GTX INC /DE/
Form 10-K
March 09, 2007

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2006

OR

o **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:

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock, par value $0.001 per share	The NASDAQ Stock Market, LLC

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

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

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 o No þ

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 þ No o

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. o

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 o Accelerated filer þ Non-accelerated filer o

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

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, 2006 as reported on the NASDAQ National Market was $116,782,839.

There were 34,857,079 shares of Registrant s common stock issued and outstanding as of March 1, 2007.

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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 2007 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 including any milestone payments or royalty payments that we may receive under our collaboration and license agreement with Ipsen Limited;
- Our and our collaborator s 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, estimate expects, intends, may, plans, potential, predicts, projects, should, will, would, and similar express 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, uncertainties and other important factors. We discuss many of these risks, uncertainties and other important factors 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 risks, uncertainties and other important factors, 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.

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PART I

ITEM 1. BUSINESS

Overview

GTx, Inc., a Delaware corporation incorporated on September 24, 1997 is a biopharmaceutical company dedicated to the discovery, development and commercialization of small molecules that selectively target hormone pathways to treat cancer, osteoporosis and bone loss, muscle wasting and other serious medical conditions. 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 multiple serious side effects of androgen deprivation therapy (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. We have licensed to Ipsen Limited, or Ipsen, exclusive rights in the European Union, Switzerland, Norway, Iceland, Lichtenstein and the Commonwealth of Independent States to develop and commercialize ACAPODENE® and other products containing toremifene in all indications which we have licensed from Orion Corporation, (Orion). We are also developing Ostarine™, a selective androgen receptor modulator, or SARM, for the treatment of cancer wasting, which is known as cancer cachexia and for chronic kidney disease (CKD) and end-stage renal disease (ESRD). We plan to initiate a Phase IIb clinical trial evaluating Ostarine™ for the treatment of cancer cachexia by the summer of 2007 and another Phase IIb clinical trial evaluating Ostarine™ for the treatment of muscle wasting in CKD/ESRD patients by the end of 2007. We believe that Ostarine™ and our other SARMs have the potential to treat a variety of other indications related to muscle wasting and bone loss including frailty and osteoporosis. Even though we will maintain our primary focus in urology and oncology, GTx is evolving into a selective nuclear hormone receptor modulator company that can target hormone pathways to address a myriad of unmet medical needs in men and women.

We currently market FARESTON® (toremifene citrate 60 mg) tablets, which have been approved by the U.S. Food and Drug Administration, or FDA, for the treatment of metastatic breast cancer in postmenopausal women in the United States. In January 2005, we acquired from Orion the right to market FARESTON® tablets in the United States for the metastatic breast cancer indication. We also acquired from Orion a license to toremifene for all indications in humans worldwide, except breast cancer outside of the United States. The active pharmaceutical ingredient in FARESTON® is the same as in ACAPODENE®, but in a different dose. We plan to build specialized sales and marketing capabilities to promote our product candidates to urologists and medical oncologists in the United States and to seek partners to commercialize our product candidates in broader markets in the United States and in the rest of the world.

We also have an extensive preclinical pipeline generated from our own discovery program that includes potential product candidates, prostarine, for benign prostatic hyperplasia, or BPH, and andromustine, an anticancer product candidate, for hormone refractory prostate cancer.

Our most advanced product candidate, ACAPODENE®, is being developed to treat the multiple serious 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 undergo ADT by 2008. It is the low estrogen levels unintentionally caused by ADT that can lead to multiple serious side effects including: severe bone loss, or osteoporosis, resulting in skeletal fractures; hot flashes; lipid profile changes that lead to higher rates of cardiovascular disease; and breast pain and enlargement, or gynecomastia. There are currently no drugs approved by the FDA for the treatment of these multiple serious side effects of ADT. We commenced a pivotal Phase III clinical trial of ACAPODENE® 80 mg 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. We reached our enrollment goal in the fall of 2005 with approximately 1,400 patients randomized in the trial. The primary endpoint is the incidence of vertebral morphometric fractures measured by x-ray, and the secondary endpoints include bone mineral density, or BMD, hot flashes, gynecomastia

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and lipid profile changes. In December 2005, we conducted a planned interim analysis of BMD in the first 197 patients to complete a year of treatment. Patients treated with ACAPODENE® 80 mg demonstrated statistically significant increases in BMD compared to placebo in all three skeletal sites measured: lumbar spine, hip and femoral neck. In June 2006, we conducted a lipid interim analysis of the same 197 patients. Patients treated with ACAPODENE® 80 mg had statistically significant lower levels of total cholesterol, LDL, and triglycerides, reduction in the ratio of total cholesterol to HDL, and higher levels of HDL, when compared to patients on placebo. However, data on all patients completing the study will need to be evaluated before any conclusions about clinical significance of the lipid profile findings can be drawn. In addition, investors should note that interim results of a clinical trial do not necessarily predict final results. We anticipate that we will complete this Phase III clinical trial in the fourth quarter of 2007. If the results are favorable, we expect to file a New Drug Application, or NDA, with the FDA in 2008.

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. 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 may unknowingly harbor this condition. Currently, there is no approved treatment to prevent prostate cancer in high risk men with high grade PIN. In January 2005, we initiated a pivotal Phase III clinical trial of orally administered ACAPODENE® 20 mg 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 reached our enrollment goal of 1,260 patients in May 2006 and have enrolled approximately 300 additional patients into the trial to also participate in substudies requested by the FDA under the SPA. We will evaluate efficacy endpoints at 36 months after completion of enrollment, with an interim efficacy analysis to be conducted after a certain number of cancer events have been recorded among study patients, which we currently expect to occur in the first quarter of 2008. If the efficacy results from the interim analysis achieve the proscribed statistical outcome, we plan to file a NDA with the FDA. If we are able to file a NDA based on the results of the interim efficacy analysis, we will need to continue to collect safety data during the review process to satisfy the FDA s safety requirements set forth in the SPA.

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. Testosterone and other anabolic steroids have been proven to reverse involuntary muscle wasting caused by aging, burns and trauma, cancer, chronic kidney disease, 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 an oral novel nonsteroidal agent designed to have anabolic activity like testosterone without unwanted side effects on the prostate and skin.

In December 2006, we announced that Ostarine™ met its primary endpoint in a Phase II proof of concept, double-blind, randomized, placebo-controlled clinical trial in 60 elderly men and 60 postmenopausal women. We initiated this proof of concept Phase II clinical trial of Ostarine™ in May 2006 and completed enrollment in July 2006. The trial was designed to evaluate the activity of Ostarine™ on building muscle as well as to assess safety in both elderly men and postmenopausal women. Without a prescribed diet or exercise regimen, all subjects treated with Ostarine™ for three months had a dose dependent increase in the primary endpoint of total lean body mass (muscle) with the 3 mg cohort achieving 1.4 kg compared to placebo ($p<0.001$). Treatment with Ostarine™ also resulted in a dose dependent improvement in functional performance, a secondary endpoint measured by a stair climb test, with the 3 mg cohort achieving a clinically significant improvement in both speed ($p=0.006$) and power ($p=0.005$) compared to placebo. Ostarine™ had a favorable safety profile, with no serious adverse events reported. Ostarine™ also exhibited tissue selectivity with beneficial effects on lean body mass and performance and with no apparent change in measurements for serum prostate specific antigen, or PSA (prostate), sebum production (skin and hair), or serum luteinizing hormone, or LH (pituitary) compared to placebo. We recently conducted discussions with various divisions of the FDA to investigate the required regulatory pathways for several indications under consideration for Ostarine™ s ongoing clinical development. With more clarity regarding the required regulatory pathway and with proof of concept Phase II clinical data, we have selected cancer cachexia as the initial indication for

Ostarine™ development. We plan to initiate a Phase IIb Ostarine™ clinical trial for cancer cachexia by the summer of 2007. We also plan to initiate a Phase IIb clinical trial of Ostarine™ for the treatment of muscle wasting in CKD/ESRD patients by the end of 2007.

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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 osteoporosis reducing the risk of skeletal fractures, may be cardio protective by having a favorable effect on lipid profile, and may reduce hot flashes. As testosterone levels decrease in aging men, there is also a gradual increase in estrogen levels in the blood relative to testosterone levels which 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 and bone strength. 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. DHT is the primary androgen involved in BPH. In aging men, there is a gradual decline in testosterone levels, which contributes to a loss of muscle mass and strength, and 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 their hormone receptors located in various tissues. Once a hormone binds with its receptor, this activates a series of cellular events that results in estrogenic or androgenic tissue effects.

