstanding Options shall terminate immediately prior to the completion of such dissolution or liquidation.

(c) CORPORATE TRANSACTION. In the event of a Corporate Transaction, any surviving corporation or acquiring corporation may assume any or all Options outstanding under the Plan or may substitute similar stock options for Options outstanding under the Plan (it being understood that similar stock options include, but are not limited to, options to acquire the same consideration paid to the stockholders or the Company, as the case may be, pursuant to the Corporate Transaction). In the event that any surviving corporation or acquiring corporation does not assume any or all such outstanding Options or substitute similar stock options for such outstanding Options, then with respect to Options that have been neither assumed nor substituted and that are held by Optionholders whose Continuous Service has not terminated prior to the effective time of the Corporate Transaction, the vesting of such Options (and, if applicable, the time at which such Options may be exercised) shall (contingent upon the effectiveness of the Corporate Transaction) be accelerated in full to a date prior to the effective time of such Corporate Transaction as the Board shall determine (or, if the Board shall not determine such a date, to the date that is five (5) days prior to the effective time of the Corporate Transaction), and the Options shall terminate if not exercised (if applicable) at or prior to such effective time. With respect to any other Options outstanding under the Plan that have been neither assumed nor substituted, the vesting of such Options (and, if applicable, the time at which such Options may be exercised) shall not be accelerated unless otherwise provided in Section 11(d) or in a written agreement between the Company or any Affiliate and the holder of such Options, and such Options shall terminate if not exercised (if applicable) prior to the effective time of the Corporate Transaction.

(d) CHANGE IN CONTROL. If a Change in Control occurs, then, immediately prior to such Change in Control, the Optionholder's Options shall become fully vested and exercisable. In the event that an Optionholder is required to resign his or her position as a Non-Employee Director as a condition of a Change in Control, the outstanding Options of such Optionholder shall become fully vested and exercisable immediately prior to the effectiveness of such resignation.

(e) PARACHUTE PAYMENTS. If the acceleration of the vesting and exercisability of Options provided for in Section 11(c), together with payments and other benefits of an Optionholder, (collectively, the "Payment") (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, or any comparable successor provisions, and (ii) but for this Section 11(e) would be subject to the excise tax imposed by Section 4999 of the Code, or any comparable successor provisions (the "Excise Tax"), then such Payment shall be either (1) provided to such Optionholder in full, or (2) provided to such Optionholder as to such lesser extent that would result in no portion of such Payment being subject to the Excise Tax, whichever of the foregoing amounts, when taking into account applicable federal, state, local and foreign income and employment taxes, the Excise Tax, and any other applicable taxes, results in the receipt by such Optionholder, on an after-tax basis, of the greatest amount of the Payment, notwithstanding that all or some portion of the Payment may be subject to the Excise Tax.

Unless the Company and such Optionholder otherwise agree in writing, any determination required under this Section 11(e) shall be made in writing in good faith by the Accountant. If a reduction in the Payment is to be made as provided above, reductions shall occur in the following order unless the Optionholder elects in writing a different order (provided, however, that such election shall be subject to Company approval if made on or after the date that triggers the Payment or a portion thereof): reduction of cash payments; cancellation of accelerated vesting of Options; reduction of employee benefits. If acceleration of vesting of Options is to be reduced, such acceleration of vesting shall be cancelled in the reverse order of date of grant of Options (i.e., earliest granted Option cancelled last) unless the Optionholder elects in writing a different order for cancellation.

For purposes of making the calculations required by this Section 11(e), the Accountant may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning the application of the Code and other applicable legal authority. The Company and the Optionholder shall furnish to the Accountant such information and documents as the Accountant may reasonably request in order to make such a determination. The Company shall bear all costs the Accountant may reasonably incur in connection with any calculations contemplated by this Section 11(e).

If, notwithstanding any reduction described above, the Internal Revenue Service (the "IRS") determines that the Optionholder is liable for the Excise Tax as a result of the Payment, then the Optionholder shall be obligated to pay back to the Company, within thirty (30) days after a final IRS determination or, in the event that the Optionholder challenges the final IRS determination, a final judicial determination, a portion of the Payment equal to the "Repayment Amount." The Repayment Amount with respect to the Payment shall be the smallest such amount, if any, as shall be required to be paid to the Company so that the Optionholder's net after-tax proceeds with respect to the Payment (after taking into account the payment of the Excise Tax and all other applicable taxes imposed on the Payment) shall be maximized. The Repayment Amount with respect to the Payment shall be zero if a Repayment Amount of more than zero would not result in the Optionholder's net after-tax proceeds with respect to the Payment being maximized. If the Excise Tax is not eliminated pursuant to this paragraph, the Optionholder shall pay the Excise Tax.

Notwithstanding any other provision of this Section 11(e), if (i) there is a reduction in the Payment as described above, (ii) the IRS later determines that the Optionholder is liable for the Excise Tax, the payment of which would result in the maximization of the Optionholder's net after-tax proceeds of the Payment (calculated as if the Payment had not previously been reduced), and (iii) the Optionholder pays the Excise Tax, then the Company shall pay or otherwise provide to the Optionholder that portion of the Payment that was reduced pursuant to this Section 11(e) contemporaneously or as soon as administratively possible after the Optionholder pays the Excise Tax so that the Optionholder's net after-tax proceeds with respect to the Payment are maximized.

If the Optionholder either (i) brings any action to enforce rights pursuant to this Section 11(e), or (ii) defends any legal challenge to his or her rights under this Section 11(e), the Optionholder shall be entitled to recover attorneys' fees and costs incurred in connection with

such action, regardless of the outcome of such action; provided, however, that if such action is commenced by the Optionholder, the court finds that the action was brought in good faith.

12. AMENDMENT OF THE PLAN AND OPTIONS.

(a) AMENDMENT OF PLAN. The Board, at any time and from time to time, may amend the Plan. However, except as provided in Section 11 relating to adjustments upon changes in Common Stock, no amendment shall be effective unless approved by the stockholders of the Company to the extent stockholder approval is necessary to satisfy the requirements of applicable laws.

(b) STOCKHOLDER APPROVAL. The Board, in its sole discretion, may submit any other amendment to the Plan for stockholder approval.

(c) NO IMPAIRMENT OF RIGHTS. Rights under any Option granted before amendment of the Plan shall not be impaired by any amendment of the Plan unless (i) the Company requests the consent of the Optionholder and (ii) the Optionholder consents in writing.

(d) AMENDMENT OF OPTIONS. The Board, at any time, and from time to time, may amend the terms of any one or more Options; provided, however, that the rights under any Option shall not be impaired by any such amendment unless (i) the Company requests the consent of the Optionholder and (ii) the Optionholder consents in writing.

