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UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

☑ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2005

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____to_____

Commission file number 000-50549

GTx, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**62-1715807**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
3 N. Dunlap Street **Van Vleet Building** **Memphis, Tennessee**	**38163**
(Address of principal executive offices)	(Zip Code)

(901) 523-9700

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, par value $0.001 per share

(Title of Class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☑

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☑

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐ Accelerated filer ☑ Non-accelerated filer ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☑

The aggregate market value of common stock held by non-affiliates of the Registrant based on the closing sales price of the Registrant's common stock on June 30, 2005 as reported on the NASDAQ National Market was $75,667,037.

There were 30,998,217 shares of Registrant's common stock issued and outstanding as of March 1, 2006.

Documents Incorporated by Reference

Certain portions of the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A, not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, in connection with the Registrant's 2006 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements. The forward-looking statements are contained principally in the sections entitled "Risk Factors," "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;
- potential future licensing fees, milestone payments and royalty payments;
- 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 are subject to risks and uncertainties. We discuss many of these risks in this Annual Report on Form 10-K in greater detail in the section entitled "Risk Factors" under Part I, Item 1A below. 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 Annual Report on Form 10-K. You should read this Annual Report on Form 10-K and the documents that we incorporate by reference in and have filed as exhibits to this Annual Report on Form 10-K, 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.

PART I

ITEM 1. BUSINESS

Overview

GTx is a biopharmaceutical company dedicated to the discovery, development and commercialization of therapeutics for cancer and serious conditions related to men's health. Our lead drug discovery and development programs are focused on small molecules that selectively modulate the effects of estrogens and androgens, two essential classes of hormones. We are developing ACAPODENE® (toremifene citrate), a selective estrogen receptor modulator, or SERM, in two separate clinical programs in men: first, a pivotal Phase III clinical trial for the treatment of serious side effects of androgen deprivation therapy, or ADT, for advanced prostate cancer, and second, a pivotal Phase III clinical trial for the prevention of prostate cancer in high risk men with precancerous prostate lesions called high grade prostatic intraepithelial neoplasia or high grade PIN. In our third clinical program we are developing ostarine, a selective androgen receptor modulator, or SARM. We believe that ostarine has the potential to treat a variety of indications including muscle wasting and bone loss in frail elderly patients, osteoporosis, muscle wasting in end stage renal disease patients, and severe burn wounds and associated muscle wasting. We are currently planning a Phase II clinical trial of ostarine for the treatment of muscle wasting and bone loss in 120 elderly men and postmenopausal women. In our fourth clinical program, we and our partner, Ortho Biotech Products, L.P., a subsidiary of Johnson & Johnson (Ortho Biotech), are developing andarine, another one of our SARMs, for the treatment of weight loss from various types of cancer, which is known as cancer cachexia. We are planning a Phase II clinical trial with Ortho Biotech.

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

Our most advanced product candidate, ACAPODENE, is being developed to treat both the multiple side effects of ADT and to prevent prostate cancer in high risk men with high grade PIN. ADT is the standard medical treatment for patients who have advanced, recurrent or metastatic prostate cancer, and we believe that there will be approximately one million prostate cancer survivors who are expected to be treated with ADT by 2008. The low estrogen levels caused by ADT can lead to serious side effects, including: severe bone loss, or osteoporosis, resulting in skeletal fractures; hot flashes; lipid changes and breast pain and enlargement, or gynecomastia. There are currently no drugs approved by the United States Food and Drug Administration, or FDA for the treatment of multiple side effects of ADT. We commenced a pivotal Phase III clinical trial of ACAPODENE under a Special Protocol Assessment, or SPA, with the, FDA for this indication in November 2003. A SPA is designed to facilitate the FDA's review and approval of drug products by allowing the agency to evaluate the proposed design and size of clinical trials that are intended to form the primary basis for determining a drug product's efficacy. If agreement is reached with the FDA, a SPA documents the terms and conditions under which the design of the subject trial will be adequate for submission of the efficacy and human safety portion of a New Drug Application, or a NDA. We reached our enrollment goal in 2005 with approximately 1,400 patients randomized. The primary endpoint is the incidence of vertebral skeletal fractures measured by x-ray, and the secondary endpoints include bone mineral density (BMD), hot flashes, gynecomastia and lipid changes. In accordance with the SPA, we completed a planned interim analysis of BMD in the first 200 patients who completed one year of treatment. Patients treated with ACAPODENE demonstrated statistically significant increases in BMD compared to placebo in all three skeletal sites measured, with lumbar spine showing an improvement of 2.3 percentage points ($p<0.001$), hip, a 2.0 percentage point improvement ($p=0.001$), and femoral neck, a 1.5 percentage point improvement ($p=0.009$). It is anticipated that this clinical trial will be completed in the fourth quarter of 2007. If the results are favorable, we expect to file a NDA with the FDA in the first half of 2008. We also plan to conduct a one-year blinded extension trial in the same patients to gather additional fracture data.

In the United States, prostate cancer is one of the most commonly diagnosed cancers and the second leading cause of cancer-related deaths in men. Scientific evidence has established that men who have high grade PIN are at high risk of developing prostate cancer (approximately 50% of the men with high grade PIN found on a prostate biopsy develop prostate cancer within three years). In the United States, there are over 115,000 new cases of high grade PIN diagnosed each year and an estimated 14 million men under the age of 80 unknowingly harbor this

condition. Currently, there is no approved treatment to prevent prostate cancer in men with high grade PIN. In January 2005, we initiated a pivotal Phase III clinical trial of orally administered ACAPODENE for the prevention of prostate cancer in men with high grade PIN which is being conducted under a SPA with the FDA. We expect to reach our total enrollment goal of 1,260 patients by the end of the first quarter of 2006. We will evaluate efficacy endpoints 36 months after completion of enrollment, with an interim efficacy analysis within 24 months of completion of enrollment. Once we have achieved the efficacy endpoint (at 24 or 36 months), we plan to file a NDA with the FDA. We anticipate that we will collect safety data required under the SPA during the NDA review process if we file a NDA based on the 24 month interim analysis. In 2004, we completed a randomized, double-blind, placebo-controlled, dose-finding Phase IIb clinical trial of ACAPODENE in men with recently diagnosed high grade PIN to determine the efficacy and safety of a daily dose of ACAPODENE for 12 months. The trial enrolled 514 men and was conducted at 64 clinical sites across the United States. The primary endpoint of this trial was the incidence of prostate cancer at 12 months. This well controlled study confirmed that men who have high grade PIN are at high risk, as 31% of placebo patients were diagnosed with prostate cancer after one year in the study. The intent-to-treat analysis, defined to include any patient who had at least one biopsy during the study, showed that ACAPODENE 20 mg had a 22% reduction in prostate cancer incidence. The reduction of prostate cancer incidence improved in men who received ACAPODENE 20 mg for a full year, with the clinical trial showing a 48% reduction in this high risk population compared to the placebo group. For men who were diagnosed with prostate cancer, those treated with ACAPODENE had similar tumor grades to those of placebo patients, providing evidence that ACAPODENE does not adversely affect the severity of the tumor in those patients who develop prostate cancer. ACAPODENE was well tolerated, as the number of adverse events was similar between those patients receiving ACAPODENE compared to placebo.

In our third clinical program, ostarine, a SARM, is being developed to treat a variety of medical conditions relating to muscle wasting and/or bone loss. After approximately age 30, people lose about one-half pound of muscle every year. This muscle loss accelerates in people with chronic illness and other conditions that stress the body and this muscle loss depletes protein reserves and detrimentally impacts recovery. Testosterone and other anabolic steroids have been proven to reverse involuntary muscle wasting caused by aging, burns and trauma, cancer, end-stage renal disease, chronic obstructive pulmonary disease and other diseases. However, testosterone and other anabolic steroids may cause serious unwanted side effects, including stimulating prostate cancer growth in men and masculinization in women. Ostarine is a novel non-steroidal agent designed to have anabolic activity like testosterone without unwanted side effects on the prostate and skin and in a once daily oral dose. We are currently planning to initiate a proof of concept Phase II clinical trial of ostarine for the treatment of muscle wasting and bone loss in elderly men and postmenopausal women to commence in the second quarter of 2006. Our recently completed second Phase I clinical trial of ostarine included 48 healthy male volunteers and 23 elderly males with truncal obesity. In the trial, 14 day treatment with ostarine demonstrated anabolic activity without unwanted androgenic side effects.

In our fourth clinical program, andarine, a SARM, is being developed in collaboration with Ortho Biotech, initially for the treatment of cachexia from various types of cancer, a potentially life-threatening muscle wasting complication of many cancers. There are currently no drugs that have been approved by the FDA for the treatment of cancer cachexia.

We market FARESTON® (toremifene citrate) 60 mg tablets for the treatment of metastatic breast cancer in post-menopausal women in the United States. FARESTON has been commercially available for over 15 years in Europe and over 8 years in the United States. In January 2005, we acquired from Orion Corporation the rights to distribute FARESTON in the United States and a license to toremifene, the active pharmaceutical ingredient in FARESTON and ACAPODENE, for all indications worldwide except breast cancer outside of the United States.

We have identified other product candidates that are currently undergoing preclinical studies, including product candidate prostarine to treat benign prostatic hyperplasia, or BPH, a benign prostate enlargement that results in obstruction of the urinary tract, and andromustine to treat hormone refractory prostate cancer.

Scientific Background on Estrogens and Androgens

Both estrogens and androgens are hormones that play critical roles in men's and women's health, regulating not only the reproductive system, but also having important effects on the muscular, skeletal, cardiovascular, metabolic 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 reducing the risk of skeletal fractures. But in aging men, as testosterone levels decrease, the gradual increase in estrogen levels in the blood relative to testosterone levels may promote BPH, initiate prostate cancer and cause gynecomastia.

Testosterone, the predominant androgen in men, 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. Male reproductive health is also dependent on testosterone to maintain sexual interest, fertility, erectile function and normal prostate growth. Testosterone is converted into a more potent androgen, dihydrotestosterone (DHT) which also stimulates sebaceous and hair glands and may cause unwanted effects like acne and hair loss. In aging men, there is a gradual decline in testosterone levels, which contributes to a loss of muscle mass and strength, decreased bone mineralization, which may result in osteoporosis and bone fractures, erectile dysfunction, decreased sexual interest, depression and mood changes.

Estrogens and androgens perform their physiologic functions by binding to and activating or inhibiting their hormone receptors located in various tissues. Once a hormone binds with its receptor, this activates a series of cellular events resulting in estrogenic or androgenic tissue effects.

Pharmaceuticals that target hormone receptors for estrogens or androgens have been medically used for over 50 years. The drugs that have been used to stimulate androgen receptors are either natural or synthetic hormones, known as steroids. Steroids activate hormone receptors in all tissue types in a non-selective manner resulting in not only beneficial effects but also in unwanted clinical effects. In men, the absence of selectivity and conversion of testosterone to DHT may result in unwanted side effects, such as the potential stimulation of latent prostate cancer, aggravation of existing BPH, acne, hair growth and gynecomastia. Currently, no orally available testosterone products have been approved for use in the United States, and those testosterone products that are available must be administered by intramuscular injections or by transdermal patches or gels that may not be convenient for patients and, in some cases, can result in inconsistent blood levels of testosterone.

There are also classes of small molecules that bind to hormone receptors that are not steroids. These nonsteroidal small molecules may either stimulate or block hormone receptors depending on the type of tissue in which the receptor is found and the interaction of the molecule with the receptor. A drug that has the ability to either block or stimulate the 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, while minimizing the unwanted, effects of natural or synthetic steroid hormones.

A SERM is a nonsteroidal 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 mimic estrogen’s beneficial action in bone, and we believe that SERMs have the potential to block estrogen’s harmful activity in the prostate and the breast. Examples of SERMs currently on the market include toremifene, which has been prescribed to treat advanced female breast cancer, and raloxifene, which is used to prevent and treat female post menopausal osteoporosis.

A SARM is a small molecule that binds to and selectively modulates androgen receptors. In men, we believe that SARMs can be engineered to stimulate testosterone’s beneficial action in bone and muscle while blocking testosterone’s unwanted action in the prostate and skin. We further believe that SARMs can be designed to either cross or not cross into the central nervous system and to selectively modulate receptors in the brain to affect mood and sexual interest. Although no SARMs have been commercialized to date, we believe that SARMs without testosterone’s or other exogenous steroid therapies’ harmful side effects could be developed to treat a range of medical conditions, 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, neurodegenerative disorders, trauma and burns; (3) muscle wasting conditions associated with aging such as frailty and sarcopenia; (4) disorders of the central nervous system, such as low libido, depression and other mood disorders; (5) male reproductive functions, such as infertility, male contraception and erectile dysfunction; (6) prostate disorders, such as BPH and prostate cancer; (7) other conditions, such as anemia, male hair loss; and (8) the prevention and/or treatment of osteoporosis.

Marketed Product

FARESTON®

We currently market FARESTON (toremifene citrate) 60 mg tablets, which have been approved by the FDA for the treatment of metastatic breast cancer in postmenopausal women in the United States. Toremifene is a selective estrogen receptor modulator compound owned and manufactured by Orion Corporation (Orion), a Finnish corporation. On January 1, 2005, we entered into a revised license and supply agreement with Orion to exclusively license toremifene for all indications in the United States and for all indications in humans, except breast cancer outside of the United States. Toremifene is the active pharmaceutical ingredient in ACAPODENE, our lead product candidate currently in Phase III clinical trials for two indications, and FARESTON. We initially licensed toremifene from Orion in March 2000 to develop ACAPODENE for certain indications in men's health. At that time, another pharmaceutical company already held the distribution rights in the United States from Orion to sell toremifene as FARESTON for the treatment of metastatic breast cancer. Under the terms of our agreement with Orion, we paid to Orion a license fee of approximately $4.8 million and purchased FARESTON inventory of approximately $448,000. We will continue to market FARESTON in the United States for the treatment of metastatic breast cancer and will pay a royalty to Orion on FARESTON sales. The royalty rate for FARESTON will be reduced after we commercialize a new toremifene based product such as ACAPODENE for men's health indications. Additionally, our license and supply agreement with Orion was amended to provide that Orion will manufacture and supply all of our needs for clinical trial and commercial grade material for toremifene-based products developed and marketed globally by us, including ACAPODENE globally and FARESTON in the United States.

We currently sell FARESTON primarily through wholesale drug distributors. The top three distributors, McKesson Corporation, Cardinal Health, Inc. and AmerisourceBergen Corporation, accounted for approximately 94% of our revenues generated from the sale of FARESTON for the year ended December 31, 2005. The loss of any of these three distributors could have a material adverse effect on continued FARESTON sales.

Product Candidates

The following table summarizes key information about our product candidates:

Program	Product Candidate and Indication	Development Phase	Status
SERM	**ACAPODENE 80 mg** Side effects of ADT	Pivotal Phase III clinical trial	Phase III clinical trial ongoing under a SPA; fully enrolled; obtained statistically significant BMD results from a planned interim analysis in fourth quarter of 2005
	ACAPODENE 20 mg Prevention of prostate cancer in men with high grade PIN	Pivotal Phase III clinical trial	Phase III clinical trial ongoing under a SPA; attainment of enrollment goal anticipated by the end of first quarter of 2006
SARM	**Ostarine** Muscle wasting and bone loss in elderly men and postmenopausal women	Planning to initiate Phase II clinical trial in second quarter of 2006	Two Phase I clinical trials completed
	Andarine Cachexia from various types of cancer	Planning Phase II clinical trial with Ortho Biotech	Four Phase I clinical trials completed
	Prostarine BPH	Preclinical	Preclinical studies
Anticancer	**Andromustine** Prostate cancer that is not responsive to ADT	Preclinical	Preclinical studies

ACAPODENE®

Our most advanced product candidate, ACAPODENE, is a SERM. ACAPODENE is being developed as a once-a-day oral tablet to (i) treat the multiple side effects of ADT (80 mg dose) and (ii) prevent prostate cancer in high risk men (20 mg dose). In January 2005, we acquired all rights to toremifene, the active ingredient in ACAPODENE, for all indications, except breast cancer outside of the United States. We licensed rights to toremifene based on our belief that a SERM can reduce the incidence of prostate cancer in men with high grade PIN and treat complications resulting from ADT, and toremifene's established record of safety in the treatment of post menopausal women with advanced breast cancer. Under our license and supply agreement, Orion manufactures and supplies us FARESTON, the 60 mg dose of toremifene citrate, for sale in the United States to treat advanced breast cancer, as well as ACAPODENE, both 80 mg dose and 20 mg dose of toremifene citrate, for our Phase III clinical trials for the treatment of multiple side effects resulting from ADT and to prevent prostate cancer in high risk men.

ACAPODENE for the Treatment of Serious Side Effects of ADT

Scientific Overview. The standard medical treatment for patients who have advanced, recurrent or metastatic prostate cancer is ADT, which reduces blood levels of testosterone, a primary growth factor for prostate cancer. ADT 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 ®, (leuprolide acetate), Zoladex® (goserelin acetate),Viadur® (leuprolide acetate) and Eligard® (leuprolide acetate). The reduction in testosterone from ADT results in very low estrogen levels in men well below even postmenopausal women.

Estrogen related side effects associated with ADT include bone loss leading to osteoporosis and skeletal fractures, hot flashes, gynecomastia, adverse lipid changes, depression, and memory loss. Bone loss leading to osteoporosis and possible skeletal fractures is a significant clinical problem because clinical studies have shown that prostate cancer patients who develop skeletal fractures have shorter survival rates, with their median survival time shortened by 39 months. Hot flashes occur because of reduced estrogen levels in the brain. Hot flashes experienced by prostate cancer patients on ADT 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 preclinical and clinical 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. Toremifene has been shown to improve lipid profiles in postmenopausal women. Also, 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 four serious side effects of LHRH agonists: osteoporosis, hot flashes, adverse lipid changes and gynecomastia. Importantly, as evidenced by two Phase II clinical trials, ACAPODENE has not been shown to stimulate prostate cancer growth or increase luteinizing hormone in men on ADT.

Potential Market. In the United States, we believe approximately 1,000,000 prostate cancer survivors will be treated with ADT by 2008, and over 100,000 new patients are 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 ADT prolongs the survival of prostate cancer patients, and second, the serum test for Prostate Specific Antigen, or PSA, is detecting advanced prostate cancer earlier than in the past. The net effect of prostate cancer being treated earlier and for longer periods is that the side effects of ADT now contribute significantly to morbidity, and in some cases mortality. Physicians are currently prescribing certain drugs on an off-label basis to help ameliorate some of the individual side effects of ADT. These drugs include bisphosphonates for osteoporosis, Megace ® (megestrol acetate) 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 ADT.

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 BMD. The secondary endpoint of both trials was the incidence of hot flashes. We measured BMD 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.

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 BMD at six months, while the patients who received the placebo on average experienced an approximately 4% decrease in lumbar vertebral spine BMD 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 BMD. 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 experienced a 3.5% average increase in lumbar vertebral spine BMD, an indicator of bone strength, while the patients who received the placebo experienced a 0.24% average increase in lumbar vertebral spine BMD. The difference in these measurements had a p-value of less than 0.05. A p-value of 0.05 or less generally represents a statistically significant difference in treatments. The BMD changes in the hip were not significant vs. placebo. 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 BMD changes seen in patients treated with ACAPODENE 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 or gynecomastia. At the lower tested doses, ACAPODENE, as compared to the placebo, did not demonstrate a meaningfully effect on lumbar vertebral spine BMD or frequency of hot flashes.

In November 2003, we initiated a pivotal Phase III clinical trial of orally administered ACAPODENE 80 mg dose in patients undergoing ADT for advanced, recurrent or metastatic prostate cancer under a special protocol assessment, or a SPA, from the FDA. 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 vertebral skeletal fractures measured by x-ray, and the secondary endpoints of the trial include BMD, hot flashes, lipid changes and gynecomastia. The Phase III trial completed enrollment in the fall 2005 with approximately 1,400 patients with advanced, recurrent or metastatic prostate cancer who have been receiving ADT for at least six months and who have significant existing bone loss, or are greater than 70 years of age. The patients were randomized to receive either a placebo or a daily 80 mg dose of ACAPODENE for 24 months. We are conducting the trial in approximately 150 sites in the United States and Mexico. In accordance with the SPA, we completed a planned interim BMD analysis among the first 200 patients who completed one year of treatment. Patients treated with ACAPODENE demonstrated statistically significant increases in BMD compared to placebo in all three different skeletal sites measured, with lumbar spine showing an improvement of 2.3 percentages points ($p<0.001$), hip, a 2.0 percentage point improvement ($p=0.001$), and femoral neck, a 1.5 percentage point improvement ($p=0.009$). For perspective, a SERM, raloxifene, study in postmenopausal osteoporosis in women showed a lumbar spine BMD increase of 2.0 percentage points after one year which resulted in a 55% fracture reduction in three years.