Pharmaceuticals that target 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 into clinical prostate cancer, and may enhance BPH, cause acne, cause loss of hair in men and hair growth in women and cause 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 are not steroids that can bind to the same hormone receptors. 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 small molecule with the receptor. A drug that has the ability to either block or stimulate the hormone receptor is called a selective receptor modulator. A selective receptor modulator that can either block or stimulate a hormone 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 lipid profiles, 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 is FDA approved to treat advanced female breast cancer, and raloxifene, which is used to prevent and treat female postmenopausal osteoporosis.

A SARM is a small molecule that binds to and selectively modulates androgen receptors, the primary receptor to which testosterone binds. In men, SARMs potentially have 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

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testosterone s or other exogenous anabolic steroid therapies harmful side effects can be developed to treat a range of medical conditions, including: (1) muscle wasting conditions of chronic diseases, such as cancer, AIDS, CKD, ESRD, neurodegenerative disorders, trauma and burns; (2) muscle wasting conditions associated with aging such as frailty and sarcopenia; (3) the prevention and/or treatment of osteoporosis; (4) prostate disorders, such as BPH and prostate cancer; (5) disorders of the central nervous system, such as low libido, depression and other mood disorders; (6) low testosterone conditions, such as hypogonadism and andropause; (7) male reproductive functions, such as infertility, male contraception and erectile dysfunction; and (8) other conditions, such as anemia, and male hair loss.

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 owned and manufactured by Orion. 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 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, 2006. The loss of any of these three distributors could have a material adverse effect on continued FARESTON® sales. FARESTON® net product sales accounted for 18% and 65% of our total revenue for the years ended December 31, 2006 and 2005, respectively.

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Product Candidates

The following table identifies the development phase and status for each of our product candidates:

Program	Product Candidate/ Indication	Development Phase	Status
SERM	**ACAPODENE®** **80 mg** Multiple serious side effects of ADT	Pivotal Phase III clinical trial	Phase III clinical trial ongoing under a SPA; attained enrollment goal; obtained statistically significant results from a planned BMD interim analysis in fourth quarter of 2005 and from a lipid interim analysis in second quarter of 2006
	ACAPODENE® **20 mg** Prevention of prostate cancer in high risk men with high grade PIN	Pivotal Phase III clinical trial	Phase III clinical trial ongoing under a SPA; attained enrollment goal
SARM	**Ostarine™** Cancer cachexia	Phase IIb clinical trial	Phase II proof of concept clinical trial completed December 2006; Phase IIb trial to treat cancer cachexia planned to commence by summer of 2007
	Ostarine™ CKD/ESRD muscle wasting	Phase IIb clinical trial	Phase IIb trial to treat muscle wasting in CKD/ESRD patients planned to commence by year end
	Andarine	Phase I clinical trial	Four Phase I clinical trials completed

ACAPODENE®

Our most advanced product candidate, ACAPODENE®, is a SERM. ACAPODENE® is being developed as a once-a-day oral tablet to (1) treat the multiple serious side effects of ADT (80 mg dose) and (2) prevent prostate cancer in high risk men (20 mg dose). In January 2005, we exclusively licensed toremifene, the active ingredient in ACAPODENE®, for all indications in humans, except breast cancer outside of the United States. We licensed rights to toremifene based on our belief that a SERM can treat complications resulting from ADT and reduce the incidence of prostate cancer in high risk men with high grade PIN and toremifene s established record of safety in the treatment of postmenopausal women with advanced breast cancer. Under our license and supply agreement, Orion manufactures and supplies to 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 serious side effects resulting from ADT and to prevent prostate cancer in

high risk men.

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In September 2006, we licensed to Ipsen exclusive rights to develop and commercialize ACAPODENE® and other products containing toremifene in all indications which we have licensed from Orion in the European Union, Switzerland, Norway, Iceland, Lichtenstein and the Commonwealth of Independent States (collectively, the European Territory).

ACAPODENE® 80 mg for the Treatment of Multiple Serious Side Effects of ADT

Scientific Overview. ADT is the standard medical treatment for patients who have advanced, recurrent or metastatic prostate cancer. ADT reduces testosterone, a primary growth factor for prostate cancer, to levels similar to that of castrated men. 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 also results in very low estrogen levels in men, because estrogen is derived from testosterone in men. In fact, estrogen levels in men on ADT have been shown to be lower than those levels in postmenopausal women.

Estrogen related side effects associated with ADT can include bone loss, which may lead to osteoporosis and skeletal fractures, hot flashes, gynecomastia, adverse lipid changes which leads to higher risk of cardiovascular diseases, 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 and may result in men being noncompliant in their prescribed ADT.

Based on the results of our two Phase II clinical trials, the interim analysis performed in our Phase III trial and our preclinical testing of ACAPODENE® 80 mg, 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 and, based on data received from our interim analysis of 197 men completing one year of treatment in the ADT trial, we believe ACAPODENE® may improve lipid profiles in men undergoing androgen deprivation therapy for prostate cancer. ACAPODENE® also can block estrogens action in the male breast, which may prevent and treat gynecomastia. As a consequence, we believe that ACAPODENE® 80 mg 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 patients 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 PSA is detecting advanced prostate cancer earlier than in the past. The net effect of prostate cancer being treated sooner and for longer periods is that the multiple serious side effects of ADT have now been shown to contribute significantly to morbidity, and in some cases may lead to increased mortality. Physicians are currently prescribing certain drugs on an off-label basis to help ameliorate some of the specific serious 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 serious 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

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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 postmenopausal 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®, compared to the placebo, did not demonstrate a meaningful 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 SPA, from the FDA. We designed this pivotal Phase III clinical trial principally based on the results of our second 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 morphometric fractures measured by x-ray, and the secondary endpoints of the trial include BMD, hot flashes, lipid changes and gynecomastia. We reached our enrollment goal 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 December 2005 and in accordance with the SPA, we completed a planned interim BMD analysis among the first 197 patients who completed one year of treatment. Patients treated with ACAPODENE® 80 mg 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 ($p=0.009$). 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. In June 2006, we conducted a lipid interim analysis of the same 197 patients. Patients treated with ACAPODENE® 80 mg had statistically lower levels of total cholesterol, LDL, and triglycerides, reduction in the ratio of total cholesterol to HDL, and higher levels of HDL, when compared to patients on placebo. However, data on all patients completing the study will need to be evaluated before any conclusions about clinical significance of the lipid findings can be drawn. In addition, investors should note that interim results of a clinical trial do not necessarily predict final results.

A Data Safety Monitoring Board (DSMB) meets every six months to review unblinded data from the ACAPODENE® 80 mg ADT and ACAPODENE® 20 mg PIN clinical trials. In January 2007, the DSMB reviewed safety data from approximately 2,900 patients and recommended to continue both trials, which we believe suggests that 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 2008.

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ACAPODENE® 20 mg for the Prevention of Prostate Cancer in High Risk Men with High Grade PIN

Scientific Overview. Patients who have an abnormal 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 routinely undergo a prostate biopsy to determine whether they have prostate cancer. Precancerous prostate lesions known as 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 for developing prostate cancer. Prostate cancer eventually occurs in approximately 50% of men within three years of their being diagnosed with high grade PIN. We believe that this strong 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.

Testosterone and estrogens together are important for the initiation of prostate cancer. Estrogens may promote the development of prostate cancer by stimulating high grade PIN and causing it to progress into prostate cancer. Estrogen receptors are found in the normal prostate and in high grade PIN lesions. In animal models of prostate cancer, blocking estrogens action has been shown to reduce the incidence of prostate cancer. Because ACAPODENE® blocks estrogen receptors, we believe that it has the potential to reduce the incidence of prostate cancer in high risk men with high grade PIN.

Potential Market. Prostate cancer is one of the most frequently diagnosed cancers and the second leading cause of cancer-related deaths in men in the United States. There are approximately 218,000 new cases of prostate cancer diagnosed each year and 27,000 prostate cancer deaths annually in the United States. In addition, there are over 115,000 new cases of high grade PIN diagnosed each year, with an estimated 14 million men who unknowingly harbor high grade PIN.

Patients who are diagnosed with high grade PIN may undergo repeat biopsies following the diagnosis 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, Onconome, Inc. (formerly known as 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® 20 mg for the prevention of prostate cancer in high risk men. Information resulting from these collaborations will be used to evaluate whether a commercial test using 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 diagnosed with 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

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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 (completers analysis).