13. TERMINATION OR SUSPENSION OF THE PLAN.

(a) PLAN TERM. The Board may suspend or terminate the Plan at any time. No Options may be granted under the Plan while the Plan is suspended or after it is terminated.

(b) NO IMPAIRMENT OF RIGHTS. Suspension or termination of the Plan shall not impair rights and obligations under any Option granted while the Plan is in effect except with the written consent of the Optionholder.

14. EFFECTIVE DATE OF PLAN.

The Plan shall become effective on the IPO Date, but no Option shall be exercised unless and until the Plan has been approved by the stockholders of the Company.

15. CHOICE OF LAW.

The law of the state of Delaware shall govern all questions concerning the construction, validity and interpretation of this Plan, without regard to such state's conflict of laws rules.

GTX, INC.
2004 NON-EMPLOYEE DIRECTORS' STOCK OPTION PLAN

STOCK OPTION AGREEMENT
(NONSTATUTORY STOCK OPTION)

Pursuant to your Stock Option Grant Notice ("GRANT NOTICE") and this Stock Option Agreement, GTx, Inc. (the "COMPANY") has granted you an option under its 2004 Non-Employee Directors' Stock Option Plan (the "PLAN") to purchase the number of shares of the Company's Common Stock indicated in your Grant Notice at the exercise price indicated in your Grant Notice. Defined terms not explicitly defined in this Stock Option Agreement but defined in the Plan shall have the same definitions as in the Plan.

The details of your option are as follows:

1. VESTING. Subject to the limitations contained herein, your option will vest as provided in your Grant Notice, provided that vesting will cease upon the termination of your Continuous Service (and, for an option granted for service on a committee of the Board, vesting will cease when you cease to be a member of such committee) and that your vesting may be accelerated as provided in the Plan.

2. NUMBER OF SHARES AND EXERCISE PRICE. The number of shares of Common Stock subject to your option and your exercise price per share referenced in your Grant Notice may be adjusted from time to time for Capitalization Adjustments.

3. EXERCISE PRIOR TO VESTING ("EARLY EXERCISE"). If permitted in your Grant Notice (i.e., the "Exercise Schedule" indicates that "Early Exercise" of your option is permitted) and subject to the provisions of your option, you may elect at any time that is both (i) during the period of your Continuous Service and (ii) during the term of your option, to exercise all or part of your option, including the nonvested portion of your option; provided, however, that:

(a) a partial exercise of your option shall be deemed to cover first vested shares of Common Stock and then the earliest vesting installment of unvested shares of Common Stock;

(b) any shares of Common Stock so purchased from installments that have not vested as of the date of exercise shall be subject to the purchase option in favor of the Company as described in the Company's form of Early Exercise Stock Purchase Agreement; and

(c) you shall enter into the Company's form of Early Exercise Stock Purchase Agreement with a vesting schedule that will result in the same vesting as if no early exercise had occurred.

4. METHOD OF PAYMENT. Payment of the exercise price is due in full upon exercise of all or any part of your option. You may elect to make payment of the exercise price

in cash or by check or in any other manner PERMITTED BY YOUR GRANT NOTICE, which may include one or more of the following:

(a) In the Company's sole discretion at the time your option is exercised and provided that at the time of exercise the Common Stock is publicly traded and quoted regularly in The Wall Street Journal, pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board that, prior to the issuance of Common Stock, results in either the receipt of cash (or check) by the Company or the receipt of irrevocable instructions to pay the aggregate exercise price to the Company from the sales proceeds.

(b) Provided that at the time of exercise the Common Stock is publicly traded and quoted regularly in The Wall Street Journal, by delivery of already-owned shares of Common Stock either that you have held for the period required to avoid a charge to the Company's reported earnings (generally six (6) months) or that you did not acquire, directly or indirectly from the Company, that are owned free and clear of any liens, claims, encumbrances or security interests, and that are valued at Fair Market Value on the date of exercise. "Delivery" for these purposes, in the sole discretion of the Company at the time you exercise your option, shall include delivery to the Company of your attestation of ownership of such shares of Common Stock in a form approved by the Company. Notwithstanding the foregoing, you may not exercise your option by tender to the Company of Common Stock to the extent such tender would violate the provisions of any law, regulation or agreement restricting the redemption of the Company's stock.

5. WHOLE SHARES. You may exercise your option only for whole shares of Common Stock.

6. SECURITIES LAW COMPLIANCE. Notwithstanding anything to the contrary contained herein, you may not exercise your option unless the shares of Common Stock issuable upon such exercise are then registered under the Securities Act or, if such shares of Common Stock are not then so registered, the Company has determined that such exercise and issuance would be exempt from the registration requirements of the Securities Act. The exercise of your option also must comply with other applicable laws and regulations governing your option, and you may not exercise your option if the Company determines that such exercise would not be in material compliance with such laws and regulations.

7. TERM. You may not exercise your option before the commencement or after the expiration of its term. The term of your option commences on the Date of Grant and expires upon the earliest of the following:

(a) three (3) months after the termination of your Continuous Service for any reason other than your Disability or death, provided that if during any part of such three (3) month period your option is not exercisable solely because of the condition set forth in Section 6, your option shall not expire until the earlier of the Expiration Date or until it shall have been exercisable for an aggregate period of three (3) months after the termination of your Continuous Service;

(b) twelve (12) months after the termination of your Continuous Service due to your Disability;

(c) eighteen (18) months after your death if you die either during your Continuous Service or within three (3) months after your Continuous Service terminates;

(d) the Expiration Date indicated in your Grant Notice; or

(e) the day before the tenth (10th) anniversary of the Date of Grant.

8. EXERCISE.

(a) You may exercise the vested portion of your option (and the unvested portion of your option if your Grant Notice so permits) during its term by delivering a Notice of Exercise (in a form designated by the Company) together with the exercise price to the Secretary of the Company, or to such other person as the Company may designate, during regular business hours, together with such additional documents as the Company may then require.

(b) By exercising your option you agree that, as a condition to any exercise of your option, the Company may require you to enter into an arrangement providing for the payment by you to the Company of any tax withholding obligation of the Company arising by reason of (1) the exercise of your option, (2) the lapse of any substantial risk of forfeiture to which the shares of Common Stock are subject at the time of exercise, or (3) the disposition of shares of Common Stock acquired upon such exercise.

9. TRANSFERABILITY. Except as otherwise provided in this Section, your option is not transferable other than by will or the laws of descent and distribution, and your option may be exercised only by you during your lifetime. However, you may, with the approval of the Board, transfer your option for no consideration to (i) any person or entity, if, at the time of such transfer, a Form S-8 registration statement under the Securities Act is available for the issuance by the Company of the shares upon exercise of the transferred option or (ii) your employer at the time of the transfer or an affiliate of your employer at the time of the transfer. Any such transfer is subject to such limits as the Board may establish, and subject to the transferee agreeing to remain subject to all the terms and conditions applicable to your option prior to such transfer. The forgoing right to transfer your option shall apply to the right to consent to amendments to this Stock Option Agreement. Notwithstanding the foregoing, until you transfer your option, you may designate a third party who, in the event of your death, shall thereafter be entitled to exercise your option by delivering written notice to the Company, in a form satisfactory to the Company.