A Drug Safety Monitoring Board (DSMB) meets every 6 months to review unblinded data from the ACAPODENE ADT and prostate cancer prevention trials. In January 2006, the DSMB reviewed safety data from approximately 2,000 patients and recommended continuing both trials, which suggests there are no clinically significant trends of serious side effects related to ACAPODENE. We currently anticipate that the ADT study will be completed in the fourth quarter of 2007, and if efficacy is demonstrated in accordance with the requirements of the SPA, we expect to file a NDA during the first half of 2008. We also plan to conduct a one-year blinded extension trial in the same patients to gather additional fracture data.

ACAPODENE for the Prevention 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, may 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 demonstrated that prostate cancer is found in approximately 50% of men within 3 years of their being diagnosed with high grade PIN. We believe that this correlation between high grade PIN and prostate cancer makes these men an appropriate population to treat to prevent prostate cancer. Currently, there is no approved treatment to prevent prostate cancer in men who are diagnosed with high grade PIN.

Estrogens play an important role in the initiation of prostate cancer. Estrogens may influence the initiation of prostate cancer 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 approximately 400,000 new cases of prostate cancer diagnosed each year 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 14 million men unknowingly harbor high grade PIN.

Patients who are diagnosed with high grade PIN may undergo repeat biopsies immediately after diagnosis and frequently 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 through the probe through the rectum into the prostate to obtain sample cores of tissue. Complications from this procedure include bleeding, pain, prostate infection and, in rare instances, life-threatening blood infection (sepsis). 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 are subject to the mental anguish of fearing that a diagnosis of prostate cancer may be imminent.

We have entered into separate collaboration agreements with diagnostic companies, including, Hybritech, Inc., a wholly owned subsidiary of Beckman Coulter, Inc., diaDexus, Inc., MacroArray Technologies, LLC, Tessera, Inc., and Gen-Probe, Incorporated, to provide clinical samples to these companies from our Phase IIb clinical trial and our ongoing Phase III clinical trial of ACAPODENE for the prevention of prostate cancer in high risk men. Information resulting from these collaborations will be used to evaluate whether a commercial test from blood or urine may be effectively developed to detect high grade PIN and/or prostate cancer. By continuing to collaborate with leading diagnostic labs, we hope to have a urine or blood test developed to detect high grade PIN in the millions of American men who may unknowingly harbor high grade PIN and/or prostate cancer.

Clinical Trials. In 2004, we completed a randomized, double-blind, placebo-controlled, dose-finding Phase IIb clinical trial of ACAPODENE in men with recently diagnosed high grade PIN to determine the efficacy and safety of a daily dose of ACAPODENE for 12 months. The trial enrolled 514 men and was conducted at 64 clinical sites across the United States. The primary efficacy endpoint of this trial was incidence of prostate cancer at 12 months. Participants were randomized to receive a 20 mg, 40 mg or 60 mg dose of ACAPODENE or placebo. A screening prostate biopsy was performed on each trial participant at the time of enrollment into the trial, and eligibility was limited to participants who were diagnosed with high grade PIN and had no evidence of prostate cancer. A second biopsy was performed six months after enrollment in an effort to identify trial participants who had prostate cancer that was not detected by the initial biopsy. The intent-to-treat population consisted of all patients initially enrolled in the trial who returned for their six-month biopsy. We also analyzed trial results in a predefined subgroup of patients that excluded patients showing biopsy evidence of prostate cancer at six months and patients who did not complete the full course of therapy in the trial.

We analyzed the results of this Phase IIb clinical trial on a stratified basis, in which we assessed the effect of individual clinical sites on the overall statistical analysis of the trial results, and on an unstratified basis, in which we did not assess such effect. In the stratified analysis of the per protocol population, which is the intent-to-treat population less two patients in the group that received 20 mg of ACAPODENE who were deemed to be not compliant with the protocol, the cumulative, or overall, risk of prostate cancer was 24.4% in the group that received 20 mg of ACAPODENE compared with 31.2% in the group that received placebo. The p-value for this result was less than 0.05. Thus, the cumulative risk of prostate cancer based on a stratified analysis of the per protocol population was 22.0% lower in the 20 mg treatment group, which would imply an annualized rate of prevention of cancers of 6.8 per 100 men treated. The p-value in the unstratified analysis of the per protocol population for the comparison between the group that received 20 mg of ACAPODENE and the group that received placebo was 0.132. In the stratified analysis of the intent-to-treat population, the cumulative risk of prostate cancer was 24.9% in the group that received 20 mg of ACAPODENE compared with 31.2% in the group that received placebo. The p-value for this result was 0.081, which was statistically significant under the protocol for this trial. Statistical significance under the protocol was defined as a p-value of 0.10 or less. The p-value in the unstratified analysis of the intent-to-treat population for the comparison between the group that received 20 mg of ACAPODENE and the group that received placebo was 0.148.

In a stratified analysis of the subgroup of patients who had no biopsy evidence of prostate cancer at their initial screening biopsy or their six-month biopsy and completed the full course of therapy in the trial, the cumulative risk of prostate cancer was 9.1% in the group that received 20 mg of ACAPODENE compared with 17.4% in the group

that received placebo, a 48.2% reduction. The p-value for this result was less than 0.05. For the 40 mg and 60 mg treatment arms, in the intent-to-treat population, the per protocol population and the predefined patient subgroup, the cumulative risk of cancer was lower than the placebo group, although these results were not statistically significant.

The overall rates of drug-related adverse events and serious adverse events did not differ to a significant degree between any of the ACAPODENE dose groups and placebo. The results of our pivotal Phase III clinical trial of ACAPODENE for this indication may not be the same as the results of this Phase IIb clinical trial.

In January 2005, we initiated a randomized, double-blind, placebo-controlled pivotal Phase III clinical trial of orally-administered ACAPODENE for the prevention of prostate cancer in men with high grade PIN. Over 160 clinical sites across the United States, Canada, Mexico and Argentina are participating in this clinical trial. Approximately 1,260 patients with high grade PIN are being randomized to receive either a daily dose of 20 mg of ACAPODENE or placebo. Only patients who have confirmed high grade PIN and a prostate biopsy that excludes cancer in the past six months are eligible to participate. The primary endpoint is the incidence of prostate cancer. We are conducting this pivotal Phase III clinical trial under a SPA. We expect to reach our patient enrollment goal by the end of the first quarter of 2006. We will evaluate efficacy endpoints 36 months after completion of enrollment, with an interim efficacy analysis within 24 months of completion of enrollment. Once we have achieved the efficacy endpoint (at 24 or 36 months), we plan to file a NDA with the FDA. We anticipate that we will collect the safety data required under the SPA during the NDA review process if we file a NDA based on the 24 month interim analysis.

OSTARINE

Our third clinical program is to develop ostarine, a SARM, for the treatment of a variety of medical conditions relating to muscle wasting and/or bone loss. Testosterone and other anabolic steroids have been proven to beneficially treat involuntary muscle wasting caused by aging, burns and trauma, cancer, end-stage renal disease, chronic obstructive pulmonary disease and other diseases. However, testosterone and other anabolic steroids may cause serious unwanted side effects, including stimulating prostate cancer growth in men and masculinization in women. Ostarine is a non-steroidal agent designed to have anabolic activity like testosterone but in an orally available once-a-day formation and without unwanted side effects on the prostate and skin.

Our recently completed Phase I studies, which commenced in 2005, provided evidence that ostarine has the desired anabolic effects without the unwanted androgenic effects. We are planning to initiate a proof of concept Phase II clinical trial of ostarine in the second quarter of 2006 for the treatment of muscle wasting and bone loss in approximately 120 elderly men and postmenopausal women.

Ostarine for the Treatment of Muscle Wasting and Bone Loss

Scientific Overview. Every year after age 30 on average people lose a half pound of muscle and gain a pound of fat. An average man may lose 35% of muscle between the ages of 30 and 90 years of age. A contributing factor to muscle loss in men is that testosterone levels decrease by roughly 1% every year after 30. Muscle tissue plays several important roles. Muscle provides strength and endurance, supports the skeletal system, plays an important role in metabolism and helps protect the body through the immune system. During an illness or trauma to the body, the energy demands of the body increase and the body may break down muscle to get protein to fuel the body's needs. Also, protein is needed to repair damaged organs and to replace immune system cells lost during periods of illness. Muscle wasting starts a vicious cycle. As people lose muscle, they become fatigued easily, making it more difficult to rehabilitate and recover. Loss of muscle can cause frailty, loss of independence and can worsen other conditions of aging such as osteoarthritis and osteoporosis. Also, people who are fatigued may become more sedentary, leading in many to a reduction in their quality of life. Once people have a low level of muscle mass, it is increasingly difficult for the body to recover from disease and the risk of dying or becoming bedridden may increase. Loss of muscle and bone with age is sometimes referred to as frailty. A 2001 study among more than 5,000 elderly adults found that over a 3-year period the death rate among the frail elderly was 18%, versus a 3% rate in the non-frail elderly. The frail were also far more likely to experience falls, hospitalizations and loss of independence.

We believe that ostarine can build muscle and bone by improving: 1) the body's efficiency at metabolizing protein from food, 2) the body's ability to recycle protein, 3) the body's ability to burn fat and build muscle and (4) the body's ability to maintain bone and promote bone formation. We believe that ostarine can increase muscle size and strength, resulting in improved function, quality of life and speed of recovery, and can prevent osteoporosis and

fractures. Ostarine has been designed to have anabolic properties in muscle and bone without unwanted androgenic side effects, such as the stimulation of prostate cancer. In preclinical studies of intact animals, ostarine has been shown to build muscle and bone while shrinking the prostate.

Potential Market. There are approximately 17 million people over the age of 65 in the United States who have age related loss of skeletal muscle mass, or sarcopenia. Additionally, a high percentage of patients with end-stage renal disease, congestive heart failure, chronic obstructive pulmonary disease, HIV and other chronic diseases experience varying degrees of muscle wasting. Roughly one quarter of men and women over 65 years of age are hospitalized annually. It has been shown that from the time of the onset of their illness, approximately one-half of the elderly declined in health after their hospital stay. Muscle wasting is a contributing factor in their inability to completely recover. We believe that ostarine may be able to improve recovery. A patient population experiencing one of the highest degree of muscle wasting is burn patients. Burn patients can lose up to 20 lbs. of muscle in two weeks as their bodies try to get the protein needed to repair trauma. We believe that ostarine may be able to reduce muscle wasting and speed healing in burn patients. We believe that current anabolic agents on the market have had limited commercial success due to concerns about their undesirable side effects, inconvenient dosing and lack of investment due to limited intellectual property. Testosterone is not available as an oral tablet in the United States with topical gels and patches as the most utilized forms of delivery.

Clinical Trials. We have data from two Phase I clinical trials of ostarine: a double-blind, placebo-controlled, single-ascending dose clinical trial and a double-blind, placebo-controlled, multiple-ascending dose clinical trial. The single-ascending dose clinical trial included 96 healthy male volunteers. Ostarine was well tolerated by the participants in this clinical trial, and there were no drug-related serious adverse events. This clinical trial demonstrated that the average half life of ostarine was approximately 24 hours, which supports a daily dosing regimen.

The second Phase I clinical trial evaluated the safety, tolerability, pharmacokinetics, and specific pharmacodynamic characteristics of ostarine using multiple-ascending doses in 48 healthy male volunteers between the ages of 18 and 45 and 23 elderly males with truncal obesity who had an average age of 68 years. Safety and pharmacodynamic measurements were taken at the beginning of the study and after 14 days of daily oral dosing. These measurements included routine blood chemistry and hematology, sex hormones and gonadotropins, serum prostate specific antigen, metabolic markers of bone and muscle, cutaneous sebum analysis and DEXA scanning for body composition. Overall, clinical laboratory values and hormonal effects for the 71 volunteers were consistent with anabolic activity. Comparisons of DEXA assessments from the beginning of the study to DEXA assessments after 14 days showed positive changes in body composition at clinically relevant doses, with increases in lean body mass and decreases in fat mass observed. Ostarine did not appear to have unwanted side effects on the prostate or the skin. We believe that these observations support the potential ability of ostarine to selectively modulate androgen receptors in a tissue-specific manner. Ostarine has been well tolerated by the participants in this Phase I clinical trial, and there have been no drug-related serious adverse events. However, Phase I clinical trials are not designed to show efficacy, and the results of future clinical trials may not be the same as these early observations.

We are planning a proof of concept Phase II clinical trial of ostarine for the treatment of muscle wasting and bone loss in approximately 120 elderly men and postmenopausal women.

ANDARINE

In our fourth clinical program, we are developing andarine, another of our SARMs, with our partner, Ortho Biotech, for the treatment of cachexia from various types of cancer. We initially selected this indication because it represents a potentially large market, and we believe it has a relatively well-defined clinical and regulatory process.

In March 2004, we entered into a joint collaboration and license agreement with Ortho Biotech for andarine for indications related to men's health and other licensed SARM compounds meeting specified criteria which Ortho Biotech may ultimately choose to develop instead of, or in addition to, andarine. We retain the right to independently develop specific SARM compounds which are excluded from the collaboration, including ostarine. Under the terms of the agreement, we received an up-front licensing fee and reimbursement of certain andarine development expenses totaling approximately $6.7 million, which is being amortized into revenue over five years. We are entitled to receive additional licensing fees and milestone payments prior to product launch of (1) up to an aggregate of $76 million for licensed products containing andarine or any replacement compound, and (2) up to $45 million for each licensed product containing any other compound developed under the agreement, upon achievement of specific clinical development milestones or receipt of regulatory approvals. Johnson & Johnson Pharmaceutical

Research & Development, an affiliate of Ortho Biotech, is responsible for further clinical development and related expenses for andarine and other licensed SARM compounds. If a licensed product containing andarine or any other SARM compound is approved for commercial sale, Ortho Biotech will have full and exclusive decision-making authority for marketing such product in the United States and in markets outside the United States. Under the agreement, we have the option, subject to meeting specified conditions, to co-promote andarine and other licensed products to urologists in the United Stated for indications specifically related to men's health. Ortho Biotech is obligated to pay us up to double digit royalties on worldwide net sales of andarine and other licensed products, and an additional royalty in excess of 20% on all co-promoted net sales to urologists in the United States. Ortho Biotech may terminate the development or commercialization of andarine or any other licensed SARM compound under the agreement upon 90 days' notice, or 30 days' notice if there are safety issues, or may terminate the agreement for our uncured material breach.

Andarine For The Treatment Of Cancer Cachexia

Scientific Overview. Cachexia is defined as the unintentional loss of over 5% of a patient's original body weight. Most of the weight loss attributable to cancer cachexia results from the loss of lean body, or muscle weight. 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.

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 testosterone can have a number of undesirable side effects in men, such as the potential stimulation of latent prostate cancer, aggravation of existing BPH and gynecomastia, and in women, masculinizing effects 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 does not stimulate sebaceous glands, the cause of hair growth and acne, or the prostate, which exacerbates BPH. In addition, andarine is being developed as an oral tablet, which makes it more convenient to administer.

Potential Market. There are approximately 1.3 million patients diagnosed with cancer each year in the United States. It has been estimated that 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, which 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 four Phase I clinical trials of andarine in a total of 134 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. However, Phase I clinical trials are not designed to show efficacy, and these early observations are not necessarily indicative of the results that will be demonstrated in future clinical trials. The details and design of Phase II clinical trials for andarine will be determined by a joint development committee established as a part of our joint collaboration with Ortho Biotech.

PROSTARINE

We are also developing another SARM product candidate, prostarine, for the potential treatment of benign prostatic hyperplasia, or BPH, which is benign prostate enlargement that results in obstruction of the urinary tract. In animal models, prostarine has been shown to have the ability to shrink and prevent growth of the prostate gland. We are conducting preclinical studies required to support clinical trials.

ANDROMUSTINE

First line therapy of patients who have advanced, recurrent or metastatic prostate cancer is ADT. Since prostate cancer is dependent on androgens, such as testosterone, to grow, the reduction in testosterone leads 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 prostate cancer.

Building on the technology of our SARM discovery program, we designed and are developing small molecules like andromustine to specifically target androgen receptors and kill cancer cells. In one approach, the andromustine molecule has two components: (1) the SARM-like part of the molecule, which binds 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, these compounds selectively kill metastatic human prostate cancer cells. We continue to use this and other approaches to identify molecules with potent in vitro and in vivo anticancer activity. Because advanced prostate cancers, including hormone refractory prostate cancer, have more androgen receptors than the normal prostate, andromustine has been designed to bind to and to selectively kill advanced prostate cancer cells.

We believe there will be up to 1,000,000 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. Once a patient develops hormone refractory prostate cancer, his prognosis is poor. Andromustine could be a second line cancer therapy for patients who develop hormone refractory prostate cancer.

DRUG DISCOVERY AND OTHER RESEARCH AND DEVELOPMENT

Steroid hormone therapies, which include estrogen and testosterone therapies, have been used to treat humans for many years. Steroid hormones by their nature have unselective effects in various tissues. As a result, they have unintended side effects, which limit their clinical value.

SERM drugs, such as toremifene, tamoxifen and raloxifene, have achieved commercial success in treating women as nonsteroidal small molecules that modulate hormone estrogen receptors in a tissue selective way and minimize some of the side effects of the natural estrogen hormone to treat breast cancer (toremifene and tamoxifen) or to treat postmenopausal osteoporosis (raloxifene). We believe that the previous commercial and scientific 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 will allow us to sustain our clinical pipeline through the design and development of nonsteroidal small molecule drugs that modulate hormone receptors. Our 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 design and synthesize new compounds based on computer, or *in silico,* models and crystal structures of a hormone receptor's binding sites. We continually modify and improve these 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 and high throughput 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 clinical product candidates for the androgen receptor, andarine and ostarine. We also have conducted other research and development efforts focused on SERM and SARM compounds, other receptor modulator compounds and anticancer agents.

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:

Obtain Regulatory Approval of ACAPODENE. We are focused on completing two pivotal Phase III clinical trials, both of which are being conducted under approved special protocol assessments with the FDA, obtaining regulatory approval and preparing for the potential commercial launch of ACAPODENE for two distinct indications in men's health.

Retain Commercial Rights to ACAPODENE in the United States and Establish Sales and Marketing Infrastructure. We are currently planning to retain 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 outside of the United States and to physicians outside of urology and medical oncology in the United States.

Extend Life Cycle of ACAPODENE. We are studying various means 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. We also intend to apply for market exclusivity and regulatory extensions of patent life under applicable European and U.S. laws, as appropriate, to protect our exclusive rights in ACAPODENE for the indications that we are currently testing in clinical trials.

Develop Diagnostic Tests for High Grade PIN. We are currently collaborating with several diagnostics companies, including Hybritech, Inc., a wholly owned subsidiary of Beckman Coulter, Inc., diaDexus, Inc., MacroArray Technologies, LLC, Tessera, Inc., and Gen-Probe, Incorporated to develop an accurate blood or urine test to detect high grade PIN. We will continue to seek additional collaborations for other companies with promising high grade PIN diagnostics. 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 blood or urine test would increase the detection of high grade PIN and thereby expand the already large potential market for ACAPODENE.

Maintain Commercial Sales of FARESTON. We intend to devote sufficient marketing efforts to maintain FARESTON sales at current trends.

Pursue Clinical Development of Ostarine. We intend to initiate a proof of concept Phase II clinical trial for ostarine in the second quarter of 2006 in 120 elderly men and postmenopausal women to determine the effects on muscle and bone of varying doses of ostarine and to assess additional safety information. We believe that ostarine has the potential to treat a variety of indications, including frailty, osteoporosis, muscle wasting in end stage renal disease patients, and severe burn wounds and associated muscle wasting. Based on the results of our planned Phase II trial, which we expect to receive in the second half of 2006, we will determine ostarine's further clinical development path.

Pursue Clinical Development of Andarine. Under our joint collaboration and license agreement with Ortho Biotech for the continued clinical development of andarine and specified backup SARM compounds, we expect to continue to pursue the clinical development of andarine for the treatment of cachexia from various types of cancer. Andarine could also potentially be developed and commercialized for other men's and women's health indications. The terms of our agreement with Ortho Biotech are more fully described below in "Licenses and Collaborative Relationships — Ortho Biotech Products L.P., a subsidiary of Johnson & Johnson".