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® 20 mg 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® 20 mg for the prevention of prostate cancer in high risk men with high grade PIN, which is being conducted under a SPA with the FDA. Approximately 130 clinical sites across the United States and Canada are participating in this trial. We reached our enrollment goal of 1,260 patients in May 2006 and have enrolled approximately 300 additional patients into the trial to also participate in substudies requested by the FDA under the SPA. We will evaluate efficacy endpoints at 36 months after completion of enrollment, with an interim efficacy analysis to be conducted after a certain number of cancer events have been recorded among study patients, which we currently expect to occur in the first quarter of 2008. If the results in this interim efficacy analysis achieve the proscribed statistical outcome, we plan to file a NDA with the FDA. If we are able to file a NDA based on the results of the interim efficacy analysis, we will need to continue to collect safety data during the review process to satisfy the FDA s safety requirements set forth in the SPA.

OSTARINE™

In our third clinical program, Ostarine™, a SARM, is being developed 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 in acute and chronic diseases caused by aging, burns and trauma, cancer, chronic kidney disease/end-stage renal disease, chronic obstructive pulmonary disease and other similar diseases. Testosterone and other anabolic steroids, however, may cause unwanted side effects, including stimulating prostate cancer growth in men and masculinization in women. Ostarine™ is an oral nonsteroidal agent designed to have anabolic activity like testosterone without unwanted side effects on prostate and skin.

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Ostarine™ for the Treatment of Cancer Cachexia

Scientific Overview. Cancer cachexia is defined as the unintentional loss of lean body mass or muscle. Cancer causes the body to go into a starvation-like state that results in the preferential loss of muscle. Loss of muscle may lead to weakness, fatigue, diminished response and greater toxicity to chemotherapy, and in some cases, death. Approximately one-third of newly-diagnosed cancer patients have cancer cachexia which 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 greater lean body weight may increase strength, 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 available delivery methods for testosterone may not be convenient 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 Ostarine™ 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 may exacerbate BPH or stimulate prostate cancer. In addition, Ostarine™ is being developed in an oral dosage form, which patients may find is more convenient to take.

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 410,000 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 anabolic steroids being prescribed off-label for the treatment of cancer cachexia, chronic use of these drugs may result in liver toxicity. Also, Megase® has not been shown to increase lean body mass in spite of increasing appetite.

Ostarine™ for the Treatment of Muscle Wasting Related to Renal Disease

Scientific Overview. In chronic kidney disease, and especially end-stage renal disease (dialysis), muscle wasting is the strongest and most consistent indicator of poor outcomes, (e.g., morbidity and mortality). The elderly with chronic kidney disease (CKD) are three times more likely to be frail than elderly without CKD. A survey of ESRD patients showed that a high percentage of these patients lives are impacted by muscle wasting, and their more common complaints include: lack of energy (90%), feeling tired (90%), change in weight (62%) and muscle weakness (54%). A high percentage of elderly ESRD patients fall each year (27% report having fallen the past 12 months with an additional 16% reporting a fall in the prior year). While it is clear that a decline in muscle function and exercise performance begin in early disease stages of CKD, the pathophysiology of muscle wasting in CKD is complex, multifactoral and not fully understood. The primary causes for the muscle wasting are thought to be sarcopenia, or the loss of muscle with aging; an increase in inflammatory, catabolic cytokines; a loss of protein stores; insulin resistance; and inactivity (a 30 year old hemodialysis patient is likely to have less activity than a 70 year old healthy sedentary individual).

Small clinical trials have demonstrated that anabolic steroids and exercise training can increase muscle mass, serum protein markers, and physical function in ESRD patients. The data on the relationship between cytokines and anabolic agents is not completely understood; however, there is evidence to support that testosterone replacement may reduce some catabolic cytokines. The data in a Phase II clinical trial of 120 elderly men and postmenopausal women indicated that Ostarine™ increased muscle mass and improved physical function.

Potential Market. There are in excess of 8.3 million Americans who are estimated to have CKD, including approximately 400,000 ESRD patients. The reduction in the physical functioning of patients who have CKD has been demonstrated in large longitudinal studies including the Health ABC study (a study of 2,135 people who were between the ages of 70 to 79 years and had no functional limitations at the initiation of the study) and the

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Cardiovascular Health Study (included a cross section of 5,317 U.S. citizens in the study aged 65 years and older). Unfortunately, in the United States, there are no approved treatments to increase muscle mass and improve physical performance for these eight million Americans. The anabolic steroids that have demonstrated the ability to increase muscle are not broadly used as they have warnings in their labels related to the increased risk of prostate cancer in men and masculinization in women. We are not aware of any pharmaceutical companies currently conducting clinical trials to obtain an indication for muscle wasting in CKD/ESRD patients.

Ostarine™ for the Treatment of Osteoporosis and Frailty

Scientific Overview. Every year after age 30, people lose on average a half pound of muscle and gain a pound of fat. A typical 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 1% every year after the age of 30 years. Muscle plays several important roles: muscle provides strength and endurance, supports the skeletal system, plays an important role in metabolism, and helps protect the body by providing protein for the immune system. During an illness or trauma to the body, the energy demands of the body increase, and the body breaks down muscle to get protein to fuel the body s needs, to repair damaged organs, and to replenish immune system cells. Muscle wasting starts a vicious cycle. As people lose muscle, they become fatigued more easily, making it more difficult for them 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. People who are fatigued may become more sedentary, which can lead to a reduction in their quality of life. Once people have lost muscle mass, it is increasingly difficult for the body to recover from disease. Loss of muscle and bone with age is sometimes referred to as frailty whereas loss of bone only is referred to as osteoporosis. A 2001 study among more than 5,000 elderly adults found that over a three-year period the death rate among the frail elderly was 18%, versus a 3% mortality 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 and promote bone. 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 side effects, such as the stimulation of prostate cancer in men and masculization in women. 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 muscle mass. In the United States in 2003, there were approximately 13.2 million hospital discharges among the 35 million people over the age of 65 years. It has been shown that from the time of the onset of their illness, approximately 50% of the elderly declined in health after their hospital stay. Muscle wasting is a contributing factor in their inability to completely recover. Current anabolic agents available in the market may be experiencing limited acceptance by patients due to concerns about their potential undesirable side effects, and inconvenient dosing. Testosterone is not available as an oral tablet in the United States and topical gels and patches are the most utilized forms of delivery for testosterone currently.

Clinical Trials. We have clinical data from two Phase I and one Phase II clinical trials of Ostarine™. In our first Phase I clinical trial, a double-blind, placebo-controlled, single-ascending dose study in 96 healthy male volunteers, Ostarine™ was well tolerated and there were no drug-related serious adverse events. This clinical trial demonstrated that the half life of Ostarine™ was approximately 24 hours.

The second Phase I clinical trial was a double-blind multiple ascending dose 14 day study to evaluate the safety, tolerability, pharmacokinetics, and specific pharmacodynamic characteristics of Ostarine™in 48 healthy male volunteers between 18 and 45 years of age and 23 elderly males with an average age of 68 years. 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

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positive changes in body composition at clinically relevant doses; increases in lean body mass and decreases in fat mass were observed. Ostarine™ did not appear to have unwanted side effects on the prostate (serum PSA) or the skin (sebum analysis). Ostarine™ was well tolerated with 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.

In May 2006, we initiated a Phase II proof of concept, double-blind, randomized, dose finding placebo-controlled clinical trial in 60 elderly men and 60 postmenopausal women. The trial was designed to evaluate Ostarine™ treatment in building muscle, as well as to assess safety in both elderly men and postmenopausal women. Enrollment was completed in July 2006, and in December 2006, we reported the top line results. Without a prescribed diet or exercise regimen, all subjects treated with Ostarine™ had dose dependent increases in the primary endpoint total lean body mass with the 3 mg cohort achieving an increase of 1.4 kg compared to placebo ($p<0.001$) after three months of treatment. Treatment with Ostarine™ also resulted in a dose dependent improvement in functional performance, a secondary endpoint, measured by a stair climb test, with the 3 mg cohort achieving a clinically significant improvement in both speed ($p=0.006$) and power ($p=0.005$) compared to placebo. Ostarine™ had a favorable safety profile, with no serious adverse events reported. Ostarine™ also exhibited tissue selectivity with beneficial effects on lean body mass and performance and with no apparent change in measurements of serum PSA, sebum production, or serum LH. We recently conducted discussions with various divisions of the FDA to investigate the required regulatory pathways for several indications under consideration for Ostarine™ s ongoing clinical development. With more clarity regarding the required regulatory pathway and with proof of concept Phase II clinical data, we have selected cancer cachexia as the initial acute indication for Ostarine™ development. We plan to initiate a Phase IIb Ostarine™ clinical trial for cancer cachexia by the summer of 2007. We also plan to initiate a Phase IIb clinical trial of Ostarine for the treatment of muscle wasting in CKD/ESRD patients by the end of the year.