10. OPTION NOT A SERVICE CONTRACT. Your option is not an employment or service contract, and nothing in your option shall be deemed to create in any way whatsoever any obligation on your part to continue in the employ of the Company or an Affiliate, or of the Company or an Affiliate to continue your employment. In addition, nothing in your option shall obligate the Company or an Affiliate, their respective stockholders, Boards of Directors, Officers or Employees to continue any relationship that you might have as a Director or Consultant for the Company or an Affiliate.

11. WITHHOLDING OBLIGATIONS.

(a) At the time you exercise your option, in whole or in part, or at any time thereafter as requested by the Company, you hereby authorize withholding from payroll and any other amounts payable to you, and otherwise agree to make adequate provision for (including by means of a "cashless exercise" pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board to the extent permitted by the Company), any sums required to satisfy the federal, state, local and foreign tax withholding obligations of the Company or an Affiliate, if any, which arise in connection with the exercise of your option.

(b) Upon your request and subject to approval by the Company, in its sole discretion, and compliance with any applicable legal conditions or restrictions, the Company may withhold from fully vested shares of Common Stock otherwise issuable to you upon the exercise of your option a number of whole shares of Common Stock having a Fair Market Value, determined by the Company as of the date of exercise, not in excess of the minimum amount of tax required to be withheld by law (or such lower amount as may be necessary to avoid variable award accounting). If the date of determination of any tax withholding obligation is deferred to a date later than the date of exercise of your option, share withholding pursuant to the preceding sentence shall not be permitted unless you make a proper and timely election under Section 83(b) of the Code, covering the aggregate number of shares of Common Stock acquired upon such exercise with respect to which such determination is otherwise deferred, to accelerate the determination of such tax withholding obligation to the date of exercise of your option. Notwithstanding the filing of such election, shares of Common Stock shall be withheld solely from fully vested shares of Common Stock determined as of the date of exercise of your option that are otherwise issuable to you upon such exercise. Any adverse consequences to you arising in connection with such share withholding procedure shall be your sole responsibility.

(c) You may not exercise your option unless the tax withholding obligations of the Company and/or any Affiliate are satisfied. Accordingly, you may not be able to exercise your option when desired even though your option is vested, and the Company shall have no obligation to issue a certificate for such shares of Common Stock or release such shares of Common Stock from any escrow provided for herein unless such obligations are satisfied.

12. NOTICES. Any notices provided for in your option or the Plan shall be given in writing and shall be deemed effectively given upon receipt or, in the case of notices delivered by mail by the Company to you, five (5) days after deposit in the United States mail, postage prepaid, addressed to you at the last address you provided to the Company.

13. GOVERNING PLAN DOCUMENT. Your option is subject to all the provisions of the Plan, the provisions of which are hereby made a part of your option, and is further subject to all interpretations, amendments, rules and regulations, which may from time to time be promulgated and adopted pursuant to the Plan. In the event of any conflict between the provisions of your option and those of the Plan, the provisions of the Plan shall control.

[*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 406 OF THE SECURITIES ACT OF 1933, AS AMENDED.

EXHIBIT 10.17

PRODUCTION AND MANUFACTURING AGREEMENT

This Production and Manufacturing Agreement (the "Agreement") is made and entered into this 9th day of September 2002 (the "Effective Date") by and between (i) ChemSyn Laboratories, a department of Eagle-Picher Technologies, LLC, with its principal place of business at 13605 W. 96th Terrace, Lenexa, Kansas 66215-1297 ("CSL "), and (ii) GTx, Inc., a Tennessee corporation with its principal place of business at 3 North Dunlap Street, 3rd Floor, Memphis, Tennessee 38163 ("GTx"), who, intending to be legally bound, hereby agree as follows:

WHEREAS, GTx has developed and owns the entire right, title and interest in and to [*] and [*] and pharmaceutical compositions comprising [*], [*] and other related pharmaceutical compositions (collectively the "Product") and desires to produce and manufacture the Product for preclinical studies and clinical trials and, if later approved by the requisite governmental authorities, for commercial sale;

WHEREAS, CSL is currently working with GTx under a contract dated March 9, 2001 (the "2001 Contract") to produce small quantities of [*] (the "[*] Product") (previously estimated to be [*] per batch) to develop a manufacturing process for the [*] Product and to manufacture the [*] Product for clinical and preclinical studies;

WHEREAS, CSL and GTx desire to enter into this Agreement to replace the 2001 Contract and to form the framework for additional work to be performed by CSL for GTx from time to time.

NOW, THEREFORE, for and in consideration of the terms and provisions set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, CSL and GTx agree as follows:

1. SERVICE

1.1 THE SERVICE. Schedule 1 sets forth a description and price for additional Services to be performed by CSL in accordance with the terms hereof. Any future Services pertaining to [*], [*] or other related compounds shall be performed by CSL under the terms of this Agreement by CSL and GTx executing an Addendum hereto identifying the additional Service to be performed, the price, time period, and other terms specific to the particular Service. Upon execution of the Addendum by the parties, the Addendum shall be considered an additional Schedule to his Agreement and a part hereof.

1.2 THE PROCESS. Operating under the 2001 Contract, CSL has synthesized [*] of material through [*] of a [*] process to manufacture the [*] Product. Current batch records documenting the manufacturing process ("Batch Records") through [*] for the manufacture of

[*] Product have been prepared by CSL and reviewed by GTx. CSL has used portions of this material to synthesize [*], under cGMP conditions, and to synthesize [*]. The remainder of the material will be stored by CSL and utilized in accordance with the agreement of GTX and CSL. Any additional Product to be manufactured in the future by CSL will be manufactured under cGMP or non-cGMP conditions, as specified in an Addendum to this Agreement.

CSL agrees that it will utilize the best available current technology known to it to synthesize [*], [*] and other compounds the parties may hereinafter agree upon, utilizing the most current Batch Records then available for a particular process. CSL also agrees that it will consult with GTx at all reasonable times during the manufacturing process to ensure that the desired Product is being manufactured in accordance with the current specifications then approved for the Product by the parties. For any Product being manufactured by CSL in accordance with then applicable Batch Records, GTx shall have the right to approve the master Batch Records for such Product, any planned deviations from the Batch Records (and GTx should be consulted as soon as possible regarding any emergency deviation from the Batch Records), as well as the final Batch records for the Product.