Build upon our Other SARM and Other Drug Discovery Capabilities to Sustain our Small Molecule Product Candidate Pipeline. We intend to develop our other SARMs, as well as other small molecule product candidates 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 continue to 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. We may seek one or more collaborators for the development and commercialization of our other SARM product candidates, including prostarine.

Licenses and Collaborative Relationships

We have established and intend to continue to pursue licenses from and collaborative relationships with pharmaceutical companies and academic institutions to further the development and commercialization of our small molecule products.

Ortho Biotech Products L.P., a Subsidiary of Johnson & Johnson

In March 2004, we entered into a joint collaboration and license agreement with Ortho Biotech for andarine for indications related to men's health and other licensed SARM compounds meeting specified criteria which Ortho Biotech may ultimately choose to develop instead of, or in addition to, andarine. We retain the right to independently develop specific SARM compounds which are excluded from the collaboration, including ostarine. Under the terms of the agreement, we received an up-front licensing fee and reimbursement of certain andarine development expenses totaling approximately $6.7 million, which is being amortized into revenue over five years. We are entitled to receive additional licensing fees and milestone payments prior to product launch of (1) up to an aggregate of $76 million for licensed products containing andarine or any replacement compound, and (2) up to $45 million for each licensed product containing any other compound developed under the agreement, upon achievement of specific clinical development milestones or receipt of regulatory approvals. Johnson & Johnson Pharmaceutical Research & Development, an affiliate of Ortho Biotech, is responsible for further clinical development and related expenses for andarine and other licensed SARM compounds. If a licensed product containing andarine or any other SARM compound is approved for commercial sale, Ortho Biotech will have full and exclusive decision-making authority for marketing such product in the United States and in markets outside the United States. Under the agreement, we have the option, subject to meeting specified conditions, to co-promote andarine and other licensed products to urologists in the United Stated for indications specifically related to men's health. Ortho Biotech is obligated to pay us up to double digit royalties on worldwide net sales of andarine and other licensed products, and an additional royalty in excess of 20% on all co-promoted net sales to urologists in the United States. Ortho Biotech may terminate the development or commercialization of andarine or any other licensed SARM compound under the agreement upon 90 days' notice, or 30 days' notice if there are safety issues, or may terminate the agreement for our uncured material breach.

Orion Corporation

In March 2000, we entered into a license and supply agreement with Orion to develop and commercialize products containing toremifene, the active pharmaceutical ingredient in Fareston and ACAPODENE. Our rights under the original license agreement were limited to specific disease fields pertaining to prostate cancer. In December 2004, we entered into an agreement with Orion to purchase specified Fareston-related assets which Orion had re-acquired from another licensee. We also entered into an amended and restated license and supply agreement with Orion which replaces the original license agreement. We paid Orion approximately $5.2 million under the 2004 agreements for the assets and related license rights.

Under the amended and restated license agreement, we obtained an exclusive license from Orion to develop and commercialize toremifene-based products, including Fareston and ACAPODENE, for all human indications worldwide, except breast cancer outside of the United States. We are required to pay Orion a royalty on sales by us and our affiliates of Fareston for breast cancer in the United States. We are also required to pay Orion a royalty on sales by us, our affiliates and third-party sublicensees of other toremifene-based products, including ACAPODENE if approved for commercial sale. We are obligated to purchase all of our clinical and commercial requirements for toremifene from Orion at transfer prices specified in the amended and restated agreement. Orion may terminate its supply obligations under specified circumstances. However, we have specified rights to assume manufacture of toremifene if Orion terminates its supply of toremifene because it has ceased to manufacture toremifene, although we would have to engage another supplier to do so. The term of the amended and restated agreement lasts, on a country-by-country basis, until the later of expiration of our own patents claiming the method of use or manufacture of toremifene for prostate cancer or the end of all marketing or regulatory exclusivity which we may obtain for

toremifene-based products. Orion may terminate the agreement as a result of our uncured material breach or bankruptcy.

University of Tennessee Research Foundation

In August 2002, we executed an amended and restated exclusive license agreement with UTRF granting us a worldwide exclusive license under their method of use patents relating to ACAPODENE for the prevention of prostate cancer in high risk men with PIN. Under the terms of the agreement, we are required to make annual maintenance fee payments and future royalty payments to UTRF. We are also required to pay all expenses to file, prosecute and maintain the patents relating to ACAPODENE for the prevention of prostate cancer in high risk men with high grade PIN.

The amended and restated license agreement superseded a 1998 license agreement with UTRF pursuant to which we reimbursed UTRF for certain patent expenses incurred by UTRF and agreed to make sublicense fee payments and future royalty payments.

In June 2002, we executed two amended and restated exclusive license agreements with UTRF granting us worldwide exclusive licenses under its composition of matter and method of use patents relating to SARM compounds, including andarine and ostarine, to market, distribute and sell licensed products. Under the terms of these license agreements, we are required to make annual maintenance fee payments and future royalty payments to UTRF. We are also required to pay all expenses to file, prosecute and maintain the patents relating to SARMs.

The amended and restated license agreements superseded a 2000 license agreement with UTRF pursuant to which we reimbursed UTRF for certain patent expenses incurred by UTRF and agreed to make sublicense fee payments and future royalty payments.

In December 2004, UTRF and the Ohio State University (OSU), entered into an inter-institutional agreement to share, in some cases, ownership of SARM technology, subject to our exclusive license rights, and royalty payments received from our SARM License with UTRF. We have agreed to amend our SARM license to require us to provide the same kind of reports and notifications to OSU that we currently provide to UTRF.

We have also executed with UTRF an amended and restated exclusive license agreement granting us worldwide exclusive licenses with UTRF's composition of matter and method of use patents for some of the preclinical programs pertaining to viral cytolytics and gene therapy.

National Cancer Institute

We had previously provided the National Cancer Institute (NCI) with ACAPODENE for their use in an independent Phase II clinical trial of ACAPODENE at the University of Pittsburgh. The objective of the trial was to assess the biological effects of ACAPODENE on the prostate gland. We have been informed that the NCI has discontinued the study early due to recruitment challenges.

Manufacturing

We do not currently own or operate manufacturing facilities for the production of clinical or commercial quantities of ACAPODENE or any of our SARMs, including andarine or ostarine. 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 toremifene citrate in specified doses, marketed as FARESTON, from Orion under an exclusive license and supply agreement providing for Orion to supply our requirements for commercial product. Orion has agreed to supply us with, and we have agreed to purchase from Orion, our worldwide requirements of toremifene citrate in specified doses 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 raw materials necessary to manufacture toremifene citrate tablets 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 any of the licensed fields, except breast cancer, is not

granted in the United States by December 31, 2009; 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 for toremifene tablets from Orion during the term of the agreement, which extends for the life of our patent rights, 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 to us 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 our bankruptcy or a material breach of the agreement by us that is not cured, we would not have the right to manufacture toremifene for ACAPODENE until Orion's patents with respect to the composition of matter of toremifene expire.

Under our joint collaboration and license agreement with Ortho Biotech, Ortho Biotech is responsible for the manufacture, packaging and supply of Andarine for our clinical trials and commercialization. We contract with EaglePicher Pharmaceutical Services, a division of EaglePicher Technologies, LLC, and Metrics, Inc. for our clinical supply needs for ostarine. Metrics uses the material provided by EaglePicher to provide us with clinical trial material for our ostarine clinical trials. We do not have a contract with EaglePicher or Metrics for the supply of ostarine for full-scale commercialization. The active ingredient in each of andarine and ostarine 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. EaglePicher Technologies, LLC, had previously filed for protection under the United States Bankruptcy Code, but has secured new financing and expects to emerge from bankruptcy in 2006. We are evaluating whether to transfer the manufacturing process to another contract manufacturer, and we expect to make a decision in the first half of the year.

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 opportunities will be reduced or eliminated if our competitors develop and commercialize similar 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 Prevention of Prostate Cancer in Men With High Grade PIN

Currently, there are no drug products that would compete with ACAPODENE for the treatment of high grade PIN to reduce the incidence of prostate cancer. There are government sponsored studies looking at supplements ability to prevent prostate cancer in men with high grade PIN. These studies are much smaller than the ACAPODENE Phase III trial and may not have enough clinical patients to show a statistically significant benefit. Avodart ® (dutasteride), from GlaxoSmithKline, is being evaluated in a Phase III clinical trial in prostate cancer prevention in men with elevated PSA. Men with high grade PIN were excluded from the Avodart trial, however.

ACAPODENE for the Treatment of Serious Side Effects of ADT

Currently, there are no products that have been approved by the FDA to treat multiple side effects of ADT. We are aware of a number of marketed drugs that are prescribed off-label for the treatment of single side effects. For

example, Evista® (raloxifene hydrochloride), a SERM marketed by Eli Lilly, Fosamax ® (aledronate sodium), a bisphosphonate marketed by Merck, and Actonel (risendronate sodium), a bisphosphonate marketed by Sanofi-Aventis and Procter & Gamble, are each prescribed for the treatment of osteoporosis. Amgen has an investigational drug, AMG-162, in Phase III trials for the prevention of fractures in men undergoing ADT. Effexor ® (venlafaxine hydrochloride), marketed by Wyeth Pharmaceuticals, Catapres ® (clonidine hydrochloride), marketed by Boehringer Ingelheim, and Megace ® (megesterol acetate), marketed by Bristol Myers Squibb, are prescribed off-label to treat hot flashes caused by ADT. External beam radiation and tamoxifen are both used to treat gynecomastia. There can be 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 ADT. In contrast, we believe that ACAPODENE, as a single product candidate, has the potential to treat multiple side effects.

Ostarine for the Treatment of Muscle Wasting

Oxandrin® (oxandrolone) is indicated as an adjunctive therapy to promote weight gain after weight loss following extensive surgery, chronic infections and severe trauma and in some patients who without pathophysiologic reasons fail to maintain normal weight. Oxandrin is marketed by Savient Pharmaceuticals and generates approximately $30 million in annual sales. Oxandrin has a black box warning for liver toxicity and has warnings and precautions related to increasing the risk for prostate cancer and virilization in women. Testosterone products have been used off-label to treat andropause and muscle wasting. Owing to its potentially unwanted effects in the prostate, inconvenient dosing and lack of investment in outcome trials, we believe that testosterone products have not had much of an impact on the market for muscle wasting. TAP Pharmaceuticals and Ligand Pharmaceuticals have announced a collaboration to develop a SARM and may be initiating Phase II studies in 2006, and other pharmaceutical companies are also developing SARMs.

Andarine for the Treatment of Cancer Cachexia

There are currently no drugs that have been approved by the FDA for the treatment of cancer cachexia. Although there are two commercially available drugs, nandrolone and oxandrolone, 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, but has been prescribed 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 oxandrolone, 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 ACAPODENE, andarine and ostarine, 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 any of our product candidates are approved for commercial sale.

FARESTON for the Treatment of Breast Cancer

There are a number of drugs that have been approved by the FDA for the treatment of breast cancer. Tamoxifen, which is marketed by AstraZeneca and several generic manufacturers, has been approved by the FDA for the treatment of advanced breast cancer and the reduction of breast cancer in women at high risk for developing the disease. The aromatase inhibitors, or AIs, such as anastrozole, letrozole and exemestane, are used to treat breast cancer in post menopausal women. The AIs are growing at the expense of SERMs due to clinical trials such as the clinical trial entitled “Arimidex and Tamoxifen: Alone or in Combination” or “ATAC,” which has shown efficacy and tolerability advantages for AIs compared to tamoxifen.

Sales and Marketing

In order to commercialize any future products, we must broaden our sales and marketing infrastructure or collaborate with third parties with sales and marketing experience and personnel. We plan to build a small, highly-focused, specialty sales and marketing infrastructure, which we expect to include 50 to 100 sales representatives, to market ACAPODENE to the relatively small and concentrated community of urologists and medical oncologists and to market FARESTON to targeted prescribers, principally medical oncologists, in the United States and to market

andarine to urologists in the United States. We believe that the urology and medical oncology markets in the United States are 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 countries in Europe and Asia and for other countries outside of the United States for prostate cancer-related conditions. We currently market FARESTON to medical oncologists in the United States.

Under the joint collaboration and license agreement we have entered into with Ortho Biotech for the development and commercialization of andarine and specified backup SARM compounds, Ortho Biotech will provide its larger sales force to market andarine or other specified collaboration compounds. We will have the right to use our sales force in the United States to market andarine and other collaboration compounds to urologists for men's health diseases. See "Licenses and Collaborative Relationships — Ortho Biotech Products L.P., a subsidiary of Johnson & Johnson".

Since ostarine for the treatment of muscle wasting and bone loss may be prescribed in the United States and abroad by general practitioners, as well as specialists like urologists, we anticipate that we will seek collaboration partners at an appropriate time to market, distribute and sell ostarine in the United States and abroad, although we expect to retain rights to sell to specialists in the United States through our specialty sales force.

We intend to devote sufficient marketing and sales efforts to maintain FARESTON sales at current trends.

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. Patents and other proprietary rights are an essential element of our business.

For ACAPODENE in the United States and internationally, we have entered into an amended and restated license and supply agreement with Orion Corporation granting us an exclusive license under Orion's patents covering the composition of matter of toremifene, the active pharmaceutical ingredient in ACAPODENE, for all uses in humans in the United States, and for all human uses outside the United States other than to treat breast cancer. The patent for toremifene will expire in the United States in 2009 and in Australia, Italy, Sweden and Switzerland in 2008. This patent has already expired in other European countries and in Japan and 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 the method of use patents that either have been already issued or other patents that may later be issued in respect of our owned and licensed patent applications relating to the use of ACAPODENE for the relevant indications we seek.

We have licensed from the UTRF method of use patents in the United States and issued 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 begin expiring 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 ADT.

In all countries in which we hold or have licensed rights to patents or patent applications related to ACAPODENE, the composition of matter patents for toremifene, the active pharmaceutical ingredient of ACAPODENE, 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 ADT 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 some patents issued and many more pending patent applications. Method of use patents for compounds where the composition of matter patents have expired, carry the risk of individual physician prescribed off-label use of the subject compounds.

In the event that patents issued 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 individual 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 ADT 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.

Until January 2005, our license from Orion was 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 ADT in the treatment of prostate cancer. We have since acquired the rights from Orion to market, sell and distribute a 60mg toremifene tablet under the trademark FARESTON for the treatment of advanced breast cancer in the United States and the rights to market, sell and distribute toremifene for all other indications in humans in the United States and in the rest of world except for breast cancer outside of the United States.

For andarine and other specified SARMs licensed to Ortho Biotech in the United States and abroad, we have an exclusive license from the UTRF under its patents and patent applications related to the composition of matter and formulations of, and methods of using, the active pharmaceutical ingredient in these compounds. 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 UTRF to its issued and pending patent applications in the United States and abroad related to methods of synthesizing the active pharmaceutical ingredient in andarine and its pending applications for methods for treating cancer cachexia with andarine.

For ostarine, we have an exclusive license from the UTRF 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 frailty, osteoporosis and andropause using ostarine.

For prostarine, we have an exclusive license from UTRF under its patent and 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 andromustine, we have an exclusive license from UTRF under its pending patent applications, as well as pending patent application of our own, in the United States and abroad 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 ADT 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 confidentiality agreements and our employees to execute assignment of invention agreements on commencement of their employment. Agreements with our employees also prevent them from bringing any 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 applicable regulations. Non-compliance with FDA regulations 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 efficacy. 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 an applicant's new drug 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 healthy human subjects. The goal of the Phase I clinical trial is to establish initial data about the safety, tolerability and pharmacokinetic properties 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 patients to determine if there are any side effects or other risks associated with the drug and to determine the optimal dose of the drug from the safety and efficacy profile developed from the clinical study. 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 pre-approval 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 a 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 fees. 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 a NDA with clinical data requires payment of a fee, with some exceptions. In return, FDA assigns a goal of six or 10 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 NDA. 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 for the drug. 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 record keeping 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 product's 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 a NDA, plus the time between the submission date of a 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 a 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 a 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, a 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 a 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 applicant submitting 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 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 applicant of 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 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. Currently, our only marketed product, FARESTON for the treatment of metastatic breast cancer, is eligible for coverage and reimbursement by third-party payors.

Research and Development

Since our inception, we have been focused on drug discovery, pre-clinical development and clinical development programs. Our research and development expenses were $30.9 million for the year ended December 31, 2005, $18.0 million for the year ended December 31, 2004 and $10.8 million for the year ended December 31, 2003.

Employees

As of December 31, 2005, we had 84 employees, 22 of whom were M.D.s and/or Ph.D.s. None of our employees is subject to a collective bargaining agreement. We believe that we have good relations with our employees.

Available Information

We file reports with the Securities and Exchange Commission (“SEC”), including annual reports on Form 10-K, quarterly reports on Form 10-Q, and other reports from time to time. The public may read and copy any materials filed with the SEC at the SEC’s Public Reference Room at 450 Fifth Street, NW, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. We are an electronic filer and the SEC maintains an Internet site at http://www.sec.gov that contains the reports, proxy and information statements, and other information filed electronically. Our website address is http://www.gtxinc.com. Please note that these website addresses are provided as inactive textual references only. We make available free of charge through our website our Annual Report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with or furnished to the SEC. The information provided on our website is not part of this report, and is therefore not incorporated by reference unless such information is otherwise specifically referenced elsewhere in this report.

Executive Officers and Other Key Employees of the Registrant

The following table sets forth information about our executive officers and other key employees as of March 1, 2006.

Name	Age	Position(s)
Directors and Executive Officers		
Mitchell S. Steiner, M.D., F.A.C.S.	45	Chief Executive Officer and Vice-Chairman of the Board of Directors
Marc S. Hanover	43	President, Chief Operating Officer and Director
Henry P. Doggrell	57	Vice President, General Counsel and Secretary
Mark E. Mosteller, CPA	43	Vice President, Chief Financial Officer and Treasurer
K. Gary Barnette, Ph.D.	38	Vice President, Clinical Research and Development Strategy
James T. Dalton, Ph.D.	43	Vice President, Preclinical Research and Development
Gregory A. Deener	44	Vice President, Sales and Marketing
Other Key Employees		
T. Gary Bird, Ph.D.	54	Director of Corporate Quality
Robert S. Boger, M.D.	59	Director of Drug Safety
Karen A. Veverka, Ph.D.	38	Director of Preclinical Development
Scott Segal, M.D.	42	Director of Clinical Development
Domingo Rodriguez, M.D.	44	Director of Clinical Operations

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. From 1995 to 2003, 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. Since 2003, Dr. Steiner has continued to serve on the faculty 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 in Memphis, Tennessee. Mr. Hanover holds a B.S. in Biology from the University of Memphis and a MBA in Finance from the University of Memphis.

Henry P. Doggrell has served as our General Counsel and Secretary since October 2001 and was appointed Vice President on January 20, 2005. 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, CPA, has served as our Chief Financial Officer since August 2001 and was appointed Vice President and Treasurer on January 20, 2005. 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.

K. Gary Barnette, Ph.D. was appointed Vice President, Clinical Research and Development Strategy in November 2005, and prior to that he served as Vice President, Clinical Research and Development since January 20, 2005. He also 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.

James T. Dalton, Ph.D. has served as Vice President, Preclinical Research and Development since January 2005. Dr. Dalton served as a scientific consultant to GTx from 1999 to 2005. Prior to joining GTx, Dr. Dalton held several academic appointments including Assistant and Associate Professor of Pharmaceutical Sciences in the College of Pharmacy at the University of Tennessee, Memphis (1992-2000) and Professor and Chair of the Division of Pharmaceutics, College of Pharmacy at The Ohio State University. SARMs were first discovered in Dr. Dalton's research laboratories, and he is co-inventor on all SARM patents. Dr. Dalton holds a B.S. in Pharmacy from the University of Cincinnati and a Ph.D. in Pharmaceutics and Pharmaceutical Chemistry from The Ohio State University.

Gregory A. Deener was appointed Vice President, Sales and Marketing on January 20, 2005, and prior to that he served as our Director of Marketing and Sales since February 2004. Mr. Deener has over 20 years of experience in Marketing and Sales and has launched a Urology medicine within the U.S. From 1996 to December 2003, Mr. Deener served as a Marketing Director for GlaxoSmithKline in various roles within the U.S. and Europe. Most recently Mr. Deener was responsible for the launch of Avodart, a urology medicine for BPH. From 1983 to 1996, Mr. Deener worked for Procter & Gamble in Brand Management and Sales. Mr. Deener holds a B.S. in Business Administration from the University of North Carolina at Chapel Hill.

T. Gary Bird, Ph.D. has served as our Director of Corporate Quality 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, a 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. was appointed Director of Drug Safety on January 20, 2005. Prior to that, he 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 a 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.