ANDARINE

Andarine is another one of our SARMs that has been in clinical development for the treatment of a variety of medical conditions relating to muscle wasting and/or bone loss. In March 2004, we entered into a joint collaboration and license agreement with Ortho Biotech Products, L.P., a subsidiary of Johnson & Johnson (Ortho Biotech) and other SARM compounds meeting specified criteria. In December 2006, we reacquired our rights to develop and commercialize andarine and the other SARM compounds previously licensed to Ortho Biotech, and the joint collaboration and license agreement was terminated by the mutual agreement of the parties. We are in the process of evaluating andarine and determining how we can maximize its value in our SARM portfolio.

PROSTARINE

We are also developing another 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 as well as evaluating other potential product candidates. It is estimated that there are twelve million men in the United States with an enlarged prostate and moderate to severe urinary symptoms. The market in the United States for BPH exceeds $1 billion and is comprised primarily of alpha blockers which relax the smooth muscle of the prostate (e.g. Flomax®) and 5-alpha reductace inhibitors (e.g. Proscar®) which shrink the prostate tissue.

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.

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We have designed and are developing small molecules to specifically target and kill cancer cells. In cell culture and in animals, these compounds selectively kill metastatic human 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, the prognosis is poor. Andromustine could be a second line cancer therapy for patients who have developed 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-based 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 such as Ostarine™, a nuclear hormone receptor modulator. We also have conducted other research and development efforts focused on other SERM and SARM compounds, other receptor modulator compounds and anticancer agents.

Our Strategy

Our objective is to develop and commercialize small molecules that selectively target hormone pathways to treat cancer, osteoporosis and bone loss, muscle wasting and other serious medical 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 SPAs 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 in the United States through a small, specialty sales force that we plan to build. We plan to collaborate with pharmaceutical companies like Ipsen to commercialize, market and sell ACAPODENE® outside of the United States and to physicians outside of urology and medical oncology in the United States.

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Partner Commercial Rights to ACAPODENE® in Europe, Asia and the Rest of the World. In September 2006, we licensed to Ipsen exclusive rights in the European Territory to develop and commercialize ACAPODENE® and other products containing toremifene for all indications which we have licensed from Orion. We are currently pursuing a similar partnership for ACAPODENE® in Asia.

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. GTx and Ipsen 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, Onconome, Inc. (formerly known as 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 with 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. In February 2007, MacroArray Technologies reported in *Clinical Cancer Research* the development of a urine test to non-invasively detect high grade PIN. 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® 20 mg.

Maintain Commercial Sales of FARESTON®. We intend to continue to market FARESTON® in the United States.

Pursue Clinical Development of Ostarine™. We intend to initiate a Phase IIb clinical trial for Ostarine™ for the treatment of cancer cachexia by the summer of 2007. We are also planning to initiate a Phase IIb clinical trial of Ostarine™ for the treatment of CKD/ESRD muscle wasting by the end of 2007. We believe that Ostarine™ and our other SARMs have the potential to treat a variety of indications related to muscle wasting and bone loss, including frailty and osteoporosis.

Build upon our Other SARM and Other Drug Discovery Capabilities to Sustain our Small Molecule Product Candidate Pipeline to Selectively Target Hormone Pathways. 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 SARM program, other SERM product candidates, or other compounds under development.

Licenses and Collaborative Relationships

In addition to our own developed and discovered small molecules, 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.

Ipsen Group

In September 2006, we entered into a collaboration and license agreement with Ipsen pursuant to which we granted Ipsen exclusive rights in the European Territory to develop and commercialize ACAPODENE® and other products containing toremifene in all indications that we have licensed from Orion, which include indications for all diseases or indications in humans except the treatment and prevention of breast cancer. In the agreement, both parties have agreed that neither party will seek to commercialize, promote, market or sell certain products within the European Territory for an agreed period of time subsequent to the time of the first commercial launch of

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ACAPODENE® within the European Territory. We and Ipsen have also granted to each other a right of first negotiation with respect to the development, marketing, sale and distribution of any new SERM-based products for the field of the prevention and treatment of prostate cancer or related side effects, or any other indication the parties may agree on. In accordance with the terms of the agreement, Ipsen agreed to pay us 23 million as a license fee and expense reimbursement, of which 1.5 million will be deferred and paid in equal installments over a three year period. In October 2006, we received 21.5 million (approximately $27.1 million) from Ipsen as initial payment for the license fee and expense reimbursement. Pursuant to the agreement, we are also entitled to receive from Ipsen up to an aggregate of 39 million in milestone payments depending on the successful development and launch of ACAPODENE® in certain countries of the European Territory for the high grade PIN indication, subject to certain conditions, and the ADT indication. Ipsen has agreed to be responsible for and to pay for all clinical development, regulatory and launch activities to commercialize ACAPODENE® in the European Territory for both the high grade PIN indication and ADT indication. We will remain similarly responsible for all development and regulatory activities outside of the European Territory. However, Ipsen has agreed to pay a portion of our ACAPODENE® development costs in the United States if certain conditions are met. Under the agreement, Ipsen must elect to retain its rights to commercialize ACAPODENE® and other products containing toremifene for the high grade PIN indication. Until such time as Ipsen shall make its election, however, it is required to initiate and carry out the development of ACAPODENE® for the high grade PIN indication in the European Territory and to pay all costs associated therewith. Depending on when Ipsen exercises this election, Ipsen may be required to pay an additional license fee as well as a premium on its share of the development and clinical trial expenses incurred by us in the United States since January 1, 2006, on account of ACAPODENE® for high grade PIN. If Ipsen does not exercise its election within a certain period, Ipsen will not be obligated to pay us for a portion of the development and clinical trial expenses incurred by us in the United States since January 1, 2006, on account of ACAPODENE® for the high grade PIN indication, and we may elect to terminate Ipsen s rights to commercialize toremifene-based products for this indication, in which event all of Ipsen s rights to ACAPODENE® for the high grade PIN indication (including all associated clinical trial data and regulatory filings and approvals) will revert to us. Ipsen has agreed to pay us a royalty equal to a graduating percentage of aggregate net sales of products containing toremifene (including ACAPODENE®) in the mid-teens, which could reach the mid-twenties based on certain sales price thresholds being met, and which rates will be dependent on whether such sales are for the high grade PIN indication or the ADT indication. We will remain responsible for paying upstream royalties on ACAPODENE® to both Orion and the University of Tennessee Research Foundation for the PIN indication and to Orion only for the ADT indication. Ipsen will purchase the bulk drug product supply directly from Orion and is responsible for the packaging and labeling of the final product.

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 and supply 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. Our license and supply agreement with Orion requires that Orion will manufacture and supply all of our and our sublicensees needs for clinical trial and commercial grade material for toremifene-based products developed and marketed in the United States and abroad, including ACAPODENE® globally and FARESTON® in the United States. 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 license and supply agreement lasts, on a country-by-country basis, until the later of expiration of our own patents claiming the method of use or manufacture

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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® 20 mg 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® 20 mg 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.

Effective as of December 2004, UTRF and The Ohio State University, or OSU, entered into two inter-institutional agreements 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 agreements 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.

On November 28, 2006, we received correspondence from counsel representing UTRF claiming $940,000 in annual license maintenance fees and residual alliance royalties under our two exclusive license agreements with UTRF relating to SARM compounds.

In December 2006, we executed a letter of intent with UTRF agreeing to modify each of the above referenced license agreements existing between the parties, including the two SARM license agreements. The revised license agreements, when executed by us and UTRF, are intended to address certain provisions of the agreements pertaining to the time and amount of payments for license maintenance fees and royalty fees to be paid by us to UTRF. Upon execution of the revised license agreements, we have agreed to pay to UTRF an aggregate consideration of $600,000 which will be allocated among the license agreements.

Ortho Biotech Collaboration and License Agreement

In March 2004, we entered into a joint collaboration and license agreement with Ortho Biotech for andarine, and specified backup SARM compounds. Under the terms of the agreement, we received in April 2004 an up-front licensing fee and expense reimbursement totaling $6.7 million. The up-front licensing fee and expense reimbursement were deferred and amortized into revenue on a straight-line basis over the estimated five year andarine development period. In December 2006, we reacquired full rights to develop and commercialize andarine and all backup compounds previously licensed to Ortho Biotech and the joint collaboration and license agreement

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was terminated by mutual agreement of the parties. In connection with the termination of the Ortho Biotech agreement, we recognized the associated $3.1 million balance of deferred revenue as additional collaboration revenue.

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.

There are no complicated chemistries or unusual equipment required in the manufacturing process for our SARMs. 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. We contract with multiple third party vendors for our clinical supply requirements for Ostarine™ and andarine. We have begun the selection process for the manufacture of full-scale commercial product which we expect to have selected by the end of 2007.