1.3 RECORD MAINTENANCE; BATCH RECORDS. For the term specified, CSL shall retain, by company Standard Operating Procedures (SOP), files, records, manufacturing logs, forms, laboratory data books and notebooks for any and all data, process information and results, for each of the Services performed under this Agreement; copies of all such records which are reasonably requested by GTx in writing shall be provided by ChemSyn's Standard Operating Procedures at GTx's expense. CSL will develop, document, and maintain current Batch Records for each step of the production process for each desired cGMP Product produced as a part of the Services hereunder, in accordance with good manufacturing practices and procedures and applicable FDA and other governmental agency requirements. CSL agrees to provide GTx with a copy of all Batch Records along with CSL's quality assurance review statement. CSL also shall provide GTx, at GTx's expense, with all information GTx may reasonably request in order to obtain or comply with any necessary regulatory approvals, permits, licenses, clearances and notifications for manufacture, shipment, sale or use of the Product. All CSL records pertaining to any GTx Product shall be maintained by CSL in accordance with applicable regulations.

1.4 TESTING. CSL will perform in-process testing for quality, quantity and yield in accordance with its planned manufacturing process for the production of each Product it is producing for GTx, including [*] and [*], and all such in-process testing for Product manufactured under cGMP conditions shall be done in accordance with then applicable regulations. Solvents and reagents used in the manufacturing process will require only an identification test by CSL and an accompanying Certification of Analysis. All test results of the Product will be shared with GTx. No other tests by CSL are contemplated under this Agreement, and any additional testing by CSL will be done only with both parties prior written approval at an agreed upon price.

1.5 TIMING. The Services to be performed hereunder are expected to take approximately the time period set forth in Schedule 1 hereof for each such Service. In the event a particular Service will exceed the estimated time period, CSL will consult with GTx to determine the appropriate additional time necessary to complete the Service. If additional manufacturing or process development time is required by CSL to complete the Service, no additional fee shall be

payable to CSL for additional work unless this Agreement shall be amended in writing by both parties.

1.6 INFORMATION. CSL will provide GTx with verbal weekly updates on the progress it is making under this Agreement, and written project updates monthly if requested by GTx. CSL also will provide to GTx copies of all test results, laboratory records, Batch Records, and other information pertaining to the Services it is performing for GTx under this Agreement.

1.7 INSPECTIONS. GTx or its designated agent may inspect CSL's production and testing facilities at Lenexa, Kansas, examine samples of the material and/or Product, as the case may be, review the records under Section 1.3 and review any other records applicable to any GTX Product including all test results, equipment, maintenance and calibration records, raw material and finished product storage area records, shipping records and all applicable SOP's developed and utilized by CSL for its development, manufacturing and/or testing processes and procedures. The inspections are limited to two (2) days per calendar year. If GTx requests additional time, then CSL shall be compensated by an amount to be agreed upon in a mutually agreed upon Addendum.

1.8 GOVERNMENT COMMUNICATION. CSL will promptly provide to GTx copies of all documents in its possession concerning communications to or from the FDA or prepared by the FDA, or to or from or prepared by any other governmental agency, which bear in any respect on compliance by CSL with FDA and other relevant governmental agency requirements pertaining to the development or manufacture of any Product under this Agreement.

2. PAYMENT AND DELIVERY

2.1 AMOUNT. The Project Fee for this Service is outlined in the workscope found in Schedule 1. The fees for subsequent projects shall be determined by GTx and CSL on a project by project basis, and will be attached to this Agreement an Addendum hereto. Applicable state sales taxes will be assessed on all shipments and/or services unless proof of exemption for the destination state(s) can be provided.

2.2 STORAGE FEE. Finished product (Active Pharmaceutical Ingredient) stored by CSL for GTx for [*] will be subject to a storage fee. The [*] storage fee for the stored finished product will be the [*]: (i) an amount equal to [*] of the contract pertaining to the stored finished product, or (ii) [*] per lot. For purposes hereof, a "lot" shall mean for each Service, the amount of finished product to be manufactured by CSL for GTx as specified for the Service. The storage fee will activate [*] after the completion of the project. In the event any finished product, which is being stored by CSL, is specified in writing by the Parties for use as an ingredient in another Product, the storage fee for such finished product shall be waived.

2.3 FIXED FEE PAYMENT. Upon execution of this Agreement, GTx will pay as an Initial Deposit [*] of the aggregate Project Fee for the initial project. GTx will pay to CSL [*] of the agreed upon amount for each additional Service upon execution of the Addendum adding each Service to this Agreement. Another [*] of the Project Fee for each such Service will be considered earned by CSL and due and payable to it upon completion of each such Service. Completion of Service will be defined as when CSL has Product packaged, batch records

reviewed and the Product is ready for shipment or is waiting for independent laboratory results to complete the certificate of analysis. A final payment of [*] of the Project Fee for each Service shall be due and payable to CSL upon CSL's completion of the Service and delivery of copies of any applicable Batch Records to GTx in accordance with this Agreement. All payments are to be made by GTx within [*] of CSL's issuance of its invoice.

2.4 TIME AND MATERIAL PAYMENT. If CSL is to perform services based on a Time and Material fee schedule, GTx will pay an Initial Deposit of [*] of each additional Service which is based on a Time and Material Addendum executed by both parties. GTx shall reimburse CSL for all related project costs including direct labor at specified hourly rates, direct material, direct suppliers and waste disposal, as well as all other reasonable out-of pocket costs incurred by CSL with unaffiliated third parties in the performance of each such additional Service thirty days after issuance by CSL of an itemized invoice of such costs. Upon completion of work covered by the Initial Deposit, CSL will commence monthly invoicing for the balance of the work preformed under the Time and Materials Addendum. CSL will invoice every thirty days for work completed during that period. All payments are to be made by GTx within [*] of CSL's issuance of its invoice.

2.5 DELIVERY. Unless otherwise stated in this Agreement, all goods are sold F.C.A. shipping point.

3. CHANGES AND DESIGNATED REPRESENTATIVES

3.1 CHANGE ORDERS. Any changes or modifications to this Agreement requiring the payment by GTx of additional fees or costs shall require the prior written approval of GTx. Any modification to the Project Fee on account of a change order will be paid in accordance with Section 2.3 or 2.4, whichever is applicable.

3.2 DESIGNATED REPRESENTATIVE. Any material change in the Services to be provided by CSL shall be confirmed in writing by the parties' authorized representative(s) designated to be anyone of the following persons:

	GTX
NAME	TITLE:
Marc Hanover	President, COO
Mark Mosteller	CFO
Karen Veverka	Director, ARTA Program
	CSL
Dr. Bill Griggs	Regional Accounts Manager
Scott B. Parker	Sales and Marketing Manager

4. INTELLECTUAL PROPERTY

4.1 CSL will acquire no rights of any kind with respect to the material or ingredients for any Product or any of the finished Product. GTx shall own the entire right, title and interest in and to the material, ingredients and the Products.