Scott Segal, M.D. has been Director of Clinical Development since June 20, 2005. Prior to joining GTx, he was Director of Clinical Operations and Medical Affairs for Men's Health at Solvay Pharmaceuticals Inc. From 2000-2004, Dr. Segal worked in various roles with Eli Lilly and Company, focusing primarily on the clinical development and global launch of Cialis, a medicine for erectile dysfunction. From 2002-2004, Dr. Segal was a Trustee of the American Academy of Pharmaceutical Physicians. Dr Segal holds a B.A in Biology from La Salle University and a M.D. from the Pennsylvania State University. Dr. Segal holds Board Certification in Internal Medicine by the American Board of Internal Medicine.

Domingo Rodriguez, M.D. was appointed Director of Clinical Operations on October 7, 2005, and prior to that, he served as our Regional Medical Scientist in the North East area of the United States since November 2004. Dr. Rodriguez has 19 years of experience in the pharmaceutical/biotech industry. Dr. Rodriguez started his career in the pharmaceutical industry in 1987 with Bristol-Myers Squibb and for almost 14 years he served in various roles including Area Director for the Medical Science Manager group, Acting Regional Sales Director, Senior Specialty District Sales Manager. From 2002 to 2004, Dr. Rodriguez served as a Medical Director, Medical Science Liaison and District Sales Manager for ICOS Corporation. Dr. Rodriguez completed medical school in Santo Domingo, Dominican Republic.

ITEM 1A. RISK FACTORS

We have identified the following additional risks and uncertainties that may have a material adverse effect on our business, financial condition or results of operations. Investors should carefully consider the risks described below before making an investment decision. Our business faces significant risks and the risks described below may not be the only risks we face. Additional risks not presently known to us or that we currently believe are immaterial may also significantly impair our business operations. If any of these risks occur, our business, results of operations or financial condition could suffer, the market price of our common stock could decline and you could lose all or part of your investment in our common stock.

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 have a limited operating history. As of December 31, 2005, we had an accumulated deficit of $194.3 million, of which $96.3 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 $36.8 million in 2005, $22.3 million in 2004, and $14.2 million in 2003. 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. We have financed our operations and internal growth almost exclusively through sales of common stock and preferred stock. In addition, we received an upfront license fee from Ortho Biotech in March 2004 for our joint collaboration for the development and commercialization of andarine and other licensed SARM compounds that Ortho Biotech may choose to develop. FARESTON is currently our only commercial product and, we expect, will account for all of our product revenue for the foreseeable future. For the twelve months ended December 31, 2005, we recognized $2.4 million in net revenues from the sale of FARESTON.

We expect our research and development expenses to increase in connection with our conduct of clinical trials. In addition, subject to regulatory approval of any of our product candidates, we expect to incur additional sales and marketing expenses 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 estimate that our current cash resources, interest on these funds and product revenue from the sale of FARESTON will be sufficient to meet our projected operating requirements through the first half of 2007. This estimate includes a milestone payment we will receive from Ortho Biotech upon initiation of our Phase II clinical trial for andarine but does not include funding from other milestone payments that we may receive under our existing collaboration, potential future collaboration agreements with pharmaceutical companies, or the potential future issuance and sale of our securities.

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 achievement of certain milestone events under our joint collaboration and license agreement with Ortho Biotech;
- the cost and timing of regulatory approvals;
- potential future licensing fees, milestone payments and royalty payments;
- 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, we expect to finance future cash needs through public or private equity offerings, debt financings or collaboration and licensing arrangements, such as our collaboration with Ortho Biotech, as well as through interest income earned on cash balances.

If we raise additional funds by issuing equity securities, our stockholders will 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 or licensing arrangements with third parties, it will be necessary to relinquish some rights to our technologies or our product candidates, or we may be required to grant licenses on terms that may not be 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. Typically, the failure rate for development candidates is high. Significant delays in clinical testing could materially impact our product development costs. We do not know whether planned clinical trials will begin on time, will need to be restructured or will be completed on schedule, if at all. 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
- our product candidates may not have 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 could 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 we 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 our worldwide requirements of toremifene, the active pharmaceutical ingredient in 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 due to our uncured material breach or bankruptcy, 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 ACAPODENE. In addition, Orion may terminate its obligation to supply us with toremifene if Orion ceases its manufacture of toremifene permanently, or if ACAPODENE is not approved for commercial sale in the United States by December 31, 2009. If such termination occurs because Orion is no longer manufacturing toremifene, or because such regulatory approval is not obtained prior to the specified date, we will have the right to manufacture ACAPODENE, but we would be required to make arrangements with a qualified alternative supplier and obtain FDA approval of such supplier to do so.

We also rely on Orion to cooperate with us in the filing and maintenance of regulatory filings with respect to the manufacture of ACAPODENE. Orion may terminate its obligation to assist us in obtaining and maintaining regulatory approval of ACAPODENE if we do not receive regulatory approval for ACAPODENE by December 31, 2009. If Orion terminates its obligation to cooperate in these activities, or does not cooperate with us or otherwise does not successfully file or maintain these regulatory filings, we would be required to make arrangements with a qualified alternative supplier, which could delay or prevent regulatory approval of ACAPODENE.

Under our joint collaboration and license agreement with Ortho Biotech, Ortho Biotech is responsible for the manufacture, packaging and supply of andarine for both clinical trials and commercialization. We relied on Eagle Picher Pharmaceutical Services as our single supplier for ostarine, but currently have sufficient supply to complete our planned Phase II clinical trials. Eagle Picher Technologies, LLC, the parent company of Eagle Picher Pharmaceutical Services, had previously filed for protection under the bankruptcy code, but has secured new financing and expects to emerge from bankruptcy in 2006. We are evaluating whether to transfer the manufacturing process to another contract manufacturer and expect to make a decision the first half of the year. If our current supply of ostarine becomes unusable, if our ostarine supply is not sufficient to complete our planned Phase II clinical trials, or if we are unsuccessful in identifying a contract manufacturer or negotiating a manufacturing agreement on a timely basis, we could experience a delay in receiving an adequate supply of ostarine for use in our clinical trials.

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 EaglePicher or Ortho Biotech for andarine, or to do so at an acceptable cost, or if these or other suppliers fail to meet our requirements for these product candidates or for ostarine for any reason, we would be required to obtain alternate suppliers. However, we may not be permitted to obtain alternate suppliers for ACAPODENE under our license agreement with Orion if Orion terminates its supply of ACAPODENE due to our uncured material breach or bankruptcy. Any inability to obtain alternate suppliers, including an inability to obtain approval of an alternate supplier from the 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;
- the possible termination or non-renewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us;
- the possible exercise by Orion of its right to terminate its obligation to supply us with toremifene;
    - if it permanently ceases manufacture of toremifene or if we do not obtain regulatory approval of ACAPODENE prior to December 31, 2009; and
    - if Orion terminates due to our uncured material breach or bankruptcy.

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 toremifene for third parties for sale outside 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 are dependent on our collaborative arrangement with Ortho Biotech to develop and commercialize andarine, and we may be dependent upon additional collaborative arrangements to complete the development and commercialization of some of our other product candidates. These collaborative arrangements may place the development of our product candidates outside our control, may require us to relinquish important rights or may otherwise be on terms unfavorable to us.

Any loss of Ortho Biotech as a collaborator in the development or commercialization of andarine, dispute over the terms of the collaboration or other adverse development in our relationship with Ortho Biotech could materially harm our business and might accelerate our need for additional capital.

We may not be successful in entering into additional 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, including our arrangement with Ortho Biotech for the development of andarine, subjects us to a number of risks, including:

- we may not be able to control the amount and timing of resources that our partners may devote to the product candidates;
- our partners 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 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 excludes the use of toremifene in humans to treat breast cancer outside the United States and may limit our ability to market ACAPODENE for human uses of toremifene outside the United States.

Our exclusive license from Orion excludes the use of toremifene for the treatment of breast cancer outside the United States. Orion has licensed to other parties the right to market, sell and distribute toremifene for the treatment of advanced breast cancer outside the United States and could license additional parties to market, sell and distribute toremifene for this indication outside the United States.

Under the terms of our license agreement with Orion, Orion may require us to modify our final ACAPODENE development plans for specified major markets outside the United States if those development plans could adversely affect Orion's or Orion's other licensees' activities related to FARESTON for breast cancer outside the United States or toremifene-based animal health products. Although we do not believe that our development plans adversely affect these activities, any future modifications to our plans imposed by Orion may limit our ability to maximize the commercial potential of ACAPODENE.

Furthermore, we and our affiliates are prohibited from marketing or selling products containing toremifene or related SERM compounds for human use (1) in the United States and other major countries located outside the European Union during the term of Orion's patents covering toremifene in such countries and (2) in major countries in the European Union through October 2006, other than in the dosage forms or formulations which are, or may in the future be, manufactured by Orion under our agreement with Orion. The binding effect of this noncompetition provision on us and our affiliates may make it more difficult for us to be acquired by some potential buyers during

the relevant time periods 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, or our licensors', patents expire or are invalidated or are found to be unenforceable, or if some or all of our patent applications do not yield issued patents or yield patents with narrow claims, or if we are estopped from asserting that the claims of an issued patent cover a product of a third party, we may be subject to competition from third parties with products with the same active pharmaceutical ingredients as our product candidates.

Our commercial success will depend in part on obtaining and maintaining patent and trade secret protection for our product candidates, the methods for treating patients in the product indications using these product candidates and the methods used to synthesize these product candidates. We will be able to protect our product candidates and the methods for treating patients in the product indications using these product candidates from unauthorized use by third parties only to the extent that we or our exclusive licensors own or control such valid and enforceable patents or trade secrets. Our rights to specified patent applications relating to SARM compounds that we have licensed from UTRF, are subject to the terms of UTRF's license with The Ohio State University, or OSU, and our rights to future related improvements are subject to UTRF's exercise of an exclusive option under its agreement with OSU for such improvements, which UTRF can exercise at no additional cost to it. In addition, under the terms of our agreements with the diagnostic companies to which we provide clinical samples from our Phase IIb clinical trial of ACAPODENE, we will not obtain any intellectual property rights in any of their developments, including any test developed to detect high grade PIN or prostate cancer.

Even if our product candidates and the methods for treating patients in the product indications using these product candidates are covered by valid and enforceable patents and have claims with sufficient scope and support in the specification, the patents will provide protection only for a limited amount of time. For example, the patent that we have licensed from Orion covering the composition of matter of toremifene expires in the United States in 2009. Foreign counterparts of this patent have either already expired or will expire in Australia, Italy, Sweden and Switzerland in 2008, that is, 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, relating to the use of ACAPODENE for the relevant product indications that have been issued or may be issued from our owned or licensed patent applications. To date, most of our applications for method of use patents filed for ACAPODENE outside of the United States are still pending and have not yielded issued patents. Although we intend to apply, if appropriate, for regulatory market exclusivity and extensions of patent term under applicable European and United States laws, we might not be able to secure any such regulatory exclusivity or extension of patent term. We are not eligible for any such exclusivity or further extension of the composition of matter patent of toremifene in the United States.

Our and our licensors' ability to obtain patents can be highly uncertain and involve complex and in some cases unsettled legal issues and factual questions. Furthermore, different countries have different procedures for obtaining patents, and patents issued in different countries provide different degrees of protection against the use of a patented invention by others. Therefore, if the issuance to us or our licensors, in a given country, of a patent covering an invention is not followed by the issuance, in other countries, of patents covering the same invention, or if any judicial interpretation of the validity, enforceability or scope of the claims in a patent issued in one country is not similar to the interpretation given to the corresponding patent issued in another country, our ability to protect our intellectual property in those countries may be limited. 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 to us or our licensors regarding our product candidates or methods of using them, those patents can be challenged by our competitors who can argue such patents are invalid or unenforceable or that the claims of the issued patents should be limited or narrowly construed. Patents also will not protect our product candidates if competitors devise ways of making or using these product candidates without legally infringing our patents. The Federal Food, Drug, and Cosmetic Act and FDA regulations and policies create a regulatory environment that encourages companies to challenge branded drug patents or to create noninfringing versions of a patented product in order to facilitate the approval of abbreviated new drug applications for generic substitutes. These same types of incentives encourage competitors to submit new drug applications that rely on literature and clinical data not prepared for or by the drug sponsor, providing another less burdensome pathway to approval.

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 toremifene products could decrease our sales of ACAPODENE and could lead to pricing pressure if such products become available at competitive prices and in dosages that are appropriate for the indications for which we are developing ACAPODENE.

In all countries in which we hold or have licensed rights to patents or patent applications related to ACAPODENE, the composition of matter patents we license from Orion will expire before our method of use patents, and in some countries outside the United States, the composition of matter patents have already expired. Our method of use patents may not protect ACAPODENE from the risk of off-label sale or use of other toremifene products in place of ACAPODENE. 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 or its equivalent. Such off-label uses are common across medical specialties and are particularly prevalent for cancer treatments. Any off-label sales of toremifene may adversely affect our ability to generate revenue from the sale of ACAPODENE, if approved for commercial sale.

Even in the event that patents are issued from 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 toremifene products for uses for which FARESTON has already been approved. Thus, physicians in such countries would be permitted to prescribe these other toremifene products for indications that are protected by our method of use patents or patents issuing from pending patent applications, even though these toremifene products would not have been approved for those uses, and in most cases the competitor would not be liable for infringing our patents. Moreover, because Orion has licensed and could further license other parties to market, sell and distribute toremifene for breast cancer outside the United States, physicians in such countries 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 are issued with respect to 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, we would have no patent to prevent competitors from marketing and selling 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 or our licensors, which may later result in issued patents that cover the production, manufacture, commercialization, formulation or use of our product candidates. In addition, the production, manufacture, commercialization, formulation 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 the patent holder 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 are insufficient for approval and require additional preclinical, clinical or other studies. For example, we believe that if the results of our ongoing Phase III clinical trial of ACAPODENE for the reduction in the incidence of prostate cancer in men with high grade PIN are sufficiently positive, that trial will be sufficient to serve as a single pivotal Phase III clinical trial for this indication. In September 2005, we received a Special Protocol Assessment from the FDA. A SPA is designed to facilitate the FDA's review and approval of drug products by allowing the agency to evaluate the proposed design and size of clinical trials that are intended to form the primary basis for determining a drug product's efficacy. If agreement is reached with the FDA, a SPA documents the terms and conditions under which the design of the subject trial will be adequate for submission of the efficacy and human safety portion of a NDA. However, there are circumstances under which we may not receive the benefits of the SPA, notably including if the FDA subsequently identifies a substantial scientific issue essential to determining the product's safety or efficacy. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate. Furthermore, even if we file an application with the FDA for marketing approval of a product candidate, it may not result in marketing approval from the FDA.

We do not expect to receive regulatory approval for the commercial sale of any of our product candidates that are in development for the next few years. The inability to obtain FDA approval or approval from comparable authorities in other countries for such candidates would prevent us from commercializing our product candidates in the United States or other countries. See the section entitled "Business — Government Regulation" under Item 1 above for additional information regarding risks associated with approval, as well as risks related to post-approval requirements.

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.

Our only marketed product generating revenue is FARESTON. FARESTON is subject to a number of risks that may cause sales of FARESTON to continue to decline.

FARESTON is currently our only marketed product generating sales. Sales of FARESTON in the United States have been declining. Continued sales of FARESTON could be impacted by many factors. The occurrence of one or more of the following risks may cause sales of FARESTON to decline:

- the loss of the availability of Orion's website to market FARESTON, which is an important source of advertising;
- the loss of one or more of our three largest wholesale drug distributors, which accounted for approximately 94% of our revenue generated from the sale of FARESTON for the year ended December 31, 2005;
- the continued success of competing products, including aromatase inhibitors;
- the loss of coverage or reimbursement for FARESTON from Medicare and Medicaid, private health insurers or other third-party payors;
- exposure to product liability claims related to the commercial sale of FARESTON, which may exceed our product liability insurance;
- the failure of Orion to maintain regulatory filings or comply with applicable FDA requirements with respect to FARESTON;
- the ability of third parties to market and sell generic toremifene products that will compete with FARESTON for the treatment of breast cancer after the composition of matter patents that we license from Orion expire in the United States in 2009;
- the loss of Orion, upon which we rely as a single source, as our supplier of FARESTON; and
- our inability to manufacture FARESTON until Orion's patents with respect to the composition of matter of toremifene expire if Orion terminates our license and supply agreement due to our uncured material breach or bankruptcy.

If we are unable to expand our 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 from such candidates.

We have limited experience as a company in the sales, marketing and distribution of pharmaceutical products. There are risks involved with building our own sales and marketing capabilities, as well as entering into arrangements with third parties to perform these services. For example, building a sales force is expensive and time-consuming and could delay any launch of a product candidate. 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 products we sell at 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 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 may suffer. In December 2003, the President of the United States signed into law the Medicare Prescription Drug, Improvement and Modernization Act of 2003, 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 the program. 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 that we may 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 or products we sell. Cost-control initiatives could decrease the price we might establish for products that we may develop or that we sell, 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, Improvement and Modernization Act of 2003 gives discretion to the Secretary of Health and Human Services to allow drug reimportation into the United States under some circumstances from foreign countries, 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 product that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or products 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;
- 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 for which we obtain or hold approvals.

We have product liability insurance that covers our clinical trials and commercial products up to a $20.0 million annual aggregate limit. 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 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 opportunities 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, Sanofi-Aventis, Procter & Gamble, Wyeth Pharmaceuticals, Boehringer Ingelheim and Bristol Myers Squibb that are prescribed off-label to treat single side effects of this therapy; that external beam radiation is used to treat breast pain and enlargement; and that Amgen Inc. is developing a product candidate for the treatment of bone loss in post-cancer patients. 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. Testosterone and other anabolic agents are used to treat involuntary weight loss in patients who have acute muscle wasting. Also, TAP Pharmaceuticals and Ligand Pharmaceuticals have entered into a collaboration agreement to develop a SARM and may be initiating Phase II studies in 2006. 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 $15.0 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 ostarine is initially commercialized, including 50 to 100 sales representatives. 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 Our Common Stock

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

The market prices for securities of biotechnology 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 or products, our clinical trials or our sales and marketing activities;
- the commercial success of any product approved by the FDA or its foreign counterparts;
- the terms and timing of any collaborative, licensing or other arrangements that we may establish;
- 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 significant 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.

Our officers, directors and largest stockholders will maintain the ability to control all matters submitted to stockholders for approval.

As of January 31, 2006, our officers, directors and holders of 5% or more of our outstanding common stock beneficially owned approximately 67.2% of our outstanding common stock. 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 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.

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.

For the 12-month period ended December 31, 2005, the average daily trading volume of our common stock on the NASDAQ National Market was less than 55,937 shares. As a result, future sales of a substantial number of shares of our common stock in the public market, or the perception that such sales may occur, could adversely affect the then-prevailing market price of our common stock. As of December 31, 2005, we had 30,993,967 shares of common stock outstanding.

Based on information currently available to us, all of the shares of our common stock currently outstanding are eligible for sale in the public market, subject in some cases to volume and other limitations under federal securities laws.

Moreover, J.R. Hyde, III, Oracle Partners, L.P. and Memphis Biomed Ventures I, L.P., three of our largest stockholders, and their affiliates, have rights, subject to some conditions, to require us to file registration statements covering the approximately 11.1 million shares of common stock they hold in the aggregate which are subject to registration rights or to include these shares in registration statements that we may file for ourselves or other stockholders. Additionally, all shares of common stock that we may issue under our employee benefit plans can be freely sold in the public market upon issuance.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

We sublease approximately 53,000 square feet of laboratory and office space in Memphis, Tennessee, under an operating lease through December 31, 2007 with an option to extend for up to three additional years. This lease is terminable by either party on 90 days' notice.

ITEM 3. LEGAL PROCEEDINGS

We are not currently involved in any material legal proceedings.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market for Registrant's Common Equity

Our common stock began trading on the NASDAQ National Market under the symbol "GTXI" on February 3, 2004. Prior to that date, there was no established public trading market for our common stock. The following table presents, for the periods indicated, the high and low closing sales prices per share of our common stock as reported on the NASDAQ National Market.

	2005		2004	
	High	Low	High	Low
First Quarter[1]	$13.66	$9.10	$ 12.90	$ 9.67
Second Quarter	11.48	8.68	14.14	10.41
Third Quarter	12.00	8.84	11.66	8.51
Fourth Quarter	9.46	7.43	14.86	11.15

(1) For the first quarter of 2004, the measurement period commences on February 3, 2004, the date our common stock began trading on the NASDAQ National Market.

On March 1, 2006 the closing price of our common stock as reported on the NASDAQ National Market was $11.52 per share and there were approximately 51 holders of record of our common stock.