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,

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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® 20 mg for the Prevention of Prostate Cancer in High Risk Men with High Grade PIN

Currently, there are no drug products that would compete with ACAPODENE® 20 mg for the treatment of high grade PIN to reduce the incidence of prostate cancer. There are government sponsored studies looking at the ability of nutritional supplements to prevent prostate cancer in men with high grade PIN. These studies are much smaller than the ACAPODENE® 20 mg 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, but men with high grade PIN were excluded from the Avodart trial.

ACAPODENE® 80 mg for the Treatment of Multiple Serious Side Effects of ADT

Currently, there are no products that have been approved by the FDA to treat multiple serious side effects of ADT. We are aware of a number of drugs that are marketed or prescribed off-label for the treatment of single side effects. For example, Evista® (raloxifene hydrochloride), a SERM marketed by Eli Lilly, Fosamax® (alendronate sodium), a bisphosphonate marketed by Merck, Zometa® (zoledronic acid) a bisphosphonate marketed by Novartis, 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 (denosumab), 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 use of these drugs and radiation treatment. Most patients would need to take several different drugs and potentially receive radiation treatments to treat multiple serious side effects of ADT. In contrast, we believe that ACAPODENE® 80 mg as a single product candidate, has the potential to treat multiple serious side effects.

SARMs for the Treatment of Cancer Cachexia and other Muscle and Bone Wasting Diseases

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® (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 but has been prescribed off-label for cancer cachexia. Oxandrin® was marketed by Savient Pharmaceuticals and generated approximately $60 million in annual sales. Savient has discontinued production of Oxandrin® following the introduction of an authorized generic. 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, and possible inconvenient dosing, we believe that testosterone products have had a limited 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 2007, and other pharmaceutical companies are also developing SARMs. Wyeth and Amgen have myostatin inhibitors in development which may compete for similar patients as Ostarine™. Megace® (megesterol acetate) and Marinol® (dronasinol) are appetite stimulants approved for AIDS patients which are used off-label for cancer cachexia. Neither Megace® nor Marinol® increase muscle and neither have been shown to improve physical function.

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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 postmenopausal 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 in the United States and to market FARESTON® to targeted prescribers, principally medical oncologists and other key specialists targeted 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 have partnered with Ipsen to commercialize ACAPODENE® in Europe. We are currently seeking partners to market ACAPODENE® in Asia and other markets outside of the United States and Europe.

If approved by the FDA, 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 such as medical oncologists. Therefore, 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® 20 mg for the reduction in the incidence of prostate cancer in high risk men with high grade PIN. The method of use patents issued in the United States related to the use of ACAPODENE® 20 mg for this indication will begin expiring in 2019.

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We have our own pending method of use patent applications in the United States and internationally related to the use of ACAPODENE® 80 mg for the treatment of osteoporosis, gynecomastia and hot flashes and improvements of lipid profiles as multiple serious side effects of ADT. A method of use patent related to the use of ACAPODENE® 80 mg for the treatment of ADT-induced osteoporosis issued in the United States and will expire in 2023.

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® 80 mg for the treatment of osteoporosis, hot flashes and gynecomastia as multiple serious side effects of ADT worldwide and the method of use of ACAPODENE® 20 mg for the reduction in the incidence of prostate cancer in high risk 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® 80 mg for the treatment of osteoporosis, hot flashes and gynecomastia as multiple serious side effects of ADT worldwide and the method of use of ACAPODENE® 20 mg for the reduction in the incidence of prostate cancer in high risk 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 FARESTON® (toremifene citrate) 60 mg tablets 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 multiple serious side effects of ADT in the treatment of prostate cancer. We have since acquired the rights from Orion to market, sell and distribute a 60 mg 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 Ostarine™ and our other SARMs, including andarine and prostarine, we have an exclusive license from the UTRF under its issued patents and pending patent applications in the United States and internationally covering the composition of matter of the active pharmaceutical ingredient in these product indications, pharmaceutical compositions and formulations and methods of synthesizing the active pharmaceutical ingredients. We also have pending patent applications in the United States and internationally related to methods for building muscle mass and bone in patients and treating frailty, osteoporosis, cancer cachexia and other wasting diseases using ostarine™, andarine and other SARMs.

We have pending patent applications in the United States and internationally related to methods for treating BPH using prostarine.

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 to the Company 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.

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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, either 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

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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 ten 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.

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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

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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.

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Research and Development

Since our inception, we have been focused on drug discovery, preclinical development and clinical development programs. Our research and development expenses were $33.9 million for the year ended December 31, 2006, $30.9 million for the year ended December 31, 2005 and $18.0 million for the year ended December 31, 2004.

Employees

As of December 31, 2006, we had 91 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 100 F 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, 2007.

Name	Age	Position(s)
Directors and Executive Officers		
Mitchell S. Steiner, M.D., F.A.C.S.	46	Chief Executive Officer and Vice-Chairman of the Board of Directors
Marc S. Hanover, MBA.	44	President, Chief Operating Officer and Director
Henry P. Doggrell, JD.	58	Vice President, General Counsel and Secretary
Mark E. Mosteller, CPA.	44	Vice President, Chief Financial Officer and Treasurer
K. Gary Barnette, Ph.D.	39	Vice President, Clinical Research and Development Strategy
James T. Dalton, Ph.D.	44	Vice President, Preclinical Research and Development
Gregory A. Deener.	45	Vice President, Sales and Marketing Product Commercialization
Other Key Employees		
T. Gary Bird, Ph.D.	54	Director of Corporate Quality
Robert S. Boger, M.D.	60	Director of Drug Safety
Karen A. Veverka, Ph.D.	39	Director of Preclinical Development
Domingo Rodriguez, M.D.	45	Director of Clinical Operations

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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, MBA, 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, JD, 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 JD 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 in the Division of Pharmaceutics, College of Pharmacy at The Ohio State University (2000-2007). 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.

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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.

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.

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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, 2006, we had an accumulated deficit of $229.8 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 $35.5 million for the year ended December 31, 2006, $36.8 million in 2005, and $22.3 million in 2004. 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 primarily financed our operations and internal growth through sales of common stock and preferred stock. In addition, we have received upfront license fees and payments pursuant to our collaboration agreement with Ortho Biotech for andarine and certain other SARMs, which was terminated in December 2006, and our collaboration agreement with Ipsen for European rights to ACAPODENE® and other toremifene-based products. FARESTON® is currently our only commercial product and, we expect, will account for all of our product revenue for the foreseeable future. For the year ended December 31, 2006, we recognized $1.4 million in net revenues from the sale of FARESTON®.

We expect our research and development expenses to increase in connection with our ongoing 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 quarter of 2009. This estimate does not include funding from milestone payments that we may receive under our existing collaboration with Ipsen, potential future collaboration agreements with pharmaceutical companies, or potential future issuance and sale of securities. This estimate does not include any potential product launch costs for ACAPODENE® in the event that it is approved for marketing by the FDA.

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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 achievement of certain milestone events under, and other matters related to, our collaboration and license agreement with Ipsen;
- The terms and timing of any future collaborative, licensing and other arrangements that we may establish;
- The cost and timing of regulatory approvals;
- Potential future licensing fees, milestone payments and royalty payments, including any milestone payments or royalty payments that we may receive under our collaboration and license agreement with Ipsen;
- 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, as well as through interest income earned on the investment of our cash balances and revenue for the sale of FARESTON®.

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 and/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. Several patients in our Phase III clinical trial of ACAPODENE® 80 mg for the side effects of androgen deprivation therapy have withdrawn from the trial, in accordance with the trial protocol, to seek treatment for a loss in bone mineral density. Even if these patients are receiving a placebo, their withdrawal from the trial may result in delays or an inability to achieve the proscribed statistical endpoint. 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:

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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.

For some of the indications for which we intend to conduct or are currently conducting clinical trials for our product candidates, we do not have evidence from prior preclinical studies in animals or clinical trials in humans of the potential effectiveness of such product candidates for such indications. In the absence of preclinical or clinical data, our beliefs regarding the potential effectiveness of our product candidates for these indications is generally based on pharmacokinetic data and analyses and pharmacological rationales. For example, our belief that ACAPODENE® has the potential to reduce hot flashes is based, in part, on our second Phase II clinical trial in which a higher percentage of the subjects in the placebo group experienced worsening in the frequency of hot flashes compared to the subjects treated with ACAPODENE®. Although this observation suggests that ACAPODENE® does not cause hot flashes or the worsening of hot flashes in men on androgen deprivation therapy, this trial was too small to establish the potential effects of ACAPODENE® on the reduction in incidence or severity of hot flashes. Similarly, an assessment of the potential to treat gynecomastia with ACAPODENE® in this second Phase II clinical trial was inconclusive. We are assessing the effect of ACAPODENE® on gynecomastia and hot flashes in our Phase III clinical trial. Our preclinical or clinical trials may produce negative or inconclusive results that would not support our belief regarding the potential effectiveness of our product candidates.