4.2 CSL will not sell or use the material, ingredients or Products for any purpose other than as provided herein without first receiving prior or written approval from GTx.

4.3 All intellectual property, information, discoveries, formulation, compounds, compositions, processes, Batch Records, test results, formulae, specifications, methods, techniques, or improvements, whether or not patentable ("Service Inventions") arising from the performance of the Services shall promptly be made known to GTx in writing, and GTx shall have sole and exclusive rights to all such Service Inventions, which shall be the sole property of GTx. CSL shall assign and will assign Service Inventions to GTx, at no cost to GTx, and execute any and all documents and do any and all things reasonably requested by GTx to vest and perfect GTx's interest in the Service Inventions. CSL further agrees to provide reasonable assistance to GTx, at GTx's expense, in making application for, obtaining, and from time to time, enforcing and defending GTx rights that may be required resulting from the Services performed, or to be performed, hereunder.

4.4 CSL shall not use the name of GTx in any advertising or sales promotional material or in any other way without the prior written consent of GTx, except where required to do so in compliance with an official government or government agency request for information.

5. PROPRIETARY INFORMATION

5.1 "Proprietary Information" shall include, but shall not be limited to, information pertaining to compounds, formulations, products, data, know-how, business strategy, ideas, and concepts and shall be (i) written or documentary technical and business information of any kind relating to the subject matter hereof and identified by the disclosing Party with a conspicuous legend appearing on such written or documentary information that it contain proprietary information of the disclosing Party; (ii) orally or visually disclosed technical and business information relating to the subject, matter hereof which is identified at the time of disclosure as confidential and which GTx or CSL reduces to writing, with the proprietary information specifically identified, bearing the legend described in subsection (i) above and delivers such writing to the receiving Party no later than thirty (30) days after such oral or visual disclosure; and (iii) models, tools or other hardware disclosed and identified and confirmed in writing, as described in subsection (ii) above.

5.2 CSL acknowledges and agrees that GTx will be disclosing Proprietary Information to CSL, (the "GTx Proprietary Information"). CSL agrees that it shall hold the GTx Proprietary Information in strict confidence, shall not disclose it to others or use it in any way, commercially or otherwise, except for purposes of performing its obligations under this Agreement. CSL further agrees to take all action necessary to protect the confidentiality of GTx including, without limitation, (a) implementing and enforcing operating procedures to minimize

the possibility of unauthorized use or copying of GTx Proprietary Information, and (b) obligating each of its subcontractors, by written agreement, to protect GTx's Proprietary Information.

5.3 GTx acknowledges and agrees that CSL will be disclosing Proprietary Information to GTX, (the "CSL Proprietary Information"). GTx agrees that it shall hold the CSL Proprietary Information in strict confidence, shall not disclose it to others or use it in any way, commercially or otherwise, except for purposes of performing its obligations under this Agreement. GTx further agrees to take all action necessary to protect the confidentiality of CSL including, without limitation, (a) implementing and enforcing operating procedures to minimize the possibility of unauthorized use or copying of CSL Proprietary Information, and (b) obligating each of its subcontractors, by written agreement, to protect CSL's Proprietary Information.

5.4 CSL shall not disclose, without the prior written consent of GTx, any GTx Proprietary Information, and any files, documents, records, data, results, experiments, formulations, manufacturing logs, specifications, compounds, compositions, and Batch Records arising from the Services to any third party without the prior written consent of GTx, except to the Food and Drug Administration upon inspection. If, during an inspection of CSL by the Food and Drug Administration (FDA), any work owned by GTx is examined, GTx must be notified in writing of the extent and nature of the review. GTx will be notified verbally when an FDA inspection of CSL is scheduled which might include a review of GTx intellectual property. Directed FDA inspections for GTx's Products are not included in the scope of work and pricing in the current Agreement. A separate addendum will be necessary for FDA inspections, should inspections be required. Any correspondence with the FDA outside the scope of an inspection where CSL discloses GTx Proprietary Information requires written approval by GTx.

5.5 All obligations of confidentiality and non-disclosure set forth herein will survive, without limitation, the expiration, or early termination, for any reason of this Agreement.

6. TERMINATION

6.1 TERM. The term of this Agreement shall commence upon the Effective Date hereof and shall remain in effect until the completion of each of the Services unless otherwise terminated in accordance with this Section.

6.2 TERMINATION BY GTX. In the event that GTx demonstrates that: 1) the material or any Product is not safe or is toxic in animal or human experiments; and/or 2) the process work indicates that GTx's proposed Product is not feasible, GTx shall promptly inform CSL of such determination and GTx may immediately and unilaterally terminate the particular Service being provided by CSL pursuant to this Agreement.

6.3 RENEWAL. This general terms of this Agreement will remain in effect for a term of five years, after which, both Parties can agree to renew or modify this Agreement.

6.4 TERMINATION FOR BREACH. This Agreement may be terminated by either party in the event that the other party has not performed any material obligation or has otherwise breached any material term of this Agreement upon the expiration of [*] (or any longer cure period authorized by the non-breaching party with respect to any individual breach) after receipt

of written notice thereof if the breach or nonperformance is capable of cure and has not then been cured.

6.5 EFFECT OF TERMINATION. Upon termination of any Service or termination of this Agreement, CSL shall immediately return to GTx at GTx's expense, all or any part of the material and any Product made as of the date of such Termination. CSL shall be entitled to reimbursement for all direct and indirect costs incurred or irrevocably obligated as of the date of such termination. In addition, CSL shall be entitled to [*] of the remaining amount of the contract price pertaining to any terminated Service which is unpaid at the time of termination, as set forth in Schedule 1 and each Addendum defining the then current Services. If the amount that GTx has previously paid to CSL exceeds the amount that is actually owed to it, CSL shall reimburse the balance to GTx within thirty (30) days of receipt of notice of termination. All materials provided by GTx unused at the effective date of termination shall be returned to GTx unless otherwise agreed to in writing.

7. NOTICE

7.1 All notices shall be in writing and shall be deemed to be delivered two (2) days after being deposited with a recognized international express courier service, or when sent by facsimile transmission promptly confirmed by return transmission. All notices shall be directed to CSL or GTx at the respective addresses first set forth above or to such other address as either party may, from time to time, designate by notice to the other party.

8. REGULATORY MATTERS

8.1 APPROVALS. CSL shall obtain all regulatory approvals, permits, licenses, clearances and notifications which it is required to have for the manufacture, shipment, sale or use of any product prior to any such manufacture, sale or use or shall ensure that such required approvals, permits, licenses, clearances and notifications are otherwise obtained. CSL shall provide GTx with all information that it may reasonably request in order to obtain or comply with any necessary regulatory approvals, permits, licenses, clearances and notifications for manufacture, shipment, sale or use of any product.