Dividend Policy

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.

Use of Proceeds from Registered Securities

We sold 5,400,000 shares of common stock in our initial public offering at $14.50 per share pursuant to a Registration Statement on Form S-1 (333-109700) that was declared effective by the SEC on February 2, 2004. The offering terminated after the sale of all of the securities registered on the Registration Statement and the expiration of the underwriters' over-allotment option. After deducting the underwriting discounts and the offering expenses, we received net proceeds of $70.4 million. From the time of receipt through December 31, 2005, we had invested the available net proceeds in short-term securities. In addition, approximately $49.2 million of the net proceeds were used to fund our operations through December 31, 2005, approximately $2.5 million of the net proceeds were used for capital expenditures and approximately $4.8 million of the net proceeds were used to acquire a license from

Orion Corporation. The application of the net proceeds from our initial public offering as set forth above represents our best estimate and does not represent a material change from the use of proceeds as described in the prospectus for our initial public offering. No such payments were made to directors, officers or persons owning 10 percent or more of our common stock or to their associates, or to our affiliates, other than payments in the ordinary course of business to officers for salaries and to non-employee directors as compensation for Board or Board committee service. We plan to use the balance of the proceeds to fund our clinical trials and other research and development activities and for general corporate purposes. In addition, we may use a portion of the proceeds to acquire products, technologies or businesses, although we currently have no binding commitments or agreements relating to any of these types of transactions.

ITEM 6. 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 audited financial statements, notes thereto and other financial information included elsewhere in this Annual Report on Form 10-K. The statements of operations data for the years ended December 31, 2003, 2004 and 2005, and the balance sheet data at December 31, 2004 and 2005, are derived from our audited financial statements included elsewhere in this Annual Report on Form 10-K. The statements of operations data for the years ended December 31, 2001 and 2002, and the consolidated balance sheet data at December 31, 2001, 2002 and 2003 are derived from our audited financial statements that are not included in this Annual Report on Form 10-K. Historical results are not indicative of the results to be expected in the future.

	Year Ended December 31,				
	2005	2004	2003	2002	2001
	(in thousands, except per share data)				
Statement of Operations Data:					
Revenues:					
Product sales, net	$ 2,445	$ –	$ –	$ –	$ –
Total collaboration revenue	1,337	1,867	–	–	–
Total revenues	3,782	1,867	–	–	–
Operating expenses:					
Cost of product sales	1,573	–	–	–	–
Research and development expenses	30,923	17,950	10,778	9,569	5,921
General and administrative expenses	9,845	7,211	3,559	2,453	2,225
Loss from operations	(38,559)	(23,294)	(14,337)	(12,022)	(8,146)
Interest income	1,720	946	143	156	83
Net loss	(36,839)	(22,348)	(14,194)	(11,866)	(8,063)
Accrued preferred stock dividends	—	(455)	(3,436)	(2,147)	(790)
Adjustment to preferred stock redemption value	—	17,125	(77,844)	(7,220)	(57)
Net loss attributable to common stockholders	$ (36,839)	$ (5,678)	$ (95,474)	$ (21,233)	$ (8,910)
Net loss per share attributable to common stockholders:					
Basic	$ (1.42)	$ (0.25)	$ (12.34)	$ (2.75)	$ (1.15)
Diluted	$ (1.42)	$ (0.93)	$ (12.34)	$ (2.75)	$ (1.15)

	As of December 31,				
	2005	2004	2003	2002	2001
			(in thousands)		
Balance Sheet Data:					
Cash and cash equivalents	$ 74,014	$ 64,528	$ 14,769	$ 8,925	$ 8,834
Working capital	70,030	61,298	12,775	7,654	8,544
Total assets	82,811	73,082	17,310	10,030	10,117
Cumulative redeemable convertible preferred stock	–	–	165,292	64,026	43,702
Accumulated deficit	(194,269)	(157,430)	(151,752)	(56,278)	(35,045)
Total stockholders' equity (deficit)	73,579	63,909	(150,231)	(55,308)	(34,075)

ITEM 7. 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 Annual Report on Form 10-K. 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 Item 1A "Risk Factors" and elsewhere in this Annual Report on Form 10-K.

GTx is a biopharmaceutical company dedicated to the discovery, development and commercialization of therapeutics for cancer and serious conditions related to men's health. Our lead drug discovery and development programs are focused on small molecules that selectively modulate the effects of estrogens and androgens, two essential classes of hormones. We are developing ACAPODENE® (toremifene citrate), a selective estrogen receptor modulator, or SERM, in two separate clinical programs in men: First, a pivotal Phase III clinical trial for the treatment of serious side effects of ADT, or ADT, for advanced prostate cancer, and second, a pivotal Phase III clinical trial for the prevention of prostate cancer in high risk men with precancerous prostate lesions called high grade prostate intraepithelial neoplasia, or high grade PIN. In our third clinical program we are developing ostarine, a selective androgen receptor modulator, or SARM. We believe that ostarine has the potential to treat a variety of indications including muscle wasting and bone loss in frail elderly patients, osteoporosis, muscle wasting in end stage renal disease patients, and severe burn wounds and associated muscle wasting. We are currently planning a Phase II clinical trial of ostarine for the treatment of muscle wasting and bone loss in 120 elderly men and postmenopausal women to commence in the second quarter of 2006. In our fourth clinical program, we and our partner, Ortho Biotech Products, L.P., a subsidiary of Johnson & Johnson (Ortho Biotech), are developing andarine, another one of our SARMs, for the treatment of weight loss from various types of cancer, which is known as cancer cachexia. We are planning a Phase II clinical trial with Ortho Biotech.

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

We commenced a pivotal Phase III clinical trial of ACAPODENE under a Special Protocol Assessment, or a SPA, with the United States Food and Drug Administration, or FDA, for the treatment of serious side effects of ADT in November 2003. We anticipate that we will complete the ADTclinical trial in the fourth quarter of 2007 with a New Drug Application, or NDA, filing expected in the first half of 2008 if the results are favorable. We also plan to conduct a one-year blinded extension trial in the same patients to gather additional fracture data. We expect that research and development expenses related to this program will continue to increase in future periods until these studies are completed.

In January 2005, we initiated a pivotal Phase III clinical trial of ACAPODENE for the prevention of prostate cancer in high risk men with high grade PIN,which is being conducted under a SPA with the FDA. We expect to reach our total enrollment goal of 1,260 patients by the end of the first quarter of 2006. We anticipate conducting an efficacy analysis within 24 months of completion of enrollment. Once we have achieved the efficacy endpoint, which may occur at or after the intermin analysis, we plan to file a NDA. We anticipate that we will collect sufficient safety data required under the SPA during the NDA review process if we file a NDA based on the 24 month interim analysis. We expect that research and development expenses related to this program will continue to increase in future periods until we have completed the NDA review process.

In our third clinical program, ostarine, a SARM, is being developed to treat a variety of medical conditions relating to muscle wasting and/or bone loss. We are currently planning to initiate a proof of concept Phase II clinical trial of ostarine for the treatment of muscle wasting and bone loss to commence in the second quarter of 2006. We expect that research and development expenses related to this program will continue to increase in future periods as we continue the clinical development of ostarine.

In our fourth clinical program, andarine, a SARM, is being developed in collaboration with Ortho Biotech, initially for the treatment of cachexia from various types of cancer, a potentially life-threatening muscle wasting complication of many cancers.

In our fourth clinical program, andarine, a SARM, is being developed in collaboration with Ortho Biotech. In March 2004, we entered into a joint collaboration and license agreement with Ortho Biotech for andarine for indications related to men's health and other licensed SARM compounds meeting specified criteria which Ortho Biotech may ultimately choose to develop instead of, or in addition to, andarine. We retain the right to independently develop specific SARM compounds which are excluded from the collaboration, including ostarine. Under the terms of the agreement, we received an up-front licensing fee and reimbursement of certain andarine development expenses totaling approximately $6.7 million, which is being amortized into revenue over five years. We are entitled to receive additional licensing fees and milestone payments prior to product launch of (1) up to an aggregate of $76 million for licensed products containing andarine or any replacement compound, and (2) up to $45 million for each licensed product containing any other compound developed under the agreement, upon achievement of specific clinical development milestones or receipt of regulatory approvals. Johnson & Johnson Pharmaceutical Research & Development, an affiliate of Ortho Biotech, is responsible for further clinical development and related expenses for andarine and other licensed SARM compounds. If a licensed product containing andarine or any other SARM compound is approved for commercial sale, Ortho Biotech will have full and exclusive decision-making authority for marketing such product in the United States and in markets outside the United States. Under the agreement, we have the option, subject to meeting specified conditions, to co-promote andarine and other licensed products to urologists in the United Stated for indications specifically related to men's health. Ortho Biotech is obligated to pay us up to double digit royalties on worldwide net sales of andarine and other licensed products, and an additional royalty in excess of 20% on all co-promoted net sales to urologists in the United States. Ortho Biotech may terminate the development or commercialization of andarine or any other licensed SARM compound under the agreement upon 90 days' notice, or 30 days' notice if there are safety issues, or may terminate the agreement for our uncured material breach.

We market FARESTON® (toremifene citrate) 60 mg tablets for the treatment of metastatic breast cancer in post-menopausal women in the United States. In January 2005, we acquired from Orion Corporation the rights to distribute FARESTON in the United States and a license to toremifene, the active pharmaceutical ingredient in FARESTON and ACAPODENE, for all indications worldwide except breast cancer outside of the United States.

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, expand our sales and marketing capabilities and grow our operations. We believe that our current cash resources, interest on these funds and product revenue from the sale of FARESTON will be sufficient to meet our projected operating requirements through the first half of 2007. Until we can generate a sufficient amount of product revenue, we expect to finance future cash needs through public or private equity offerings, debt financings or collaboration and licensing arrangements. 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.

Sales and Marketing

We market FARESTON, a SERM, for the treatment of metastatic breast cancer. Sales of pharmaceuticals in the SERM class sales have declined in recent years as aromatase inhibitors (AIs) have gained market share. We believe that AIs will continue to capture market share from SERMs, including FARESTON, resulting in a continued decline in FARESTON sales.

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 and FARESTON prescribers, principally medical oncologists, in the United States and to market andarine to urologists in the United States.

Research and Development

Since our inception in 1997, we have been focused on drug discovery and development programs. Research and development expenses represented 76% of our total operating expenses for the year ended December 31, 2005. 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, toxicology studies, clinical trials, regulatory affairs, and quality assurance activities.

We expect that research and development expenditures will continue to increase in future years due to (1) the continuation of the pivotal Phase III clinical trial of ACAPODENE for the treatment of serious side effects of ADT for advance prostate cancer, (2) the continuation of the pivotal Phase III clinical trial of ACAPODENE for the prevention of prostate cancer in men with high grade PIN, (3) the continued clinical and preclinical development of other product candidates in our SARM program that are not included in our collaboration with Ortho Biotech, including ostarine and prostarine, (4) the continued preclinical development of other product candidates, including andromustine and (5) the increase in research and development personnel.

Research and Development Expenses

The following table identifies, for each of our product candidates, the development phase, the status, and research and development expenses for each product candidate as well as information pertaining to our other research and development efforts for each of the periods presented. Research and development spending for past periods is not indicative of spending in future periods.

Program	Product Candidate/ Indication	Development Phase	Status	Year Ended December 31,		
				2005	2004	2003
					(in thousands)	
SERM	**ACAPODENE 80 mg** Side effects of ADT	Pivotal Phase III clinical trial	Phase III clinical trial ongoing under a SPA; fully enrolled; obtained statistically significant BMD results from a planned interim analysis in fourth quarter of 2005	$11,720	$6,484	$1,625
	ACAPODENE 20 mg Prevention of prostate cancer in men with high grade PIN	Pivotal Phase III clinical trial	Phase III clinical trial ongoing under a SPA; attainment of enrollment goal anticipated by the end of the first quarter of 2006	7,615	2,247	2,833
SARM	**Ostarine** Muscle wasting and bone loss in elderly men and postmenopausal women	Planning to initiate Phase II clinical trial in second quarter of 2006	Two Phase I clinical trials completed	4,750	4,011	–
	Andarine Cancer cachexia from various types of cancer	Planning Phase II clinical trial with Ortho Biotech	Four Phase I clinical trials completed	173	2,212	5,305
Other research and development		Preclinical	Preclinical studies	6,665	2,996	1,015
Total research and development expense				$30,923	$17,950	$10,778

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 Item 1A “Risk Factors” of this Annual Report on Form 10-K, 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 a NDA, the FDA may refuse to file the application, or if accepted for filing, the FDA may not 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 under Item 1A “Risk Factors” of this Annual Report on Form 10-K.

General and Administrative Expense

Our general and administrative expenses consist primarily of salaries and other related costs for personnel serving executive, finance, legal, human resources, information technology, public relations and marketing functions. Other costs include facility costs not otherwise included in research and development expense and professional fees for legal, accounting, public relations, and marketing services. General and administrative expenses also include insurance costs and FARESTON selling and distribution expenses. We expect that our general and administrative expenses will increase in future periods as we add personnel and infrastructure to support the planned growth of our business. In addition, we plan to expand our sales and marketing efforts which will result in increased sales and marketing expenses in future years.

Our net loss for the year ended December 31, 2005 was $36.8 million. Our net loss included FARESTON net product sales of $2.4 million and the recognition of collaboration revenue of $1.3 million. We have financed our operations and internal growth almost exclusively through private placements of preferred stock and our initial public offering. On October 17, 2005, we completed an underwritten public offering of 6,325,000 shares of common stock and received net proceeds of approximately $45.7 million. 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, expand our sales and marketing capabilities and grow our operations.

Critical Accounting Policies

Our management’s discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires us to make estimates and

assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported revenues and expenses during the reporting periods. In preparing these financial statements, management has made its best estimates and judgments of certain amounts included in the financial statements giving due consideration to materiality. On an ongoing basis, we evaluate our estimates and judgments related to revenue recognition, income taxes, intangible assets, long-term service contracts and other contingencies. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 to our financial statements appearing at the end of this Annual Report on Form 10-K, we believe that the following accounting policies are most critical to aid you in fully understanding and evaluating our reported financial results.

Revenue Recognition

We use revenue recognition criteria outlined in Staff Accounting Bulletin ("SAB") No. 101, *"Revenue Recognition in Financial Statements"* as amended by SAB No. 104 (together, "SAB" 104) and Statement of Financial Accounting Standards No. 48 "Revenue Recognition When Right of Return Exists" (FAS 48) and Emerging Issues Task Force ("EITF") Issue 00-21, *"Revenue Arrangements with Multiple Deliverables"* ("EITF 00-21"). Accordingly, revenues from licensing agreements are recognized based on the performance requirements of the agreement. Non-refundable up-front fees, where we have an ongoing involvement or performance obligation, are generally recorded as deferred revenue in the balance sheet and amortized into license fees in the statement of operations over the term of the performance obligation. We estimated the performance obligation period to be five years for the development of andarine. The factors that drive the actual development period of a pharmaceutical product are inherently uncertain, and include determining the timing and expected costs to complete the project, projecting regulatory approvals and anticipating potential delays. We use all of these factors in initially estimating the economic useful lives of our performance obligations, and we also continuously monitor these factors for indications of appropriate revisions.

We recognize net product sales revenue from the sale of FARESTON less deductions for estimated sales rebates, sales discounts and sales returns. We recognize revenue from product sales when the goods are shipped and title and risk of loss pass to the customer and the other criteria of SAB 104 and FAS 48 are satisfied. We accept returns of products near their expiration date.

Revenues derived from reimbursements of costs associated with the development of andarine are recorded in compliance with EITF Issue 99-19, *"Reporting Revenue Gross as a Principal Versus Net as an Agent"* ("EITF 99-19"). According to the criteria established by this EITF Issue, in transactions where we act as a principal, have discretion to choose suppliers, bear credit risk and perform part of the services required in the transaction, we have met the criteria to record revenue for the gross amount of the reimbursements.

Research and Development Costs

We expense 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 our behalf.

Patent Costs

We expense patent costs, including legal expenses, in the period in which they are incurred. Patent expenses are included in general and administrative expenses in our statements of operations.

Deferred Stock Compensation

In anticipation of our initial public offering in February 2004, 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 from June 30, 2003 to December 31, 2003. Accordingly, we recorded non-cash deferred stock-based compensation expense of $4.1 million in 2003, and are amortizing the related expense on the straight-line basis over the service period, which is generally five years. Deferred stock compensation for options granted to employees has

been determined as the difference between the deemed fair value of our common stock for financial reporting purposes on the date such options were granted and the applicable exercise price.

Income Taxes

We account 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 basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some portion or all of the deferred tax assets will not be realized. This valuation allowance is estimated by management based on our projected future taxable income. The estimate of future taxable income is highly subjective. We have incurred losses since inception and anticipate that we will incur continued losses for the foreseeable future. However, these assumptions may be inaccurate, and unanticipated events and circumstances may occur in the future. To the extent actual results differ from these estimates, our future results of operations may be affected. At December 31, 2005, net of the valuation allowance, the net deferred tax assets were reduced to zero.

Purchased Intangible Assets

We account for our purchased intangible assets in accordance with Statement of Financial Accounting Standards ("SFAS") No. 142, *Goodwill and Other Intangible Assets*, which requires that purchased intangible assets with finite lives be amortized over their estimated economic lives. Our purchased intangible asset, license fee, represents a license fee paid to Orion in connection with entering into an amended and restated license and supply agreement. The license fee is being amortized on a straight-line basis over the term of the agreement which we estimate to be 16 years. Other purchased intangible assets represent the costs incurred to acquire software used by us. We amortize the cost of purchased software on a straight-line basis over the estimated useful lives of the software, generally three years. We use a discounted cash flow model to value our license fee. The discounted cash flow model requires assumptions about the timing and amount of future cash inflows and outflows, risk and the cost of capital. Each of these factors can significantly affect the value of the license fee. We review our license fee for impairment on a periodic basis using an undiscounted net cash flows approach. If the undiscounted cash flows of our license fee are less than its carrying value, it is written down to the discounted cash flow value. We determined that there was no impairment to our license fee at December 31, 2005 and 2004. If we are unsuccessful in obtaining regulatory approval for ACAPODENE, we may not be able to recover the carrying amount of our license fee.

Preferred Stock Redemption Value

Our preferred stock was recorded at its redemption value. The per share redemption price was equal to the greater of liquidation value, which included accrued dividends, or the fair value calculated on an as-if converted to common stock basis. We determine a 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. At December 31, 2003, the per share redemption value was determined based on the estimated projected midpoint on the range of our initial public offering price per common share. The changes in redemption value affected the loss attributable to common stockholders.

Recent Accounting Pronouncements

In December 2004, the Financial Accounting Standards Board ("FASB") issued SFAS No. 123 (revised 2004), *Share-Based Payment* ("SFAS 123R"), which replaces SFAS No. 123, *Accounting for Stock-Based Compensation* ("SFAS123"), and supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*. SFAS 123R requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values. The pro forma disclosures previously permitted under SFAS 123 no longer will be an alternative to financial statement recognition. We adopted the provisions of SFAS 123R effective January 1, 2006 utilizing the modified prospective method. The modified prospective method requires that compensation expense be recorded in our statement of operations for all unvested stock options and restricted stock beginning January 1, 2006. The adoption of this standard did not have a material effect on our financial condition and we do not expect that the adoption will result in amounts that are materially different from the current pro forma disclosure under SFAS 123.

Results of Operations

Comparison of Years Ended December 31, 2005 and December 31, 2004

Revenues. Revenues for the year ended December 31, 2005 were $3.8 million as compared to $1.9 million for the same period of 2004. Revenues for the year ended December 31, 2005 included net sales of FARESTON marketed for the treatment of metastatic breast cancer, which the Company acquired the rights to distribute effective January 1, 2005 from Orion Corporation. During the year ended December 31, 2005, FARESTON net sales were $2.4 million while cost of product sales was $1.6 million. Revenues also included collaboration income of $1.3 million and $1.1 million for the years ended December 31, 2005 and 2004, respectively, from our partner, Ortho Biotech for andarine, one of our proprietary SARM compounds. Revenues for the year ended December 31, 2004 also included $812,000 from the reimbursement of andarine development costs received from Ortho Biotech.

Research and Development Expenses. Research and development expenses increased 71.7% to $30.9 million for the year ended December 31, 2005 from $18.0 million for the year ended December 31, 2004. The $12.9 million increase in research and development expenses included increased expenditures of approximately $5.2 million related to a pivotal Phase III clinical trial of ACAPODENE for the treatment of side effects of ADT, and $5.4 million related to a pivotal Phase III clinical trial of ACAPODENE for the prevention of prostate cancer in men with high grade PIN. In addition, we incurred additional expenses of approximately $739,000 related to the preclinical and clinical development of ostarine and approximately $3.6 million on other research and development efforts. These increases were offset by a reduction in research and development spending on andarine of approximately $2.0 million.