If we observe serious or other adverse events during the time our product candidates are in development or after our products are approved and on the market, we may be required to perform lengthy additional clinical trials, may be denied regulatory approval of such products, may be forced to change the labeling of such products or may be required to withdraw any such products from the market, any of which would hinder or preclude our ability to generate revenues.

To date, in our two Phase III clinical trials for ACAPODENE®, some patients have experienced venous thromboembolic events, such as deep vein thromboses, pulmonary embolisms, and myocardial infarctions, one of which resulted in a patient s death, which were considered by investigators as possibly related to treatment with ACAPODENE®. Because these trials are blinded, we cannot establish whether these patients received placebo or ACAPODENE® in the trial. There have been no drug-related serious adverse events related to our other product candidates. A drug safety monitoring board meets every six months to review unblinded data from the ACAPODENE® Phase III clinical trials that we are conducting. In January 2007, the drug safety monitoring board reviewed safety data from in excess of 2,900 patients, including the venous thromboembolic events and myocardial infarctions referred to above, and recommended continuing both clinical trials with no changes to the trial protocols. In addition, in our Phase II clinical trial for Ostarine™, we observed a dose-related elevation of hepatic enzymes, and in our preclinical studies for Ostarine™, we observed expected effects on the reproductive organs in the male

population, since our drug targets the androgen receptor which is located on these organs.

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If the incidence of these events increases in number or severity, if a regulatory authority believes that these events constitute an adverse effect caused by the drug, or if other effects are identified during clinical trials that we are currently conducting, during clinical trials that we may conduct in the future or after any of our product candidates are approved and on the market:

We may be required to conduct additional preclinical or clinical trials, make changes in labeling of any such approved products, reformulate any such products, or implement changes to or obtain new approvals of our or our contractors manufacturing facilities;

Regulatory authorities may be unwilling to approve our product candidates or may withdraw approval of our products;

We may experience a significant drop in the sales of the affected products;

Our reputation in the marketplace may suffer; and

We may become the target of lawsuits, including class action suits.

Any of these events could prevent approval or harm sales of the affected product candidates or products or could substantially increase the costs and expenses of commercializing and marketing any such products.

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. Similarly, Ipsen has agreed to purchase from Orion ACAPODENE® tablets for clinical testing and commercial sale in the European Union, Switzerland, Norway, Iceland, Lichtenstein and the Commonwealth of Independent States, which we refer to collectively as the European Territory, under an amended supply agreement with Orion. As such, both we and Ipsen rely on Orion as the single source supplier of ACAPODENE®.

In the event that Orion terminates our license and supply agreement due to our uncured material breach or bankruptcy, we would not be able to manufacture ACAPODENE® until the expiration of Orion s patents with respect to the composition of matter of toremifene, the active pharmaceutical ingredient in ACAPODENE®. Although Orion s composition of matter patents within the European Territory have expired, and as such, would not prevent Ipsen from manufacturing ACAPODENE® within the European Territory, there is no obligation on the part of Orion to transfer its manufacturing technology to Ipsen or to assist Ipsen in developing manufacturing capabilities to meet Ipsen s supply needs if Ipsen is in material breach of its supply agreement with Orion. Although we and Ipsen have agreed to collaborate with each other in the event either of our supply rights are terminated by Orion for any reason, a disruption in the supply of ACAPODENE® could delay the development of and impair our and Ipsen s ability to commercialize ACAPODENE®. In addition, Orion may terminate its obligation to supply us and Ipsen with toremifene if Orion ceases its manufacture of toremifene permanently, or Orion may terminate its obligation to supply us with toremifene 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 and Ipsen will have the right to manufacture ACAPODENE®, but any arrangements we make for an alternative supply would still have to be made with a qualified alternative supplier with appropriate FDA approval in order for us to obtain our supply requirements for

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ACAPODENE®. We and Ipsen have mutually agreed to cooperate in the manufacture of ACAPODENE® in the event Orion ceases manufacture of toremifene for any of the above-mentioned reasons.

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® in the United States 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®.

We have relied on third party vendors for Ostarine™, and we are currently assessing our manufacturing needs for additional clinical trial materials and commercial supply of Ostarine™ as we continue to review our clinical strategy for Ostarine™. We will evaluate whether to continue to rely on the manufacturing capabilities of these third party vendors or whether some or all of the manufacturing process should be transferred to other contract manufacturers as we plan for our clinical trials and potential commercial launch of Ostarine™. Under our joint collaboration and license agreement with Ortho Biotech, which was terminated in December 2006, Ortho Biotech was responsible for the manufacture, packaging and supply of andarine for both clinical trials and commercialization. We are currently assessing our manufacturing needs for additional clinical trial materials and commercial supply of andarine as we continue to review our clinical strategy for andarine. If our current supply of Ostarine™ or andarine becomes unusable, if our Ostarine™ or andarine supply is not sufficient to complete our clinical trials, or if we are unsuccessful in identifying a contract manufacturer or negotiating a manufacturing agreement on a timely basis for our clinical trials and potential commercial launch, we could experience a delay in receiving an adequate supply of Ostarine™ or andarine.

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 third party vendors for Ostarine™, 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 andarine 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 from the FDA of an alternate supplier, 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; and

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® in the United States prior to December 31, 2009; or

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

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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®. Further, Orion has agreed to supply ACAPODENE® tablets to Ipsen for clinical trials and commercial supply in the European Territory. Orion also manufactures toremifene for third parties for sale outside the United States for the treatment of advanced breast cancer in postmenopausal 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 to 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 Ipsen to develop and commercialize ACAPODENE® in the European Territory. We may also 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 and commercialization of our product candidates outside our control, may require us to relinquish important rights or may otherwise be on terms unfavorable to us.

The loss of Ipsen as a collaborator in the development or commercialization of ACAPODENE®, any dispute over the terms of our collaborations with Ipsen, or any other adverse development in our relationship with Ipsen could materially harm our business and might accelerate our need for additional capital. For example, Ipsen is obligated to initiate and conduct appropriate clinical studies as required by the appropriate regulatory authorities in order to obtain marketing approvals of ACAPODENE® within the European Territory. Any failure on the part of Ipsen to initiate these studies could delay the commercialization of ACAPODENE® within the European Territory.

We may not be successful in entering into additional collaborative arrangements with other 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 other product candidates and could increase our costs of development and commercialization. Dependence on collaborative arrangements, including our arrangement with Ipsen for the development and commercialization of ACAPODENE®, subjects us to a number of risks, including:

We are not able to control the amount and timing of resources that Ipsen devotes to ACAPODENE®;

We may not be able to control the amount and timing of resources that our potential future partners may devote to our product candidates;

Our partners may experience financial difficulties or changes in business focus;

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Under certain circumstances, Ipsen may not be required to commercialize ACAPODENE® in certain countries of the European Territory if it is determined that it is not commercially reasonable for it to do so;

Pricing reimbursement constraints within the European Territory may diminish the prospects of our receiving royalty payments from Ipsen on aggregate net sales of ACAPODENE® in some or all of the countries within the European Territory;

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;

Collaborative arrangements are often terminated or allowed to expire, which would delay the development and may increase the cost of developing our product candidates; and

We may be required to relinquish important rights such as marketing and distribution rights.

Additionally, we and Ipsen have agreed that neither party will seek to commercialize, promote, market or sell certain products within the European Territory for an agreed period of time subsequent to the time of the first commercial launch of ACAPODENE® within the European Territory. We and Ipsen have also agreed to grant to the other a right of first negotiation with respect to the development, marketing, sale and distribution of any new SERM-based products for the field of the prevention and treatment of prostate cancer or related side effects, or any other indication the parties agree on. Furthermore, our royalty rates under our collaboration agreement with Ipsen are subject to a possible reduction if a generic version of toremifene achieves specified sales levels in a major country within the European Territory or if Ipsen licenses patent rights from a third party that would otherwise be infringed by Ipsen s use, manufacture, sale or import of toremifene. Ipsen has the right to terminate the collaboration agreement with 12 months prior written notice for any reason and with 30 days prior written notice as a result of legitimate and documented safety concerns. If the royalty rates under our collaboration agreement are reduced or if Ipsen terminates the collaboration agreement, the anticipated benefits to us from this agreement would be significantly reduced or eliminated. In addition, if Ipsen terminates the collaboration agreement, the development of ACAPODENE® in the European Territory could be delayed and our costs of development would increase.