9. GENERAL PROVISIONS

9.1 WARRANTY. CSL warrants that it has the right to enter into the Agreement including these terms and conditions; that the execution of the Agreement and the terms and conditions and the performance by CSL of its obligations hereunder will not result in any breach or violation or default under any other agreement; that the execution, delivery and performance of the Agreement and the terms and conditions have been duly authorized; and that the Agreement and the terms and conditions constitute an agreement that is the legal, valid and binding obligation of CSL, enforceable against it in accordance with its terms.

CSL warrants that it has the appropriate registrations, licenses and any other governmental authorizations to carry out its obligations under the Agreement and the terms and conditions.

CSL warrants that it will perform all services and work under the Agreement and the terms and conditions in accordance with the Regulatory Requirements specified herein, and that it shall follow in all respects the terms and provisions of, and shall at all times meet the standards of quality specified in the Agreement and the terms and conditions.

9.3 DISCLAIMER. CSL HEREBY MAKES NO OTHER WARRANTIES UNDER THIS AGREEMENT, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTY; OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

9.4 If, as a result of CSL's negligence any of the materials and/or Products manufactured by CSL for GTx does not conform to the applicable specifications, GTx shall give CSL written notice of the nonconformity. CSL shall promptly rework or replace the nonconforming shipment, without charge, with a like amount that satisfies the applicable specifications within a period of time to be mutually agreed to by both parties. In the event that CSL is unable to produce a replacement amount of materials and/or Products that satisfies the applicable specifications within a reasonable time after receipt of the notice of nonconformity, GTx shall have no obligation to CSL for payment for the nonconforming shipment, and if payment has already been made, GTx shall be entitled to an immediate refund of the price of the nonconforming material and/or Product.

9.5 CERTIFICATION OF ANALYSIS. Promptly on the date of each CSL shipment of any Product actually delivered to GTx or GTx designee and promptly on the date of each CSL shipment of Product, CSL shall furnish GTx with a certificate of analysis, in the form specified by GTx and signed by a CSL representative reasonably acceptable to GTx, which certifies the actual content of those components of the Product, which are identified in the applicable specifications. Notwithstanding the foregoing, GTx shall have the right to designate an independent laboratory to provide the certificate of analysis, in which case it shall so notify CSL in writing. No shipment of Product (except to the independent lab designated by GTx and except for developmental batches of Product provided to GTx or its designee) shall be made by CSL until it shall have received the appropriate certificate of analysis from the independent laboratory.

9.6 STOP WORK ORDERS. Stop work orders may be issued in writing by GTx for any Service under this Agreement for an effective period [*] but only if received in writing by CSL. GTx's stop work orders [*] shall constitute a termination and be subject to the terms set forth in Section 6.2 unless extensions of the [*] stop work period are agreed to in writing by CSL. GTx will be responsible for reasonable costs that were incurred due to stoppage of the Service prior to completion. CSL will provide a detailed written list of such costs to which both parties must agree.

9.7 LICENSES AND PERMITS (INTER-AND INTRASTATE SHIPMENTS). Persons intending to use any goods involving humans in clinical investigations must obtain an approved status for such use from the U.S. Food and Drug Administration. The responsibility to obtain appropriate

permits/licenses is that of GTx. Proof of permit/license may be requested at the discretion of the CSL.

9.8 SEVERABILITY. If any provision of this Agreement shall be held to be invalid, illegal or unenforceable for any reason, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby.

9.9 RELATIONSHIP OF THE PARTIES. For purposes of this Agreement, CSL and GTx will be and shall act as independent contractors, and neither party is authorized to act as an agent or partner of, or joint venturer with, the other party for any purpose. Neither party by virtue of this Agreement shall have any right, power, or authority to act or create any obligation, express or implied, on behalf of the other party.

9.10 FORCE MAJEURE. Neither party shall be liable for any damages or penalty for any delay in performance of, or failure to perform, any obligation hereunder or for failure to give the other party prior notice thereof when such delay or failure is due to the elements, acts of God, delays in transportation, strikes or labor disputes, delays in delivery by vendors or other causes beyond that party's reasonable control.

9.11 NO WAIVERS. No express or implied waiver by either party of any event of default hereunder shall in any way be or be construed as a waiver of any future or subsequent event of default.

9.12 SURVIVAL. The respective rights and obligations of the parties under Article 4, 5 and 8 shall survive the termination of this Agreement.

9.13 ENTIRE AGREEMENT. The parties acknowledge that this Agreement sets forth the complete, exclusive and integrated understanding of the parties which supersedes all proposals or prior agreements, oral or written, and all other prior communications between the parties relating to the subject matter of this Agreement.

9.14 ASSIGNMENT. Neither this Agreement nor any rights granted hereby may be assigned by CSL without GTx's prior written consent. Any assignment of this Agreement by GTx shall require that it notify CSL in writing of any assignment.

9.15 GOVERNING LAW. This Agreement, and any and all tort claims that may arise in connection with any product and any related services, will be governed by the substantive laws of the State of Missouri.

9.16 INDEMNIFICATION/LIMITATION OF LIABILITY. Seller's liability for damages whether based on seller's negligence, breach of contract, warranty or otherwise, shall not exceed [*]. Seller shall not indemnify buyer or otherwise be liable in contract or in tort for special, indirect, incidental, or consequential damages such as, but not limited to, loss of profits or revenue. Buyer assumes all risk and liability resulting from use of the products delivered hereunder whether used singly or in combination with other products.

9.17 Contract for Commercial Supplies. The parties acknowledge that this Agreement is for the manufacture and production of developmental material and services. If the manufacture

of commercial quantities of product is required, the parties will negotiate in good faith a commercial manufacturing agreement.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed this 9th day of September, 2002.

CHEMSYN LABORATORIES A DEPARTMENT OF EAGLE-PICHER LABORATORIES, LLC	GTX, INC.
By: /s/ Bradley J. Waters	By: /s/ Henry P. Doggrell
Title: CFO, Eagle Picher Tech, LLC	Title: General Counsel
Date: 9-6-02	Date: Sept. 9, 2002

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SCHEDULE 1
PROJECT WORKSCOPE

RE: Please refer to CSL Inquiry No. 807836c

ChemSyn Laboratories (CSL) is pleased to submit this Project Workscope in response to your recent request.

I. Proposed Scope of Work:

Utilizing the current technology available, begin a synthesis of a variety of compounds and intermediates. [*] of the synthesis will begin with [*] of [*] to prepare intermediate [*]. All of the product will be carried forward to [*] to prepare intermediate [*]. Again, all of the product will be carried forward to [*] to prepare intermediate [*].