General and Administrative Expenses. General and administrative expenses increased 37% to $9.8 million for the year ended December 31, 2005 from $7.2 million for the year ended December 31, 2004. The increase of $2.6 million was primarily due to an increase in personnel related expenses, insurance costs, intellectual property related expenses, FARESTON selling and distribution expenses and Sarbanes Oxley compliance expenses.

Interest Income. Interest income increased to approximately $1.7 million for the year ended December 31, 2005 from $946,000 for the year ended December 31, 2004. The increase was the result of higher average yields which were partially offset by lower average cash and cash equivalents balances during the year ended December 31, 2005 as compared to the prior year.

Comparison of Years Ended December 31, 2004 and December 31, 2003

Revenue. We recognized collaboration revenue for the year ended December 31, 2004 of $1.9 million. Collaboration revenue included $1.1 million form the amortization of the up-front license fee received in April 2004 in connection with our collaboration and license agreement with Ortho Biotech. In addition, collaboration revenue included $812,000 from the reimbursement of andarine development costs under our collaboration and license agreement. No revenue was recognized for the year ended December 31, 2003.

Research and Development Expenses. Research and development expenses increased 66.5% to $18.0 million for the year ended December 31, 2004 from $10.8 million for the year ended December 31, 2003. The $7.2 million increase in research and development expenses included increased expenditures of approximately $4.9 million related to a pivotal Phase III clinical trial of ACAPODENE for the treatment of side effects of ADT. In addition, we incurred additional expenses of approximately $4.0 million related to the preclinical development of ostarine and approximately $2.0 million on other research and development efforts. These increases were offset by a reduction in clinical trial expenses for the Phase IIb clinical trial of ACAPODENE for the prevention of prostate cancer in men with high grade PIN, which was completed in the second quarter of 2004, of approximately $586,000, and a reduction in research and development spending on andarine of approximately $3.1 million.

General and Administrative Expenses. General and administrative expenses increased 102.6% to $7.2 million for the year ended December 31, 2004 from $3.6 million for the year ended December 31, 2003. The increase of $3.6 million was primarily due to an increase in personnel related expenses, insurance costs, intellectual property related expenses, marketing and investor relations costs, professional fees and other administrative costs to support the planned growth of our business, as well as additional expenses associated with operating as a public company.

Interest Income. Interest income increased to approximately $946,000 for the year ended December 31, 2004 from approximately $143,000 for the year ended December 31, 2003. The increase was the result of higher average cash and cash equivalents balances during the year ended December 31, 2004 as compared to the prior year, primarily as a result of the net proceeds of approximately $70.4 million from our initial public offering and the $6.7 million received as an up-front milestone payment form Ortho Biotech.

Adjustment to Preferred Stock Redemption Value. Our preferred stock was recorded at its redemption value. The per share redemption price was equal to the greater of liquidation value, which included accrued dividends, or the fair value calculated on an as-if converted to common stock basis. At December 31, 2003, the per share redemption value was determined based on the estimated projected midpoint of the range of our initial public offering price per common share of approximately $14.50 per share. At February 6, 2004, the date of the closing of our initial public offering and automatic conversion of all outstanding preferred stock, and accrued dividends thereon, into common stock, the market price of our common stock was $12.90 per share. Prior to conversion into common stock, the carrying value of the preferred stock and accrued dividends was adjusted to reflect the per share redemption value on the date of conversion resulting in a decrease in the carrying value of preferred stock of $17.1 million and an offsetting decrease in net loss attributable to common stockholders. The adjustment to the preferred stock redemption value for the year ended December 31, 2003 was an increase of $77.8 million with an offsetting increase to net loss attributable to common stockholders. The increase in the redemption value for the year ended December 31, 2003 was the result of the achievement of significant milestones and clinical trials, general market conditions, and was made in connection with our anticipated initial public offering.

Liquidity and Capital Resources

Through December 31, 2005, we had financed our operations and internal growth through private placements of preferred stock and with the proceeds of our initial public offering and our follow-on offering in October 2005. We 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 December 31, 2005, we had an accumulated deficit of $194.3 million, of which $96.3 million related to non-cash dividends and adjustments to the preferred stock redemption value. Our accumulated deficit resulted primarily from:

- our research and development activities associated with;
  - ACAPODENE for the treatment of side effects of ADT, including two Phase II clinical trials and an ongoing pivotal Phase III clinical trial;
  - ACAPODENE for the prevention of prostate cancer in men with high grade PIN, including our Phase IIb clinical trial and an ongoing pivotal Phase III clinical trial;
  - preclinical and clinical development of andarine and ostarine, which is being developed for the treatment of muscle wasting and bone loss in elderly men and postmenopausal women;
- general and administrative expenses; and
- non-cash dividends and adjustments to the preferred stock redemption value of $96.3 million related to our cumulative redeemable convertible preferred stock. See “Critical Accounting Policies —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, expand our sales and marketing capabilities and grow our operations.

At December 31, 2005, we had cash and cash equivalents of $74.0 million, compared to $64.5 million at December 31, 2004, and $14.8 million at December 31, 2003. On February 6, 2004, we successfully completed an initial public offering of 5,400,000 shares of common stock at an offering price to the public of $14.50 per share, resulting in net proceeds of approximately $70.4 million. On October 17, 2005, we completed an underwritten public offering of 6,325,000 shares of common stock at an offering price to the public of $7.80 per share resulting in net proceeds of approximately $45.7 million.

Net cash used in operating activities was $34.8 million, $15.7 million and $13.0 million for the years ended December 31, 2005, 2004 and 2003, respectively. The use of cash in all periods resulted primarily from funding our net losses. Net cash used in operating activities for the year ended December 31, 2004 was reduced by the up-front license fee and reimbursement of development expenses of approximately $6.7 million received in connection with our collaboration with Ortho Biotech which is being amortized as income over the development period. Cash requirements for operating activities are expected to increase in future periods, due in part to significant costs related to the continuation of two pivotal Phase III clinical trials for ACAPODENE as well as the clinical and preclinical development of our other product candidates.

Net cash used in investing activities for the year ended December 31, 2005 was $1.4 million and was primarily for the purchase or research and development equipment, leasehold improvements, office and computer equipment, software and furniture and fixtures. Net cash used in investing activities was $6.0 million and $108,000 for the years ended December 31, 2004 and 2003, respectively. The use of cash in 2004 and 2003 was primarily for the purchase or research and development equipment, office equipment and the purchase of an intangible asset (license fee) of $4.8 million in 2004. We currently expect to make expenditures for capital equipment and leasehold improvements of up to $1.5 million for the year ended December 31, 2006.

Net cash provided by financing activities, was $45.7 million, $71.4 million and $18.9 million for the years ended December 31, 2005, 2004 and 2003, respectively. Net cash provided by financing activities for the year ended December 31, 2005 reflected net proceeds from our follow-on public offering, which closed on October 17, 2005, less underwriters' commission and related offering expenses. Net cash provided by financing activities for the year ended December 31, 2004 reflected net proceeds from our initial public offering which closed February 6, 2004 less underwriters' commission and offering expenses paid during the period. Net cash provided by financing activities for the year ended December 31, 2003 reflected the net proceeds received from the issuance of preferred stock in private placements.

We believe that our current cash resources, interest on these funds and product revenue from the sale of FARESTON, will be sufficient to meet our projected operating requirements through the first half of 2007. This estimate includes a milestone payment that we anticipate receiving from Ortho Biotech upon initiation of our Phase II clinical trial for andarine but does not include funding from other milestone payments that we may receive under our existing collaboration with Ortho Biotech, potential future collaboration agreements with pharmaceutical companies, or the potential future issuance and sale of our securities.

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 under Item 1A "Risk Factors" section of this annual report on Form 10-K. 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 achievement of certain milestone events under our joint collaboration and license agreement with Ortho Biotech;
- the cost and timing of regulatory approvals;
- potential future licensing fees, milestone payments and royalty payments;
- 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, we expect to finance future cash needs through public or private equity offerings, debt financings or collaboration and licensing arrangements, such as our arrangement with Ortho Biotech, as well as through interest income earned on cash balances and revenues from the sale of FARESTON. With the exception of payments that we may receive under our collaboration with Ortho Biotech, 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, such as our arrangement with Ortho Biotech, 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. At December 31, 2005, we had contractual obligations as follows:

	Payment Due by Period (in thousands)				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Capital lease obligations	$ 20	$ 4	$ 16	$ —	$ —
Operating lease obligations	1,462	668	794	—	—
Purchase obligations	104	104	—	—	—
Total	$ 1,586	$ 776	$ 810	$ —	$ —

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 December 31, 2007, unless we exercise certain options granted to us to extend the lease. The table above excludes contingent payments under the license agreements to which we are a party.

ITEM 7A. 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. The effect of a hypothetical 20% change in all interest rates on our investments would have resulted in a change in interest income of $344,000 for the year ended December 31, 2005.

We operate primarily in the United States. Through December 31, 2005, we had not experienced any material exposure to foreign currency rate fluctuations. Our exposure to foreign currency rate fluctuations will increase because we are obligated to pay Orion Corporation, our supplier of ACAPODENE and FARESTON, in Euros; however such exposure is not expected to be material. We do not currently use derivative financial instruments to mitigate this exposure.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our financial statements and the report of our independent registered public accounting firm are included in this Annual Report on Form 10-K beginning on page F-1, which are incorporated by reference herein. The index to this report and the financial statements are included in Item 15 below.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934) that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities and Exchange Act of 1934 is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate, to allow for timely decisions regarding required disclosure.

We have carried out an evaluation, under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities and Exchange Act of 1934) as of the end of the period covered by this report. Based on the evaluation of these disclosure controls and procedures, our chief executive officer and chief financial officer have concluded that our disclosure controls and procedures were effective.

Management's Report on Internal Control over Financial Reporting

We, as management of GTx, are responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Securities Exchange Act Rule 13a-15(f). Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with United States generally accepted accounting principles. Any system of internal control, no matter how well designed, has inherent limitations, including the possibility that a control can be circumvented or overridden and misstatements due to error or fraud may occur and not be detected. Also, because of changes in conditions, internal control effectiveness may vary over time. Accordingly, even an effective system of internal control will provide only reasonable assurance that the objectives of the internal control system are met.

Under the supervision and with the participation of management, including our chief executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2005 using the criteria for effective internal control over financial reporting as described in "Internal Control – Integrated Framework," issued by the Committee of Sponsoring Organization of the Treadway Commission. Based on this evaluation, we concluded that, as of December 31, 2005, our internal control over financial reporting was effective. Ernst & Young LLP, an independent registered public accounting firm, has issued an attestation report on management's assessment of our internal control over financial reporting, as stated in their report which is included elsewhere herein.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the fourth quarter of 2005 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

Not applicable.

PART III

Certain information required by Part III is omitted from this Annual Report on Form 10-K because we will file our definitive proxy statement for our 2006 Annual Meeting of Stockholders with the U.S. Securities and Exchange Commission pursuant to Regulation 14A (the "2006 Proxy Statement") not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and certain information included in the 2006 Proxy Statement is incorporated herein by reference.

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

(a) The information required by this Item concerning our directors, audit committee and audit committee financial expert, may be found under the section entitled "Proposal No. 1 – Election of Directors" and "Additional Information About the Board of Directors" appearing in the 2006 Proxy Statement. Such information is incorporated herein by reference.

(b) The information required by this Item concerning compliance with Section 16(a) of the Securities Exchange Act of 1934 may be found in the section entitled "Security Ownership of Certain Beneficial Owners and Management–Section 16(a) Beneficial Ownership Reporting Compliance" appearing in the 2006 Proxy Statement. Such information is incorporated herein by reference.

(c) The information required by this Item concerning our executive officers is set forth in the section entitled "Executive Officers and Other Key Employees of Registrant" in Part I, Item 1 of this Form 10-K and is incorporated herein by reference.

(d) Our Board has adopted a Code of Business Conduct and Ethics applicable to all officers, directors and employees as well as guidelines on Governance Issues. These documents are available on the Company's website (www.gtxinc.com) under "Investor Relations" at "Corporate Governance." The Company will provide a copy of these documents to any person, without charge, upon request, by writing to the Company at GTx, Inc. Investor Relations Manager, 3 North Dunlap Street, Memphis, Tennessee 38163. We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding an amendment to, or waiver from, a provision of the Code of Business Conduct and Ethics by posting such information on our website at the address and the locations specified above.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item is incorporated herein by reference to the information from the 2006 Proxy Statement under the sections entitled "Additional Information About the Board of Directors – Board Compensation and Benefits" and "Executive Compensation."

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this Item with respect to security ownership of certain beneficial owners and management is incorporated herein by reference to the information from the 2006 Proxy Statement under the section entitled "Security Ownership of Certain Beneficial Owners and Management". The information required by this Item with respect to securities authorized for issuance under our equity compensation plans is incorporated herein by reference to the information from the 2006 Proxy Statement under the section entitled "Proposal No. 2 Approval of the Amended and Restated 2004 Non-Employee Directors' Stock Option Plan – Equity Compensation Plan Information."

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information required by this Item is incorporated herein by reference to the information from the 2006 Proxy Statement under the sections entitled "Certain Relationships And Related Transactions."

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item is incorporated herein by reference to the information from the Proxy Statement under the section entitled "Proposal No. 3 – Ratification of Appointment of Independent Registered Public Accounting Firm".

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)(1) Index to Financial Statements

(a)(2) Financial statement schedules are omitted as they are not applicable.

(a)(3) See 15(b) below.

(b) Exhibits

Number	Description
3.1	Restated Certificate of Incorporation of GTx, Inc. (1)
3.2	Amended and Restated Bylaws of GTx, Inc. (2)
4.1	Reference is made to Exhibits 3.1 and 3.2
4.2	Specimen of Common Stock Certificate (3)
4.3	Amended and Restated Registration Rights Agreement between Registrant and Oracle Partners, L.P. dated August 7, 2003 (3)
4.4*	Amended and Restated Registration Rights Agreement between Registrant and J. R. Hyde, III dated August 7, 2003 (3)
4.5	Amended and Restated Registration Rights Agreement between Registrant and Memphis Biomed Ventures dated August 7, 2003 (3)
10.1*	Genotherapeutics, Inc. 1999 Stock Option Plan (3)
10.2*	GTx, Inc. 2000 Stock Option Plan (3)
10.3*	GTx, Inc. 2001 Stock Option Plan (3)
10.4*	GTx, Inc. 2002 Stock Option Plan (3)
10.5*	2004 Equity Incentive Plan and Form of Stock Option Agreement (3)
10.6*	2004 Non-Employee Directors' Stock Option Plan and Form of Stock Option Agreement (3)
10.7	Reserved
10.8*	Employment Agreement dated October 1, 2003, between Registrant and Mitchell S. Steiner, M.D. (3)
10.9*	Employment Agreement dated October 1, 2003, between Registrant and Marc S. Hanover (3)
10.10*	Employment Agreement dated October 1, 2003, between Registrant and Mark E. Mosteller (3)
10.11*	Employment Agreement dated October 1, 2003, between Registrant and Henry P. Doggrell (3)
10.12*	Form of Indemnification Agreement (3)
10.13	Lease Agreement, dated March 7, 2001, between The University of Tennessee and TriStar Enterprises, Inc. (3)
10.14	Sublease Agreement dated October 1, 2000, as amended, between Registrant and TriStar Enterprises, Inc. (3)
10.15†	Amended and Restated License and Supply Agreement dated October 22, 2001, between Registrant and Orion Corporation (3)
10.16†	Amendment No. 1 to the License and Supply Agreement dated March 5, 2003, between Registrant and Orion Corporation (3)
10.17†	Production and Manufacturing Agreement dated September 9, 2002, between Registrant and ChemSyn Laboratories (Department of EaglePicher Technologies, LLC)(3)
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)(3)

Number	Description
10.19†	Quotation Agreement dated August 8, 2003 between Registrant and EaglePicher Pharmaceutical Services (3)
10.20†	Amended and Restated Exclusive License Agreement dated June 3, 2002, between Registrant and University of Tennessee Research Foundation (3)
10.21†	Amended and Restated Exclusive License Agreement dated June 14, 2003, between Registrant and University of Tennessee Research Foundation (3)
10.22†	Amended and Restated Exclusive License Agreement dated August 30, 2003, between Registrant and University of Tennessee Research Foundation(3)
10.23	Amendment No. 2 to the License and Supply Agreement dated December 29, 2003, between Registrant and Orion Corporation (3)
10.24†	Joint Collaboration and License Agreement dated March 16, 2005, between Registrant and Ortho Biotech, L.P. (4)
10.25†	Purchase Agreement dated December 13, 2004, between Registrant and Orion Corporation (5)
10.26†	Amended and Restated License and Supply Agreement effective January 1, 2005, between Registrant and Orion Corporation (6)
10.27	Sublease Agreement dated April 1, 2005, as amended, between Registrant and TriStar Enterprises, Inc. (7)
10.28*	Employment Agreement dated January 1, 2005, between Registrant and James T. Dalton (7)
10.29*	Compensation Information for Registrant's Executive Officers, effective as of January 1, 2006 (8)
10.30*	Employment Agreement dated August 26, 2005, between Registrant and K. Gary Barnette (9)
10.31*	Employment Agreement dated August 26, 2005, between Registrant and Gregory A. Deener (10)
23.1	Consent of Ernst & Young LLP
24.1	Power of Attorney (included on the signature pages hereto)
31.1	Certification of Chief Executive Officer, as required by Rule 13a-14(a) or Rule 15d-14(a)
31.2	Certification of Chief Financial Officer, as required by Rule 13a-14(a) or Rule 15d-14(a)
32.1	Certification of Chief Executive Officer, as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350)(11)
32.2	Certification of Chief Financial Officer, as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350)(11)

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

* Indicates a management contract or compensation plan or arrangement

(1) Filed as Exhibit 4.1 to the Registrant's registration statement on Form S-3 (File No. 333-127175), filed with the SEC on August 4, 2005, and incorporated herein by reference.

(2) Filed as Exhibit 3.4 to the Registrant's registration statement on Form S-1 (File No. 333-109700), filed with the SEC on October 15, 2003, as amended, and incorporated herein by reference.

(3) Filed as the like numbered Exhibit to the Registrant's registration statement on Form S-1 (File No. 333-109700), filed with the SEC on October 15, 2003, as amended, and incorporated herein by reference.

(4) Filed as the like numbered Exhibit to the Registrant's Quarterly Report on Form 10-Q (File No. 000-50549), filed with the SEC on May 7, 2004, and incorporated herein by reference.

(5) Filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 000-50549), filed with the SEC on March 7, 2005, and incorporated herein by reference.

(6) Filed as Exhibit 10.2 to the Registrant's Current Report on Form 8-K/A (File No. 000-50549), filed with the SEC on March 7, 2005, and incorporated herein by reference.

(7) Filed as the like numbered Exhibit to the Registrant's Quarterly Report on Form 10-Q (File No. 000-50549), filed with the SEC on July 27, 2005, and incorporated herein by reference.

(8) Filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 000-50549), filed with the SEC on November 7, 2005, and incorporated herein by reference.

(9) Filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 000-50549), filed with the SEC on September 8, 2005, and incorporated herein by reference.

(10) Filed as Exhibit 10.2 to the Registrant's Current Report on Form 8-K (File No. 000-50549), filed with the SEC on September 8, 2005, and incorporated herein by reference.

(11) This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

GTx, Inc.

By /s/ Mitchell S. Steiner
Mitchell S. Steiner, M.D., F.A.C.S.
Chief Executive Officer, Vice Chairman and Director Date: March 2, 2006

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENT, that each person whose signature appears below constitutes and appoints Mitchell S. Steiner and Mark E. Mosteller, and each of them, acting individually, as his attorney-in-fact, each with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

		Date
/s/ J. R. Hyde, III J. R. Hyde, III	Chairman of the Board of Directors	March 2, 2006
/s/ Mitchell S. Steiner Mitchell S. Steiner, M.D., F.A.C.S.	Chief Executive Officer, Vice Chairman and Director	March 2, 2006
/s/ Mark E. Mosteller Mark E. Mosteller, CPA	Vice President, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	March 2, 2006
/s/ Marc S. Hanover Marc S. Hanover	President, Chief Operating Officer and Director	March 2, 2006
/s/ Andrew M. Clarkson Andrew M. Clarkson	Director	March 2, 2006
/s/ J. Kenneth Glass J. Kenneth Glass	Director	March 2, 2006
/s/ Robert W. Karr Robert W. Karr, M.D.	Director	March 2, 2006
/s/ Rosemary Mazanet Rosemary Mazanet, M.D., Ph.D.	Director	March 2, 2006

/s/ John H. Pontius John H. Pontius	Director	March 2, 2006
/s/ Timothy R. G. Sear Timothy R. G. Sear	Director	March 2, 2006

GTx, Inc.