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 and supply agreement 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 and Ipsen 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 or Ipsen s development plans adversely affect these activities, any future modifications to our or Ipsen s plans imposed by Orion may limit our and Ipsen s ability to maximize the commercial potential of ACAPODENE®.

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Furthermore, we and our affiliates are prohibited from marketing or selling products containing toremifene or related SERM compounds for human use 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, which in the United States expire in September 2009. 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. Additionally, Ipsen s ability to successfully market ACAPODENE® within a substantial portion of the European Territory may depend on the granting of marketing and data exclusivity from the appropriate regulatory authorities.

Our rights to certain patent applications relating to SARM compounds that we have licensed from UTRF are subject to the terms of UTRF s interinstitutional agreements with OSU, and our rights to future related improvements in some instances are subject to UTRF s exercise of exclusive options under its agreements with OSU for such improvements, which UTRF can exercise at no additional cost to UTRF. In addition, under the terms of our agreements with the diagnostic companies to which we provide clinical samples from our Phase IIb and Phase III 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 for prescribed 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 September 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 or Ipsen will receive regulatory approval to 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. Within the European Union, Ipsen may need to rely primarily on the protection afforded by marketing and data exclusivity for the ACAPODENE® products to be sold within the countries comprising the European Union. 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 extensions of patent terms under applicable United States laws pertaining to our method of use patents, we may not be able to secure any such regulatory exclusivity or extension of patent term. Loss of marketing and data exclusivity for the ACAPODENE® products to be commercialized within the European Union could adversely affect its ability to successfully commercialize these products, and our failure to obtain any extension of patent terms for our method of use patents could adversely affect our prospects for protecting our ACAPODENE® products from competitive pressures in the United States for the time periods we currently expect. We are not eligible for any such exclusivity or further extension of the composition of matter patent of toremifene licensed to us by Orion 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

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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.

If we lose our licenses from Orion and UTRF, we may be unable to continue our business.

We have licensed intellectual property rights and technology from Orion and UTRF under our license agreements with each of Orion and UTRF. Each of these license agreements may be terminated by the other party if we are in breach of our obligations under, or fail to perform any terms of, the agreement and fail to cure that breach. If any of these agreements were terminated, then we may lose our rights to utilize the technology and intellectual property covered by that agreement to market, distribute and sell our licensed products, which may prevent us from continuing our business. For example, on November 28, 2006, we received correspondence from counsel representing UTRF claiming we owed additional annual license maintenance fees and residual alliance royalties under two exclusive license agreements we entered into with UTRF granting us worldwide exclusive licenses under UTRF s composition of matter and method of use patents relating to SARM compounds, including andarine and Ostarine™, to market, distribute and sell licensed products. In December 2006, we entered into a letter of intent with UTRF agreeing to modify each of the license agreements between us and UTRF including the two SARM license agreements. Upon execution of the revised license agreements, we will pay UTRF an aggregate consideration of $600,000. Under our exclusive license agreements with UTRF, in the event of a default or failure by us to perform any of the terms, covenants or provisions of these agreements, we have 30 days after the giving of written notice of any default to correct the default. If the default is not corrected within this 30-day period, UTRF has the right, at its option, to cancel and terminate these exclusive license agreements. In the event that we and UTRF do not execute revised license agreements or we do not pay the $600,000 consideration for the new license agreements, UTRF may elect to continue its claims against us, which if not resolved, could result in a termination of the existing SARM license agreements. If we did not prevail in our position that we are not in default under these license agreements or otherwise establish that UTRF did not have a right to terminate them, then the loss of these licenses would have a material adverse effect on the continued development of our SARM program and our business prospects would suffer.

Off-label sale or use of toremifene products could decrease sales of ACAPODENE® and could lead to pricing pressure if such products become available at competitive prices and in dosages that are appropriate for the indications for which we and Ipsen 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

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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 or Ipsen s 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 other toremifene products would not have been approved for those uses, and in most cases, the physician would not be liable for contributing to the infringement of 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 and Ipsen 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® in the countries outside of the United States where these applications are currently pending, 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. Also, regulatory authorities may not recognize marketing and data exclusivity for ACAPODENE® in the European Union for the treatment of prostate cancer and the multiple side effects resulting from androgen deprivation therapy. If generic versions of toremifene are able to be sold in countries within the European Territory for the indications for which Ipsen anticipates marketing ACAPODENE®, the royalties to be paid to us by Ipsen will be reduced if the total generic sales exceed a certain threshold for a certain period of time. Similarly, the royalties we will be paying to Orion for its licensing and supply of toremifene will be reduced if the same generic sales thresholds are reached.

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.

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In addition, under our collaboration and license agreement with Ipsen, Ipsen may be entitled to offset a portion of any royalties due to us in any calendar year on account of ACAPODENE® sales to pay for costs incurred by Ipsen to obtain a license to any dominant intellectual property rights that are infringed by such ACAPODENE® sales.

Risk Related to Regulatory Approval of Our Product Candidates

If we or our collaborators are not able to obtain required regulatory approvals, we or our collaborators 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 our product candidate and will prevent our collaborators from commercializing the product candidate in the licensed territories. 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. In addition, we will not receive a substantial majority of the milestone payments provided under our collaboration and license agreement with Ipsen or any royalty payments if Ipsen is unable to obtain the necessary regulatory approvals to commercialize ACAPODENE® within the European Territory. 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 are conducting our Phase III clinical trials of ACAPODENE® to treat the side effects of androgen deprivation therapy and for the reduction in the incidence of prostate cancer in high risk men with high grade PIN under Special Protocol Assessments 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 a 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. Similarly, it is not anticipated that Ipsen will receive the appropriate regulatory approvals to market ACAPODENE® within the European Territory any sooner than we will achieve regulatory approval in the United States, and it may be thereafter. The inability to obtain FDA approval or approval from comparable authorities in other countries for our product candidates would prevent us or our collaborators from commercializing these product candidates in the United States or other countries. See the section entitled

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Business Government Regulation under Part I, 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, healthcare 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. Sales of FARESTON® in the United States have been declining and we anticipate that they will continue to do so. 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 more than we currently anticipate:

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, 2006;

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 September 2009;

The loss of Orion, upon which we rely as a single source, as our supplier of FARESTON®; and

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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.

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

If we are unable to expand our sales and marketing capabilities or enter into and maintain 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. Similarly, we are relying on Ipsen to market and distribute our ACAPODENE® product candidates through Ipsen s established sales and marketing network within the European Territory. If our collaboration and license agreement with Ipsen is terminated for any reason, our ability to sell our ACAPODENE® product candidates in the European Territory would be adversely affected, and we may be unable to develop or engage an effective sales force to successfully market and sell our ACAPODENE® product candidates in the European Territory. 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 or our collaborators 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.

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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 marketing approvals.

We have product liability insurance that covers our clinical trials and commercial products up to a $25.0 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 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 androgen deprivation therapy, we are aware of a number of drugs marketed by Eli Lilly (Evista®), Merck (Fosamax®), Sanofi-Aventis and Procter & Gamble (Actonel®), Wyeth Pharmaceuticals (Effexor®), Boehringer Ingelheim (Catapres®), Novartis (Zometa®) and Bristol Myers Squibb (Megace®) 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 is developing a product candidate for the treatment of osteoporosis in prostate cancer patients. While we have the only pharmaceutical product in clinical development to prevent prostate cancer in high risk men with high grade PIN,

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GlaxoSmithKline is conducting a Phase III study for Avodart® on prostate cancer prevention which purposely excludes the high risk patient group of men with high grade PIN. In addition, there are nutritional supplement studies (for example, selenium) investigating prostate cancer prevention in men with high grade PIN. Similarly, while there are no drugs that have been approved by the FDA for the treatment of muscle wasting 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 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 2007. In addition, there are other SARM product candidates at an earlier stage of development that may compete with our product candidates. Wyeth and Amgen have myostatin inhibitors in development which may compete for similar patients as Ostarine™. 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 $25 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.

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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 so 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;

Developments with respect to our collaboration with Ipsen;

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.

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

As of January 31, 2007, our officers, directors and holders of 5% or more of our outstanding common stock beneficially owned approximately 81.8% of our outstanding common stock and our officers and directors alone owned approximately 50.9% 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, 2006, the average daily trading volume of our common stock on the NASDAQ Global Market was approximately 90,000 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, 2006, we had 34,822,362 shares of common stock outstanding.