At this point the product will be [*]. [*] will be delivered to GTx Inc. ([*]). The [*] ([*]) will be converted to the [*] of [*] ([*]). The [*] ([*]) will be used to synthesize the [*] ([*]). Synthesis of the [*] compound ([*]) requires process development. [*] is assumed to be similar to [*] in terms of time and materials. GTx Inc. will be contacted to verify the quantity of [*] compound for each of the [*] parts. Note, [*] of [*] product yields approximately [*] of final product.

Phase I Process Development Costs

Perform two lab experiments [*]. These experiments allow the chemist to gain an understanding of the chemistry before the large batch is committed to the procedure. The first experiment will duplicate the best technology to date and identify any scale up issues with the small scale experimental procedure. The issues that are identified in the first experiment will cause changes to be tried in the second experiment before performing the large scale work.

Budget [*], [*]
Timing [*]

Phase II [*]
[*]

- Perform [*] of synthetic scheme starting from [*] of [*].
- The yield is expected to be approximately [*] of the [*].

Budget Synthesis	[*],	$[*]
Project Management [*],		$[*]
	Total	$[*]

Timing [*]

[*] ([*] intermediate, yield approx. [*])

Budget Synthesis	[*],	$[*]
In-Process HPLC, [*]		$[*]
Project Management [*],		$[*]
	Total	$[*]

Timing [*] after completion of any development work required.

[*] ([*], yield approx. [*])
Assumption is that the technology for [*] will work for this [*].

Budget Synthesis [*],		$[*]
In-Process HPLC, [*]		$[*]
Project Management [*],		$[*]
	Total	$[*]

Timing [*] after completion of any development work required.

II. Project Costs and Billing

Process Development [*]		$[*]
Synthesis [*]		$[*]
Perform [*]		$[*]
Perform [*]		$[*]
	Labor Total	$[*]
Materials Estimate (cost [*] fee)		$[*]
	Total	$[*]

GTx shall reimburse CSL for all related project costs (estimated above) including direct labor, direct material, direct suppliers and waste disposal, as well as all other reasonable out-of pocket costs incurred by CSL with unaffiliated third parties in the performance of the project thirty days after issuance by CSL of an itemized invoice of such costs. CSL will invoice every thirty days for work completed during that period. WE ASK THAT GTX REMIT TO CSL THE [*] OF CONTRACT AMOUNT ([*]) AT THE COMMENCEMENT OF THE PROJECT.

A formal costs accounting system is maintained that is approved by or capable of being approved by Deloitte and Touche, our independent auditors; as well as the U.S. Government. CSL represents and certifies that it will maintain all fiscal records for three years from the date of final payment and all costs will be allocated to this project in accordance with CSL's disclosed accounting practices. Costs outlined above do not include any applicable taxes. Applicable state sales taxes will be assessed on all shipments and/or services unless proof of exemption for the destination state(s) can be provided.

III. Period of Performance

Process Development [*]	[*]
Synthesis [*]	[*]
Synthesis of [*]	[*]
Synthesis of [*]	[*]

*- from the completion of any process development work required and from the completion of Synthesis [*]

IV. Authorization

The project described above may be authorized by returning to CSL a signed copy of our proposal and your purchase order. This proposal remains effective until Oct 05, 2002. Please reference Inquiry Number 807836c in all correspondence.

We appreciate your consideration of CSL to support your research endeavors. If you have questions or require additional information please contact me at (800) 233-6643. Thank you.

Sincerely,

/s/ Scott B. Parker

Scott B. Parker
Sales and Marketing Manager

Approved by GTx:

/s/ Karen Veverka

Karen Veverka, Ph.D.
Director ARTA Research
Date Sept. 09,2002

September 19, 2002

GTx, Inc. ("GTx") and ChemSyn Laboratories ("ChemSyn") herby agree to the following:

1. The attached Addendums 1 and 2 to Schedule 1 to the Production and Manufacturing Agreement dated September 9, 2002 (the "Contract"), describing additional Scope of Work to be undertaken by ChemSyn on behalf of GTx, is hereby approved by the Parties and shall become a part of the Contract.

2. Except as amended hereby, all other terms and provisions of the Contract shall remain in full force and effect.

IN WITNESS WHEREOF, the parties have caused their duly authorized representatives to execute this Agreement as of this 19th day of September, 2002.

GTx, Inc.	ChemSyn Laboratories
By: /s/ Henry P. Doggrell	By: /s/ Donald R. Leggett
Title: General Counsel	Title: Business Unit Leader

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Addendum 1

(CHEMSYN LABORATORIES LOGO)

Addendum 1

September 17, 2002

Dr. Karen Veverka
Director ARTA Research
GTx Inc.
3 North Dunlap
3rd Floor Van Vleet
Memphis, TN 38163

RE: Please refer to CSL Inquiry No. 807941a

Dear Karen:

ChemSyn Laboratories (CSL) is pleased to submit this proposal in response to your recent request.

I. Proposed Scope of Work:

[*] Synthesis ([*] Product)
- Perform [*] of synthetic scheme starting from [*] of [*].
- -The yield is expected to be approximately [*] of the [*].

II. Project Costs and Billing (Fixed Fee)

Budget Synthesis	[*],	$[*]
Project Management	[*],	$[*]
Materials (cost [*] fee)		$[*]
	Total	$[*]

WE ASK THAT GTX REMIT TO CSL THE [*] OF CONTRACT AMOUNT ($[*]) AT THE COMMENCEMENT OF THE PROJECT. Payment terms are specified in the Production and Manufacturing Agreement dated September 9, 2002

III. Deliverable

Approximately [*] of [*], [*] product

IV. Period of Performance

Synthesis [*] ([*] Product)	[*]

V. Authorization

The project described above may be authorized by returning to CSL a signed copy of our proposal and your purchase order. This proposal remains effective until October 15, 2002. Terms and conditions are attached. Please reference Inquiry Number 807941a in all correspondence.

We appreciate your consideration of CSL to support your research endeavors. If you have questions or require additional information please contact me at (800) 233-6643. Thank you.

Sincerely,

/s/ Scott B. Parker

Scott B. Parker
Sales and Marketing Manager

Approved by GTx:

/s/ Karen Veverka / M.S. Macbeth 9/18/02

Karen Veverka, Ph.D.
Director ARTA Research
Date 9/17/02

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(CHEMSYN LABORATORIES LOGO)

Addendum 2

September 17, 2002

Dr. Karen Veverka
Director ARTA Research
GTx Inc.

3 North Dunlap
3rd Floor Van Vleet
Memphis, TN 38163

RE: Please refer to CSL Inquiry No. 808033a

Dear Karen:

ChemSyn Laboratories (CSL) is pleased to submit this proposal in response to your recent request.

1. Proposed Scope of Work:

This work is an extension of the Development Batch - Inquiry No. 807836c

Currently, [*] of [*] intermediate [*] ([*]) was prepared and [*] shipped to GTx for development work.