INDEX TO FINANCIAL STATEMENTS

MANAGEMENT'S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

We, as management of GTx, Inc., are responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Securities Exchange Act Rule 13a-15(f). Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with United States generally accepted accounting principles. Any system of internal control, no matter how well designed, has inherent limitations, including the possibility that a control can be circumvented or overridden and misstatements due to error or fraud may occur and not be detected. Also, because of changes in conditions, internal control effectiveness may vary over time. Accordingly, even an effective system of internal control will provide only reasonable assurance that the objectives of the internal control system are met.

Under the supervision and with the participation of management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2005 using the criteria for effective internal control over financial reporting as described in "Internal Control — - Integrated Framework," issued by the Committee of Sponsoring Organization of the Treadway Commission. Based on this evaluation, we concluded that, as of December 31, 2005, our internal control over financial reporting was effective. Ernst & Young LLP, an independent registered public accounting firm, has issued an attestation report on management's assessment of our internal control over financial reporting, as stated in their report which is included elsewhere herein.

/s/ Mitchell S. Steiner
Mitchell S. Steiner, M.D., F.A.C.S.
Vice Chairman and
Chief Executive Officer

/s/ Mark E. Mosteller
Mark E. Mosteller, CPA
Vice President, Chief Financial Officer
and Treasurer

Memphis, Tennessee
February 24, 2006

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
GTx, Inc.

We have audited management's assessment, included in the accompanying Management's Report on Internal Control Over Financial Reporting, that management of GTx, Inc.'s assessment of the effectiveness of internal control over financial reporting, that GTx, Inc. maintained effective internal control over financial reporting as of December 31, 2005, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). GTx, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that GTx, Inc. maintained effective internal control over financial reporting as of December 31, 2005, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, GTx, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2005, based on the COSO criteria .

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the accompanying balance sheets as of December 31, 2005 and 2004, and the related statements of operations, cumulative redeemable convertible preferred stock and stockholders' equity (deficit) and cash flows of GTx, Inc., for each of the three years in the period ended December 31, 2005 and our report dated February 24, 2006 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Memphis, Tennessee
February 24, 2006

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
GTx, Inc.

We have audited the accompanying balance sheets of GTx, Inc. as of December 31, 2005 and 2004, 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, 2005. 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 the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit 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.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of GTx, Inc. at December 31, 2005 and 2004, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2005, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of GTx, Inc.'s internal control over financial reporting as of December 31, 2005, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 24, 2006 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Memphis, Tennessee
February 24, 2006

GTx, Inc.
BALANCE SHEETS
(in thousands, except share data)

	December 31, 2005	December 31, 2004
ASSETS		
Current assets:		
Cash and cash equivalents	$ 74,014	$ 64,528
Accounts receivable	153	—
Inventory	135	448
Prepaid expenses and other current assets	1,702	1,176
Total current assets	76,004	66,152
Property and equipment, net	1,746	1,537
Purchased intangible assets:		
License fee	4,524	4,826
Other	454	117
Other assets	83	450
Total assets	$ 82,811	$ 73,082
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,407	$ 900
Accrued expenses	3,230	2,617
Deferred revenue — current portion	1,337	1,337
Total current liabilities	5,974	4,854
Deferred revenue, less current portion	2,958	4,295
Other long term liability	280	—
Capital lease obligation	20	24
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.001 par value: 60,000,000 shares authorized; 30,993,967 shares issued and outstanding at December 31, 2005 and 24,664,716 shares issued and outstanding at December 31, 2004	31	25
Deferred stock compensation	(1,725)	(2,701)
Additional paid-in capital	269,542	224,015
Accumulated deficit	(194,269)	(157,430)
Total stockholders' equity	73,579	63,909
Total liabilities and stockholders' equity	$ 82,811	$ 73,082

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

GTx, Inc.
STATEMENTS OF OPERATIONS
(in thousands, except share and per share data)

	Year Ended December 31,		
	2005	2004	2003
Revenues:			
Product sales, net	$ 2,445	$ —	$ —
Collaboration revenue	1,337	1,055	—
Reimbursement of development costs	—	812	—
Total revenues	3,782	1,867	—
Costs and expenses:			
Cost of product sales	1,573	—	—
Research and development expenses	30,923	17,950	10,778
General and administrative expenses	9,845	7,211	3,559
Total costs and expenses	42,341	25,161	14,337
Loss from operations	(38,559)	(23,294)	(14,337)
Interest income	1,720	946	143
Net loss	(36,839)	(22,348)	(14,194)
Accrued preferred stock dividends	—	(455)	(3,436)
Adjustments to preferred stock redemption value	—	17,125	(77,844)
Net loss attributable to common stockholders	$ (36,839)	$ (5,678)	$ (95,474)
Net loss per share attributable to common stockholders:			
Basic	$ (1.42)	$ (0.25)	$ (12.34)
Diluted	$ (1.42)	$ (0.93)	$ (12.34)
Weighted average shares used in computing net loss per share attributable to common stockholders:			
Basic	25,982,478	22,993,221	7,735,125
Diluted	25,982,478	24,062,271	7,735,125

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

GTx, Inc.
STATEMENTS OF CUMULATIVE REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
For the Years Ended December 31, 2005, 2004 and 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	Accumulated (Deficit)	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balances at January 1, 2003	902,419	$ 64,026	7,734,998	$ 8	$ —	$ 962	$ (56,278)	$ (55,308)
Exercise of employee stock options	—	—	850	—	—	1	—	1
Sale of Series E Redeemable Convertible Preferred Stock at $60.692, net of issuance costs of $14	329,536	19,986	—	—	—	—	—	—
Preferred stock dividends	—	3,436	—	—	—	—	(3,436)	(3,436)
Preferred stock adjustment to redemption value	—	77,844	—	—	—	—	(77,844)	(77,844)
Deferred stock-based compensation	—	—	—	—	(4,055)	4,055	—	—
Amortization of stock-based compensation	—	—	—	—	550	—	—	550
Net loss and comprehensive loss	—	—	—	—	—	—	(14,194)	(14,194)
Balances at December 31, 2003	1,231,955	165,292	7,735,848	8	(3,505)	5,018	(151,752)	(150,231)
Preferred stock dividends	—	455	—	—	—	—	(455)	(455)
Preferred stock adjustment to redemption value	—	(17,125)	—	—	—	—	17,125	17,125
Conversion of preferred stock to common stock	(1,231,955)	(148,622)	11,521,075	12	—	148,610	—	148,622
Issuance of common stock	—	—	5,400,000	5	—	70,360	—	70,365
Amortization of stock-based compensation	—	—	—	—	804	—	—	804
Exercise of employee stock options	—	—	7,793	—	—	27	—	27
Net loss and comprehensive loss	—	—	—	—	—	—	(22,348)	(22,348)
Balances at December 31, 2004	—	—	24,664,716	25	(2,701)	224,015	(157,430)	63,909
Issuance of common stock	—	—	6,325,000	6	—	45,657	—	45,663
Amortization of stock-based compensation	—	—	—	—	487	—	—	487
Exercise of employee stock options	—	—	4,251	—	—	27	—	27
Forfeitures of stock-based compensation	—	—	—	—	489	(489)	—	—
Directors' deferred compensation	—	—	—	—	—	180	—	180
Stock-based compensation related to the modification of employee stock options	—	—	—	—	—	152	—	152
Net loss and comprehensive loss	—	—	—	—	—	—	(36,839)	(36,839)
Balances at December 31, 2005	—	$ —	30,993,967	$ 31	$ (1,725)	$269,542	$ (194,269)	$ 73,579

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

GTx, Inc.
STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,		
	2005	2004	2003
Cash flows from operating activities:			
Net loss	$(36,839)	$ (22,348)	$ (14,194)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,038	475	357
Stock-based compensation	639	804	550
Directors' deferred compensation	180	—	—
Deferred revenue amortization	(1,337)	(1,055)	—
Loss on retirement of property and equipment	33	—	—
Changes in assets and liabilities:			
Accounts receivable	(153)	—	—
Inventory	313	(448)	—
Prepaid expenses and other current assets	(460)	(921)	(214)
Other assets	367	(567)	—
Accounts payable	507	439	(153)
Accrued expenses	893	1,263	657
Deferred revenue	—	6,687	—
Net cash used in operating activities	(34,819)	(15,671)	(12,997)
Cash flows from investing activities:			
Purchase of property and equipment	(935)	(1,174)	(108)
Purchase of intangible assets	(446)	(4,826)	—
Net cash used in investing activities	(1,381)	(6,000)	(108)
Cash flows from financing activities:			
Proceeds from issuance of common stock	45,663	71,836	1
Proceeds from issuance of preferred stock, net	—	—	19,986
Deferred initial public offering costs	—	(433)	(1,038)
Payments on capital lease obligation	(4)	—	—
Proceeds from exercise of employee stock options	27	27	—
Net cash provided by financing activities	45,686	71,430	18,949
Net increase in cash and cash equivalents	9,486	49,759	5,844
Cash and cash equivalents, beginning of year	64,528	14,769	8,925
Cash and cash equivalents, end of year	$ 74,014	$ 64,528	$ 14,769
Supplemental schedule of non-cash investing and financing activities:			
Preferred stock dividends	$ —	$ 455	$ 3,436
Preferred stock adjustment to redemption value	$ —	$ (17,125)	$ 77,844
Deferred initial public offering costs in accrued expenses	$ —	$ —	$ 433
Capital lease	$ —	$ 24	$ —
Transfer of deferred IPO costs to stockholders' equity	$ —	$ 1,471	$ —

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

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1. Organization and Basis of Presentation

GTx, Inc. ("GTx" or the "Company") is a biopharmaceutical company dedicated to the discovery, development and commercialization of therapeutics for cancer and serious conditions related to men's health. GTx's lead drug discovery and development programs are focused on small molecules that selectively modulate the effects of estrogens and androgens, two essential classes of hormones. GTx operates in one business segment.

GTx, headquartered in Memphis, Tennessee, currently has four clinical programs. GTx is developing ACAPODENE ® (toremifene citrate), a selective estrogen receptor modulator, or SERM, in two separate clinical programs in men: First, a pivotal Phase III clinical trial for the treatment of serious side effects of ADT, or ADT, for advanced prostate cancer and second, a pivotal Phase III clinical trial for the prevention of prostate cancer in high risk men with precancerous prostate lesions called high grade prostatic intraepithelial neoplasia, or high grade PIN. In its third clinical program, GTx is developing ostarine, a selective androgen receptor modulator, or SARM. We believe ostarine has the potential to treat a variety of indications including frailty, osteoporosis, muscle wasting in end stage renal disease patients, and treatment of severe burn wounds and associated wasting. In its fourth clinical program, GTx and its partner, Ortho Biotech Products, L.P., a subsidiary of Johnson & Johnson, (Ortho Biotech), are developing andarine, another of GTx's SARMs, for the treatment of cancer cachexia.

GTx also has an extensive preclinical pipeline generated from its own discovery program, which includes the specific product candidates prostarine, a SARM for benign prostatic hyperplasia, and andromustine, an anticancer drug, for hormone refractory prostate cancer.

2. Significant Accounting Policies

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.

Cash and Cash Equivalents

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

Inventory

Inventory consists of FARESTON tablets that are manufactured by Orion Corporation and delivered to the Company as finished goods. Inventory is stated at the lower of cost (first-in, first-out method) or market.

GTx, Inc.
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Property and Equipment

Property and equipment is stated at cost. Amortization of leasehold improvements is recognized over the shorter of the estimated useful life of the leasehold improvement or the lease term. Depreciation is computed using the straight-line method over the estimated useful lives as follows:

Equipment	3 to 5 years
Leasehold improvements	3 to 5 years
Furniture and fixtures	5 years

Impairment of Long-Lived Assets

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, 2005 and 2004. 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.

Purchased Intangible Assets

The Company accounts for its purchased intangible assets in accordance with SFAS No.142, *Goodwill and Other Intangible Assets*, which requires that purchased intangible assets with finite lives be amortized over their estimated economic lives. The Company's purchased intangible asset, license fee, represents the value of a license and supply agreement purchased by the Company as described in Note 5. The license fee is being amortized on a straight-line basis over the term of the agreement which the Company estimates to be 16 years. Other purchased intangible assets represent the costs incurred to acquire software used by the Company. The Company amortizes the cost of purchased software on a straight-line basis over the estimated useful lives of the software, generally three years. Management analyzed the license fee in accordance with SFAS No. 144 and determined that there was no impairment as of December 31, 2005 and 2004.

Fair Value of Financial Instruments

The carrying amounts of the Company's financial instruments, which include cash and cash equivalents, accounts receivable and accounts payable approximate their fair values.

Concentration of Risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents and accounts receivable. The Company has established guidelines relating to diversification and maturities of its cash equivalents which allow the Company to manage risk. The Company's cash equivalents consist primarily of money market funds. Bank deposits may at times be in excess of FDIC insurance limits. The Company's three largest customers are wholesale drug distributors and account for approximately 92% of accounts receivable as of December 31, 2005.

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Revenue Recognition

Revenues associated with the Company's collaboration and license agreement discussed in Note 7 consist of non-refundable, up-front license fees and reimbursement of development expenses.

The Company recognizes revenue in accordance with the Securities and Exchange Commission's Staff Accounting Bulletin ("SAB") No. 101, *"Revenue Recognition in Financial Statements"* as amended by SAB No. 104 (together, "SAB 104") and Statement of Financial Accounting Standards No. 48 "Revenue Recognition when Right of Return Exists" ("FAS 48") and Emerging Issues Task Force ("EITF") Issue 00-21, *"Revenue Arrangements with Multiple Deliverables"*. Accordingly, revenues from licensing agreements are recognized based on the performance requirements of the agreement. Non-refundable up-front fees, where the Company has an ongoing involvement or performance obligation, are recorded as deferred revenue in the balance sheet and amortized into license fees in the statements of operations over the term of the performance obligation.

The Company recognizes net product sales revenue from the sale of FARESTON less deductions for estimated sales rebates, sales discounts and sales returns. The Company recognizes revenue from product sales when the goods are shipped and title and risk of loss pass to the customer and the other criteria of SAB 104 and FAS 48 are satisfied. We accept returns of products near their expiration date.

Revenues derived from reimbursements of costs associated with the development of andarine are recorded in compliance with EITF Issue 99-19, *"Reporting Revenue Gross as a Principal Versus Net as an Agent"*. According to the criteria established by this EITF Issue, in transactions where the Company acts as a principal, has discretion to choose suppliers, bears credit risk and performs part of the services required in the transaction, the Company has met the criteria to record revenue for the gross amount of the reimbursements.

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 trials 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 basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some portion or all of the deferred tax assets will not be realized. Accordingly, at December 31, 2005 and 2004, net of the valuation allowance, the net deferred tax assets were reduced to zero.

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 SFAS No. 123, *Accounting for Stock-Based Compensation ("*SFAS No. 123"), as amended by SFAS No. 148, *Accounting for Stock-Based Compensation, Transition and*

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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 of the related option.

SFAS No. 123 requires pro forma disclosure of net loss attributable to common stockholders, assuming all stock options were valued on the date of grant using the minimum value option pricing model for stock options granted prior to the Company's initial public offering ("IPO") in February 2004 and using the Black-Scholes option-pricing model for stock options granted after the IPO.

The weighted average assumptions used in the valuation of stock options granted in 2005, 2004 and 2003, respectively, are as follows:

	Year Ended December 31,		
	2005	2004	2003
Risk free interest rate	4.06%	3.90%	4.28%
Expected volatility	61.64%	59.70%	0.00%
Dividend yield	0.00%	0.00%	0.00%
Expected option life	5.7 years	6 years	8 years

If compensation cost for stock-based compensation plans had been determined under SFAS No. 123, the Company's net loss attributable to common stockholders would have been the pro forma amounts indicated as follows:

	Year Ended December 31,		
	2005	2004	2003
Net loss attributable to common stockholders, as reported	$ (36,839)	$ (5,678)	$(95,474)
Add: Stock-based employee compensation and amortization of deferred stock-based compensation included in reported net loss	639	804	550
Deduct: Stock-based employee compensation determined under fair value based method for all awards	(1,854)	(1,319)	(424)
Pro forma net loss attributable to common stockholders	$ (38,054)	$ (6,193)	$(95,348)
Pro forma SFAS No. 123 disclosure:			
Net loss per share attributable to common stockholders as reported:			
Basic	$ (1.42)	$ (0.25)	$ (12.34)
Diluted	$ (1.42)	$ (0.93)	$ (12.34)
Net loss per share attributable to common stockholders pro forma:			
Basic	$ (1.46)	$ (0.27)	$ (12.33)
Diluted	$ (1.46)	$ (0.95)	$ (12.33)

Deferred Stock Compensation

In anticipation of the Company's IPO on February 6, 2004, the Company 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 from June 30, 2003 to December 31, 2003. Accordingly, the Company recorded non-cash deferred stock-based compensation of $4,055, and is amortizing the related expense over the service period, which is generally five years on the straight-line basis. Deferred stock compensation for options granted to employees has been determined as the difference between the deemed fair value of the Company's common stock for financial

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reporting purposes on the date such options were granted and the applicable exercise price. The Company recorded amortization of deferred stock compensation of approximately $487, $804, and $550 for years ended December 31, 2005, 2004, and 2003 respectively. Of these amounts, $315, $530, and $472 for the respective periods were included in research and development expenses and $172, $274, and $78, respectively, were included in general and administrative expenses in the statements of operations. At December 31, 2005, the Company had approximately $1,725 of deferred stock-based compensation to be amortized over the remaining vesting periods of the related stock options.

Basic and Diluted Net Loss Per Share

The Company computed net loss per share attributable to common stockholders according to Statement of Financial Accounting Standards No. 128, *"Earnings per Share,"* which requires disclosure of basic and diluted earnings (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 gives effect to the dilutive effect of potential common stock consisting of stock options and convertible preferred stock.

The following tables set forth the computation of the Company's basic and diluted net loss per share attributable to common stockholders for the years ended December 31, 2005, 2004 and 2003:

	Year Ended December 31,		
	2005	2004	2003
Basic net loss per share attributable to common stockholders			
Numerator:			
Net loss attributable to common stockholders	$ (36,839)	$ (5,678)	$ (95,474)
Denominator:			
Common stock outstanding at beginning of period	24,664,716	7,735,848	7,734,998
Conversion of preferred stock to common stock	–	10,387,855	–
Issuance of common stock in initial public offering	–	4,868,852	–
Issuance of common stock in public offering	1,316,986	–	–
Exercise of employee stock options	776	666	127
Weighted average shares used in computing basic net loss per share	25,982,478(1)	22,993,221	7,735,125
Basic net loss per share attributable to common stockholders	$ (1.42)	$ (0.25)	$ (12.34)

(1) The weighted average shares used in computing basic net loss per share attributable to common stockholders for the year ended December 31, 2005 include 1,316,986 shares, which represent the weighted average effect during the period of the Company's issuance of 6,325,000 shares of common stock on October 17, 2005. At December 31, 2005, the Company had outstanding 30,993,967 shares of common stock.

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	Year Ended December 31,		
	2005	2004	2003
Diluted net loss per share attributable to common stockholders			
Numerator:			
Net loss	$ (36,839)	$ (22,348)(2)	$ (14,194)(3)
Denominator:			
Common stock outstanding at beginning of period	24,664,716	7,735,848	7,734,998
Conversion of preferred stock to common stock	–	11,456,905	–
Issuance of common stock in initial public offering	–	4,868,852	–
Issuance of common stock in public offering	1,316,986	–	–
Exercise of employee stock options	776	666	127
Weighted average shares used in computing diluted net loss per share	25,982,478(1)	24,062,271	7,735,125
Diluted net loss per share attributable to common stockholders	$ (1.42)	$ (0.93)	$ (12.34)

(2) Diluted net loss per share attributable to common stockholders is calculated as if the conversion of all preferred stock, and accrued dividends thereon, into shares of common stock occurred as of the beginning of the period. As a result, the diluted net loss per share attributable to common stockholders does not include accrued preferred stock dividends or the adjustments to preferred stock redemption value.

(3) Diluted net loss per share attributable to common stockholders is not calculated as if the conversion of all preferred stock, and accrued dividends thereon, into shares of common stock occurred as of the beginning of the year because their inclusion would have an anti-dilutive effect on the net loss for the year.