This proposal consists of splitting the [*] into [*], synthesis of [*], synthesis of [*], an additional shipment to GTx Inc., and process development work for [*] This proposal does not include final release testing.

1) [*].

[*] of [*] will be used to synthesis [*]. The scope includes starting from [*] of [*] and performing [*] to synthesis [*] using the best technology available, non-GMP. [*] of [*] will be shipped to GTx Inc., the remainder will be used in [*]. [*] will be performed under GMP conditions to yield [*]. The targeted amount is [*] of [*]. [*] will require dedicated glassware, estimated to be [*].

2) [*].

[*] of [*] will be used to synthesize [*]. Starting with [*] of [*] should yield approx [*] of [*] ([*] product) non-GMP. The scope of Inquiry number 807836c included [*] ([*] intermediate, yield approx [*]). No additional cost is required for the larger scale in this proposal. [*] will be invoiced under Inquiry number 807836c. This current inquiry includes [*] performed under GMP conditions to yield [*]. The targeted amount is [*] of [*].

3) Shipment to GTx

[*] of [*] will be shipped to GTx [*].

4) The remainder [*] of [*] will be used during Inquiry number 807836c for [*] for lab scale development of [*].

II. Project Costs and Billing (Fixed Fee)

1) [*]

[*] ([*] intermediate, starting with [*] of [*])			
	Budget	Synthesis [*]	$[*]
	Project Management [*]		$[*]
[*] ([*] [*] GMP, yield target [*])			
	Budget	Synthesis [*]	$[*]
		In-Process HPLC, [*]	$[*]
		Project Management [*]	$[*]
Materials Estimate (cost [*] fee)			$[*]
Dedicated glassware			$[*]
		Total	$[*]

2) [*]

[*] ([*])		Included in Inquiry number 80 7836c	
[*] ([*] [*] GMP, yield target [*])			
	Budget	Synthesis [*]	$[*]
		In-Process HPLC, [*]	$[*]
		Project Management [*]	$[*]
Materials Estimate (cost [*] fee)			$[*]
		Total	$[*]

3) Shipment of Intermediate Included in Inquiry number 807836c

4) Phase I Process Development Costs Included in Inquiry number 807836c

GRAND TOTAL $[*]

WE ASK THAT GTX REMIT TO CSL THE [*] OF CONTRACT AMOUNT ($[*]) AT THE COMMENCEMENT OF THE PROJECT. Payment terms are specified in the Production and Manufacturing Agreement dated September 9, 2002. Applicable state sales taxes will be assessed on all shipments and/or services unless proof of exemption for the destination state(s) can be provided.

III. Deliverables

1) Approximately [*] of [*]
2) Approximately [*] of [*]
3) Shipment of [*] Included in Inquiry number 807836c
4) Process Development Report Included in Inquiry number 807836c

IV. Period of Performance

Synthesis of [*]	[*]
Synthesis of [*]	[*]
Synthesis of [*]	[*]

V. Authorization

The project described above may be authorized by returning to CSL a signed copy of our proposal and your purchase order. This proposal remains effective until Oct 15, 2002. Please reference Inquiry Number 808033a in all correspondence.

We appreciate your consideration of CSL to support your research endeavors. If you have questions or require additional information please contact me at (800) 233-6643. Thank you.

Sincerely,

/s/ Scott B. Parker

Scott B. Parker
Sales and Marketing Manager

Approved by GTx:

/s/ Karen Veverka / M.S. Macbeth 9/18/02

Karen Veverka, Ph.D.
Director ARTA Research
Date 9/17/02

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EXHIBIT 10.23

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AMENDMENT

This amendment made and executed this 29th day of December, 2003 (herein after referred to as the "Amendment") to the Amended and Restated License and Supply Agreement by and between Orion Corporation, Espoo, Finland ("Orion") and GTx, Inc., Memphis, Tennessee ("GTX") concerning Toremifene

WITNESSETH

WHEREAS, GTX is desirous of being granted certain negotiation rights concerning [*];

WHEREAS, Orion is willing to grant such rights to GTX in accordance with, and subject to, the terms and conditions herein after contained;

NOW THEREFORE, intending to be legally bound, and in consideration of the mutual covenants contained herein, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto agree as follows:

1. Section 2.1.5 shall be supplemented to include additional paragraphs to read as follows:

With respect to [*], GTX shall have the following rights:

Should Orion at any time during the term of [*], as the case may be [*] rights to commercialize [*] and should it contemplate granting such rights to a Third Party distributor/licensee, then GTX shall have a right to negotiate with Orion for the exclusive rights to market, sell and distribute [*] on the following basis:

No later than [*] after Orion having become in the possession of such above referred to unrestricted rights, Orion shall notify GTX thereof. Should GTX be interested in negotiating with Orion for the exclusive rights to market, sell and distribute [*], it shall notify Orion thereof in writing within [*] of having been so notified of Orion holding such rights. Upon such GTX notification the Parties shall negotiate in good faith for a period of [*] on a mutually acceptable definitive written agreement for such commercialization by GTX and during said period Orion shall not grant such rights to any Third Party. In the event the Parties fail within such [*] period of Orion's First Offer, or any separately agreed written extension of such period, to execute a mutually acceptable definitive agreement for such commercialization by GTX, then GTX's negotiation rights shall not extend to [*] and Orion shall thereafter be free to contract with any Third Party with respect to commercialization of [*].

For the avoidance of doubt, it is hereby acknowledged and agreed that the above referred to right of first negotiation shall in no way limit or restrict Orion's right to engage or retain a Third Party contract sales organization or similar entity to act on behalf of Orion or an Orion Affiliate for the

commercialization and/or distribution, or continued commercialization and/or distribution, as the case may be, of [*].

2. All other terms and conditions of the Agreement shall remain unchanged.

IN WITNESS WHEREOF, the Parties' duly authorized representatives hereto have executed this Amendment as of the date first above written.

Orion Corporation		GTx, Inc.	
By:	/s/ Risto Mieltvnen	By:	/s/ Henry P. Doggrell
Title:	President Orion Pharma	Title:	General Counsel/Secretary
By:	/s/ Timo Lappalainen		
Title:	Senior Vice President		

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Exhibit 23.1

Consent of Independent Auditors

We consent to the reference to our firm under the caption “Experts”, “Selected Financial Data”, and “Summary Financial Data” and to the use of our report dated May 9, 2003, except Note 1, as to which the date is December 1, 2003, and except Note 13, as to which the date is January 14, 2004 in Amendment No. 3 to the Registration Statement (Form S-1 No. 333-109700) and related Prospectus of GTx, Inc. for the registration of 5,400,000 shares of its common stock.

/s/ Ernst & Young LLP

Memphis, Tennessee
January 14, 2004