Weighted average options outstanding to purchase shares of common stock of 1,244,232, 997,059, and 539,372 were excluded from the calculation of diluted net loss per share attributable to common stockholders for the years ended December 31, 2005, 2004 and 2003, respectively, as inclusion of the options would have an anti-dilutive effect on the net loss per share for the periods.

Adjustment to Preferred Stock Redemption Value

The Company's preferred stock was recorded at its redemption value. The per share redemption price was equal to the greater of liquidation value, which included 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. At December 31, 2003, the per share redemption value was determined based on the estimated projected midpoint on the range of the Company's initial public offering price per common share. The changes in redemption value affect the loss attributable to common stockholders for the years ended December 31, 2004 and 2003.

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 2004, the financial Accounting Standards Board ("FASB") issued SFAS No. 123 (revised 2004), *Share-Based Payment* ("SFAS 123R"), which replaces SFAS No. 123, *Accounting for Stock-Based Compensation* ("SFAS 123"), and supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*. SFAS 123R requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values. The pro forma disclosures previously permitted under SFAS 123 no

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longer will be an alternative to financial statement recognition. The Company adopted the provisions of SFAS 123R effective January 1, 2006 utilizing the modified prospective method. The modified prospective method used by the Company requires that compensation expense be recorded for all unvested stock options and restricted stock at the beginning of the first quarter of adoption of SFAS 123R. The adoption of the standard did not have a material effect on the Company's financial condition and the Company does not expect that the adoption will result in amounts that are materially different from the current pro forma disclosure under SFAS 123.

3. Property and Equipment, Net

Property and equipment, net consist of the following:

	December 31,	
	2005	2004
Equipment	$ 2,813	$ 2,640
Leasehold improvements	669	144
Furniture and fixtures	307	198
	3,789	2,982
Less: accumulated depreciation	(2,043)	(1,445)
	$ 1,746	$ 1,537

Depreciation expense for the years ended December 31, 2005, 2004 and 2003 was $639, $454 and $346, respectively. Of these amounts, $468, $396 and $310, respectively, were included in research and development expenses in the statements of operations.

4. Accrued Expenses

Accrued expenses consist of the following:

	December 31,	
	2005	2004
Professional fees	$ 444	$ 60
Research and development	1,148	1,465
Clinical trial	893	849
Other	745	243
	$ 3,230	$ 2,617

5. Purchased Intangible Assets

Purchased intangible assets consist of the following:

	December 31,	
	2005	2004
License fee	$ 4,826	$ 4,826
Less: accumulated amortization	(302)	—
	$ 4,524	$ 4,826
Other purchased intangible assets	$ 592	$ 161
Less: accumulated amortization	(138)	(44)
	$ 454	$ 117

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In accordance with the terms of the Amended and Restated License and Supply Agreement with Orion Corporation, the Company was required to pay a license fee of $4,826. This license fee is being amortized on a straight-line basis over the term of the agreement which the Company estimates to be 16 years (see Note 7). Other purchased intangible assets consist of software which is being amortized on a straight-line basis over its estimated useful life of three years. Amortization expense for the years ended December 31, 2005, 2004 and 2003 was $400, $21, and $11, respectively.

Estimated future amortization expense for purchased intangible assets at December 31, 2005 is as follows:

Year Ended December 31,	
2005	$ 486
2006	476
2007	397
2008	302
2009	302
Thereafter	3,015
Total	$ 4,978

6. Common and Preferred Stock

The Company's certificate of incorporation authorizes the Company to issue 60,000,000 shares of common stock with $0.001 par value per share and 5,000,000 shares of Preferred Stock, par value $0.001.

On February 6, 2004, we successfully completed an IPO of 5,400,000 shares of common stock at an offering price to the public of $14.50 per share resulting in net proceeds of $70.4 million. Upon the closing of the IPO, all outstanding shares of preferred stock, and accrued dividends thereon, were converted into 11,521,075 shares of common stock.

On October 17, 2005, the Company completed an underwritten public offering of 6,325,000 shares of its common stock including the exercise of the over-allotment option by the underwriters, at a price to the public of $7.80 per share. Net cash proceeds from this offering were $45,663 after deducting underwriting discounts and other offering expenses.

7. License and Collaboration Agreements

University of Tennessee Research Foundation License Agreement

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 for the treatment and/or prevention of prostate cancer and premalignant lesions ("PIN") that may develop into prostate cancer. 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 superseded a 1998 license agreement with UTRF pursuant to which 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 composition of matter and method of use patents relating to SARM compounds, including andarine, to market, distribute and sell licensed 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 superseded a 2000 license agreement with UTRF pursuant to which the Company reimbursed UTRF for certain patent expenses incurred by UTRF and agreed to make sublicense fee payments and future royalty payments.

The Company also has executed with UTRF an Amended and Restated Exclusive License Agreement granting the Company worldwide exclusive licenses with UTRF's composition of matter and method of use patents for some of the Company's preclinical programs pertaining to viral cytolytics and gene therapy.

Orion Corporation License and Supply Agreement

On December 29, 2004, the Company entered into an Amended and Restated License and Supply Agreement ("License and Supply Agreement") with Orion Corporation ("Orion") granting the Company exclusive rights to Orion's compound, toremifene, for all products for human uses, including the Company's product candidate, ACAPODENE, excluding, however products for breast cancer sold outside of the United States. The License and Supply Agreement, which has an effective date of January 1, 2005, replaces an earlier agreement entered into with Orion in 2000, and subsequently amended in 2001 and 2003 ("Original License"). Under the agreement, the Company was required to pay a license fee of $4,826. The term of the agreement will survive for the term of the Company's patents, including the patents it licenses from UTRF pertaining to ACAPODENE for the treatment and/or prevention of PIN and prostate cancer. The Company believes that its patents pertaining to methods of use extend through 2022.

Under the Original License, the Company paid Orion $400, which it is allowed to offset along with clinical trial expenses against licensing fees and milestone payments it will pay to Orion if the Company sublicenses rights to its patents to third parties. The License and Supply Agreement retains these provisions and obligates the Company to make future royalty payments of varying amounts for toremifene based products for breast cancer in the United States (FARESTON) or ACAPODENE to treat or prevent PIN or prostate cancer or to treat complications arising from ADT.

The Company has agreed to achieve specified minimum sales requirements of ACAPODENE in the United States after commercialization of the product or it must pay Orion royalties based on the amount of the shortfall. In addition, the Company is required to pay up to $1,000 if the Company is acquired before receiving marketing approval for the use of ACAPODENE for the prevention or treatment of PIN or prostate cancer or to treat complications arising from ADT. Orion may terminate its supply Agreement if marketing approval for ACAPODENE is not granted in the United States by December 31, 2009.

Ortho Biotech Collaboration, License and Co-Promotion Agreement

In March 2004, the Company entered into a joint collaboration and license agreement with Ortho Biotech for andarine, its most advanced SARM compound, and specified backup SARM compounds. Under the terms of the agreement, the Company received in April 2004 an up-front licensing fee and reimbursement of development expenses of the completed Phase Id clinical trial for andarine totaling $6,687. Additionally, the Company will receive licensing fees and milestone payments of up to $76,000 based on andarine and up to $45,000 for each additional licensed compound achieving specific clinical development decisions or obtaining regulatory approvals. All milestone payments are based on achievements prior to the commercial launch of andarine. Johnson & Johnson Pharmaceutical Research & Development will be responsible for further clinical development and related expenses for andarine and other licensed SARM compounds. Ortho Biotech will be responsible for commercialization and related expenses for andarine and other licensed SARM compounds. If andarine is approved for commercial sale, Ortho Biotech will exclusively market andarine in the United States and in markets outside the United States. Under the agreement, the Company has the option to co-promote andarine and the other licensed SARM compounds to urologists in the United States for indications specifically related to men's health. The Company will receive up to

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double digit royalties on all United States and worldwide sales plus additional royalty payments in excess of 20% on all co-promoted sales generated from urologists in the United States.

The up-front licensing fee and reimbursement of Phase Id clinical trial expenses for andarine totaling $6,687 are expected to be amortized into revenue on a straight-line basis through March 2009. The Company recognized revenue of $1,337 and $1,055 for the years ended December 31, 2005 and 2004, respectively, from the amortization of the up-front license fee and expense reimbursement. Additionally, the Company recognized revenue of $812 for the year ended December 31, 2004 from the reimbursement of andarine development costs in accordance with this collaboration and license agreement. The reimbursement amount approximated the Company's actual expenses of which $514 and $298 were incurred in 2004 and 2003, respectively.

8. 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 tax assets consist of the following:

	December 31,	
	2005	2004
Deferred income tax assets:		
Net federal and state operating loss carryforwards	$ 34,246	$ 20,437
Research credits	3,229	1,961
Cash basis method	1,185	786
Deferred stock compensation	744	528
Deferred revenue	1,622	2,196
Total deferred tax assets	41,026	25,908
Deferred income tax liabilities:		
Depreciation	120	49
Total deferred tax liabilities	120	49
Net deferred income tax assets	40,906	25,859
Valuation allowance	(40,906)	(25,859)
	$ —	$ —

At December 31, 2005, the Company had net federal operating loss carryforwards of approximately $88.7 million, which expire from 2018 through 2025 as follows: 2018 $0.5 million, 2019 $1.8 million, 2020 $7.8 million, 2021 $2.5 million, 2022 $10.8 million, 2023 $12.8 million, 2024 $16.3 million and 2025 $36.2 million. The Company had state operating loss carryforwards of approximately $75.8 million, which expire from 2013 through 2020 as follows: 2013 $0.5 million, 2014 $1.8 million, 2015 $7.8 million, 2016 $2.5 million, 2017 $10.8 million, 2018 $12.8 million, 2019 $15.8 million and 2020 $23.8 million. The Company also had research and development credits of $3.2 million, which expire from 2018 through 2025. Utilization of the net operating loss carryforwards and credits may be subject to a substantial annual limitation if certain events occur which result in an ownership change as defined 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. The Company has reduced its deferred tax assets by a valuation allowance after considering available evidence concerning the realizations of these assets. At December 31, 2005 and 2004, net of the valuation allowance, the net deferred tax assets were reduced to zero.

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9. 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"). On January 14, 2004, the Company adopted its 2004 Equity Incentive Plan and 2004 Non-Employee Directors' Stock Option Plan, both of which became 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, which amount may be increased annually on January 1st of each year from 2005 until 2013, by the lesser of five percent of the number of shares of common stock outstanding on such date or an amount designated by the Company's Board of Directors. By actions of the Company Board of Directors in 2004 and 2005, the Board elected not to increase for either 2005 and 2006, the number of shares available under the 2004 Equity Incentive Plan. The Company may issue options for up to 268,000 shares of common stock under the 2004 Non-Employee Directors' Stock Option Plan, which may be increased annually January 1st of each year, from 2005 until 2013, by the lesser of the number of shares of options granted during the prior calendar year or such amount designated by the Company's Board of Directors. On January 1, 2006, the options available for issuance under the plan increased to a total of 268,000, from 250,000 at December 31, 2005. The Company's stock option plans allow 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 24,650 options under the 1999 Plan, 102,708 options under the 2000 Plan, 296,649 options under the 2001 Plan and 845,749 options under the 2002 Plan in the aggregate at any time. At December 31, 2005, 1,718,006 stock options were available for future issuance under the Company's equity compensation plans. The employee stock 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 options under the 2001 Plan vest one-fifth per year beginning on the first anniversary of the date the options were granted. The non-employee directors' stock options vest one-third on the first anniversary, one-third on the second anniversary and one-third on the third anniversary. 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 outstanding options issued under the 1999 Plan, the 2000 Plan, the 2001 Plan and the 2002 Plan will become fully vested and will be converted to cash, options or stock of equivalent value. Under the 2004 Non-Employee Directors' Stock Option Plan, in the event of certain corporate transactions, the vesting of all outstanding options will be accelerated in full if the surviving or acquiring entity elects not to assume or substitute for such options, and in the event of a change in control transaction, the vesting of all stock options will be accelerated in full. Under the 2004 Equity Incentive Plan, in the event of certain corporate transactions, the vesting of all outstanding options will be accelerated in full if the surviving or acquiring entity elects not to assume or substitute for such options, and following a change in control transaction, the vesting of outstanding stock options will be accelerated only if the option holders option agreement so specifies. At December 31, 2005, 2004 and 2003, respectively, 292,926, 184,172 and 101,269 of the Company's stock options were exercisable.

GTx, Inc.
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The following is a summary of stock option transactions for the three years ended December 31, 2005:

	Options	Weighted Average Exercise Price Per Share
Balances at January 1, 2003	363,375	$ 5.71
Options granted	533,375	6.24
Options forfeited	(67,150)	4.08
Options exercised	(850)	0.94
Balances at December 31, 2003	828,750	6.18
Options granted	323,250	11.35
Options forfeited	(1,000)	8.90
Options exercised	(7,793)	3.48
Balances at December 31, 2004	1,143,207	7.66
Options granted	236,000	10.71
Options forfeited	(73,206)	6.83
Options exercised	(4,251)	8.87
Balances at December 31, 2005	1,301,750	$ 8.27

The following table summarizes information about stock options outstanding at December 31, 2005:

	Options Outstanding			Options Exercisable	
Exercise Price	Number Outstanding	Weighted Averag Remaining Contractual Life(years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$2.24 - $2.24	43,208	4.89	$ 2.24	43,208	$ 2.24
$6.24 - $8.90	863,542	7.34	6.85	233,048	6.67
$10.26 - $14.50	395,000	8.86	12.02	16,670	14.05
	1,301,750	7.72	$ 8.27	292,926	$ 6.44

The Company accounts for its stock-based compensation in accordance with APB Opinion No. 25. 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 $1,215 and $515 for the years ended December 31, 2005 and 2004, respectively, and decreased by $126 for the year ended December 31, 2003. The pro forma disclosures may not be representative of that to be expected in future years. The weighted average grant date fair value of options granted were $8.27, $6.58 and $8.02 for the years ended December 31, 2005, 2004 and 2003, respectively. For the year ended December 31, 2005, the Company recognized stock-based compensation expense of $152 related to the acceleration of the vesting period of certain stock options granted to former employees.

10. Directors' Deferred Compensation Plan

Since June 30, 2004, non-employee directors have had the opportunity to defer all or a portion of their fees under the Directors' Deferred Compensation Plan until termination of their status as directors. Deferrals can be made into a cash account, a stock unit account, or a combination of both. Stock unit accounts will be paid out in the form of Company stock, except that any fractional shares will be paid out in cash valued at the then current market price of the Company's common stock.

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For the years ended December 31, 2005, 2004, and 2003, the Company incurred board of director fee expense of $137, $98, and $0, respectively, of which $125, $55, and $0 was deferred and will be paid in common stock. At December 31, 2005, 17,169 stock units had been credited to individual director stock unit accounts.

11. Employee Benefit Plan

The Company maintains 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 a statutory limit of their pre-tax compensation which was $14 for employees under age 50 and $18 for employees 50 and older in calendar year 2005. 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.

12. Commitments and Contingencies

Operating Lease Commitments

The Company leases laboratory facilities and office space pursuant to a lease which is accounted for as an operating lease. The lease expires December 31, 2007, with an option to extend for up to three additional years and is terminable by either party upon 90 day's notice. The lease provides for a credit against future rent payments equal to the amount of leasehold improvements made by the lessee up to $500. Rent expense was approximately $599, $219 and $184 for the years ended December 31, 2005, 2004 and 2003, respectively.

Purchase Commitments

The Company had outstanding contractual purchase obligations of $104 and $110 at December 31, 2005 and 2004, respectively. These outstanding contractual purchase obligations are not recorded in the accompanying financial statements as the amounts represent future obligations, not liabilities, at December 31, 2005 and 2004, respectively.

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13. Quarterly Financial Data (Unaudited)

The following is a summary of the quarterly results of operations for the years ended December 31, 2005 and 2004.

	Quarters Ended Year 2005			
	March 31	June 30	September 30	December 31
Revenues:				
Product sales, net	$ 353	$ 1,492	$ 288	$ 312
Collaboration revenue	334	335	334	334
Total revenues	687	1,827	622	646
Costs and expenses:				
Cost of product sales	245	920	185	223
Research and development expenses	7,326	8,639	8,454	6,504
General and administrative expenses	2,520	2,642	2,271	2,412
Total costs and expenses	10,091	12,201	10,910	9,139
Loss from operations	(9,404)	(10,374)	(10,288)	(8,493)
Interest income	324	354	345	697
Net loss	(9,080)	(10,020)	(9,943)	(7,796)
Net loss attributable to common stockholders	$ (9,080)	$ (10,020)	$ (9,943)	$ (7,796)
Net loss per share attributable to common stockholders:				
Basic	$ (0.37)	$ (0.41)	$ (0.40)	$ (0.26)
Diluted	$ (0.37)	$ (0.41)	$ (0.40)	$ (0.26)

	Quarters Ended Year 2004			
	March 31	June 30	Sept. 30	December 31
Revenues:				
Collaboration revenue	$ 52	$ 334	$ 335	$ 334
Reimbursement of development costs	—	760	42	10
Total revenues	52	1,094	377	344
Operating expenses:				
Research and development	4,411	4,224	3,971	5,344
General and administrative	1,612	1,601	1,801	2,197
Total operating expenses	6,023	5,825	5,772	7,541
Loss from operations	(5,971)	(4,731)	(5,395)	(7,197)
Interest income	150	212	270	314
Net loss	(5,821)	(4,519)	(5,125)	(6,883)
Accrued preferred stock dividends	(455)	—	—	—
Adjustments to preferred stock redemption value	17,125	—	—	—
Net (loss) income attributable to common stockholders	$ 10,849	$ (4,519)	$ (5,125)	$ (6,883)
Net income (loss) per share attributable to common stockholders:				
Basic	$ (0.60)	$ (0.18)	$ (0.21)	$ (0.28)
Diluted	$ (0.26)	$ (0.18)	$ (0.21)	$ (0.28)

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-8 No. 333-118882) pertaining to the GTx, Inc. Directors' Deferred Compensation Plan,

(2) Registration Statement (Form S-8 No. 333-112576) pertaining to the GTx, Inc. 2004 Equity Incentive Plan, 2004 Non-Employee Directors' Stock Option Plan, 2002 Stock Option Plan, 2001 Stock Option Plan, 2000 Stock Option Plan, and 1999 Stock Option Plan, and

(3) Registration Statement (Form S-3 No. 333-127175) pertaining to a registration to sell $100 million of common stock;

of our reports dated February 24, 2006, with respect to the financial statements of GTx, Inc., GTx, Inc.'s report on management's assessment of internal control over financial reporting, and the effectiveness of internal control over financial reporting of GTx, Inc., included in the Annual Report (Form 10-K) for the year ended December 31, 2005.

/s/ ERNST & YOUNG LLP

Memphis, Tennessee
February 24, 2006

EXHIBIT 31.1

CHIEF EXECUTIVE OFFICER CERTIFICATION

I, Mitchell S. Steiner, certify that:

1. I have reviewed this Annual Report on Form 10-K of GTx, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 2, 2006

/s/ Mitchell S. Steiner

Mitchell S. Steiner, M.D., F.A.C.S.
Chief Executive Officer and
Vice-Chairman of the Board of Directors

EXHIBIT 31.2

CHIEF FINANCIAL OFFICER CERTIFICATION

I, Mark E. Mosteller, certify that:

1. I have reviewed this Annual Report on Form 10-K of GTx, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 2, 2006

/s/ Mark E. Mosteller

Mark E. Mosteller, CPA
Vice President and Chief Financial Officer

EXHIBIT 32.1

CERTIFICATION PURSUANT TO
18 U. S. C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of GTx, Inc. (the "Company") on Form 10-K for the year ended December 31, 2005, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Mitchell S. Steiner, Chief Executive Officer of the Company certify, pursuant to Rule 13a-14(b) or Rule 15d-14(b) and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 2, 2006

/s/ Mitchell S. Steiner

Mitchell S. Steiner, M.D., F.A.C.S.
Chief Executive Officer and
Vice-Chairman of the Board of Directors

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934 (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

EXHIBIT 32.2

CERTIFICATION PURSUANT TO
18 U. S. C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of GTx, Inc. (the "Company") on Form 10-K for the year ended December 31, 2005, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Mark E. Mosteller, Chief Financial Officer of the Company certify, pursuant to Rule 13a-14(b) or Rule 15d-14(b) and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 2, 2006

/s/ Mark E. Mosteller

Mark E. Mosteller, CPA
Vice President and Chief Financial Officer

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934 (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.