We, along with our executive officers and directors, have agreed to specified lock-up provisions with regard to future sales of our common stock for a period of 90 days after our recently completed public offering of common stock, which closed on December 18, 2006, as set forth in the placement agent agreement executed in connection with the public offering, subject to certain exceptions. The market price for shares of our common stock may drop significantly if stockholders subject to these lock-up provisions sell a substantial number of shares when the restrictions on resale lapse, or such shares are sold pursuant to specified exceptions, or if the placement agents waive these lock-up provisions and allow the stockholders to sell some or all of their shares. Based on information

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currently available to us, all of the shares to be outstanding after this offering will be eligible for sale in the public market following expiration of these lock-up provisions, subject in some cases to volume and other limitations under federal securities laws.

Moreover, J.R. Hyde, III, and Oracle Partners, L.P., two of our largest stockholders, and their affiliates, have rights, subject to some conditions, to require us to file registration statements covering the approximately 10.8 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

None.

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 Global 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 Global Market.

	2006		2005	
	High	Low	High	Low
First Quarter	$12.08	$7.57	$13.66	$9.10
Second Quarter	11.57	8.11	11.48	8.68
Third Quarter	9.53	7.71	12.00	8.84
Fourth Quarter	18.30	9.26	9.46	7.43

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On March 1, 2007 the closing price of our common stock as reported on The NASDAQ Global Market was $22.01 per share and there were approximately 67 holders of record of our common stock.

The rules of the SEC require that the Company include in this annual Report on Form 10-K a line-graph presentation comparing cumulative stockholder returns on its common stock with a broad equity market index that includes companies whose equity securities are traded on the NASDAQ and either a published industry or line-of-business standard index or an index of peer companies selected by the Company. The Company has elected to use the NASDAQ Composite Index (which tracks the aggregate price performance of equity securities of companies traded on NASDAQ) and the NASDAQ Biotechnology Index (consisting of a group of approximately 130 companies in the biotechnology sector, including the Company) for purposes of the performance comparison that appears below.

The following graph shows the cumulative total stockholder return assuming the investment of $100.00 at the closing prices on February 3, 2004, the first day of trading of the Company s common stock on the NASDAQ Global Market: (1) the Company s common stock; (2) NASDAQ Composite Index and (3) NASDAQ Biotechnology Index. All values assume reinvestment of the full amounts of all dividends. No dividends have been declared on the Company s common stock. The closing sale price of our common stock on December 31, 2006 as reported on the NASDAQ Global Market was $17.84.

The stockholder return shown on the graph below is not necessarily indicative of future performance, and the Company does not make or endorse any predictions as to future stockholder returns.

COMPARISON OF 35 MONTH CUMULATIVE TOTAL RETURN*

Among GTx Inc., The NASDAQ Composite Index

And The NASDAQ Biotechnology Index

* $100 invested on 2/3/04 in stock or on 1/31/04 in indices-including reinvestment of dividends.

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The material in this section is not soliciting material, is not deemed filed with the SEC and is not to be incorporated by reference in any filing of the Company under the Securities Act of 1933 or the Exchange Act whether made before or after the date hereof and irrespective of any general incorporation language in such filing.

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.

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, 2004, 2005 and 2006, and the balance sheet data at December 31, 2005 and 2006, 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, 2002 and 2003, and the consolidated balance sheet data at December 31, 2002, 2003 and 2004, 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.

	Years Ended December 31,				
	2006	2005	2004	2003	2002
	(in thousands, except per share data)				
Statement of Operations Data:					
Revenues:					
Product sales, net	$ 1,357	$ 2,445	$	$	$
Total collaboration revenue	6,148	1,337	1,867		
Total revenues	7,505	3,782	1,867		
Operating expenses:					
Cost of product sales	773	1,573			
Research and development expenses	33,897	30,923	17,950	10,778	9,569
General and administrative expenses	11,352	9,845	7,211	3,559	2,453
Loss from operations	38,517	(38,559)	(23,294)	(14,337)	(12,022)
Interest income	3,007	1,720	946	143	156
Net loss	(35,510)	(36,839)	(22,348)	(14,194)	(11,866)
Accrued preferred stock dividends			(455)	(3,436)	(2,147)
Adjustment to preferred stock redemption value			17,125	(77,844)	(7,220)
Net loss attributable to common stockholders	$ (35,510)	$ (36,839)	$ (5,678)	$ (95,474)	$ (21,233)
Net loss per share attributable to common stockholders:					
Basic	$ (1.14)	$ (1.42)	$ (0.25)	$ (12.34)	$ (2.75)

Diluted	$ (1.14)	$ (1.42)	$ (0.93)	$ (12.34)	$ (2.75)

	As of December 31,				
	2006	**2005**	**2004**	**2003**	**2002**
			(in thousands)		
Balance Sheet Data:					
Cash and cash equivalents	$ 119,550	$ 74,014	$ 64,528	$ 14,769	$ 8,925
Working capital	111,363	70,030	61,298	12,775	7,654
Total assets	129,255	82,811	73,082	17,310	10,030
Cumulative redeemable convertible preferred stock				165,292	64,026
Accumulated deficit	(229,779)	(194,269)	(157,430)	(151,752)	(56,278)
Total stockholders equity (deficit)	97,049	73,579	63,909	(150,231)	(55,308)

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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.

Overview

We are a biopharmaceutical company dedicated to the discovery, development and commercialization of small molecules that selectively target hormone pathways to treat cancer, osteoporosis and bone loss, muscle wasting and other serious medical conditions. 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 multiple serious side effects of androgen deprivation therapy (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. We have licensed to Ipsen Limited, or Ipsen, exclusive rights in the European Union, Switzerland, Norway, Iceland, Lichtenstein and the Commonwealth of Independent States to develop and commercialize ACAPODENE® and other products containing toremifene in all indications which we have licensed from Orion Corporation, (Orion). We are also developing Ostarine™, a selective androgen receptor modulator, or SARM, for the treatment of cancer wasting, which is known as cancer cachexia and for chronic kidney disease (CKD) and end-stage renal disease (ESRD). We plan to initiate a Phase IIb clinical trial evaluating Ostarine™ for the treatment of cancer cachexia by the summer of 2007 and another Phase IIb clinical trial evaluating Ostarine™ for the treatment of muscle wasting in CKD/ESRD patients by the end of the year. We believe that Ostarine™ and our other SARMs have the potential to treat a variety of other indications related to muscle wasting and bone loss including frailty and osteoporosis. Even though we will primarily maintain our focus in urology and oncology, GTx is evolving into a selective nuclear hormone receptor modulator company that can target hormone pathways to address a myriad of unmet medical needs in men and women.

We also have an extensive preclinical pipeline generated from our own discovery program that includes potential product candidates, prostarine, for benign prostatic hyperplasia, and andromustine, an anticancer product candidate, for hormone refractory prostate cancer.

We commenced a pivotal Phase III clinical trial of ACAPODENE® 80 mg under a Special Protocol Assessment, or a SPA, with the United States Food and Drug Administration, or FDA, for the treatment of multiple serious side effects of ADT in November 2003. We reached our enrollment goal in the fall of 2005 with approximately 1,400 patients randomized into the trial. We anticipate that we will complete the ADT clinical trial in the fourth quarter of 2007 with a New Drug Application, or NDA, filing expected in 2008 if the results are favorable.

In January 2005, we initiated a pivotal Phase III clinical trial of ACAPODENE® 20 mg 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 reached our enrollment goal of 1,260 patients in May 2006. We have enrolled approximately 300 additional patients into the trial to also participate in substudies requested by the FDA under the SPA. We anticipate conducting an efficacy analysis within 24 months of completion of enrollment. We will evaluate efficacy endpoints at 36 months after completion of enrollment, and with an interim efficacy analysis to be conducted after a certain number of cancer events have been recorded among study patients, which we currently expect to occur in the first quarter of 2008. If the efficacy results from the interim analysis achieve the expected statistical outcome, we plan to file a NDA with the FDA. If we are able to file a NDA based on the results of the interim efficacy analysis, we will need to continue to collect safety data during the review process to satisfy the FDA s safety requirements set forth in the SPA.

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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. In December 2006, we announced that Ostarine™ met its primary endpoint in a Phase II proof of concept, double-blind, randomized, placebo-controlled clinical trial in 60 elderly men and 60 postmenopausal women. The trial was designed to evaluate the activity of Ostarine™ on building muscle as well as to assess safety in both elderly men and postmenopausal women. We recently conducted discussions with various divisions of the FDA to investigate the required regulatory pathways for several indications under consideration for Ostarine™ s ongoing clinical development. With more clarity regarding the required regulatory pathway and with proof of concept Phase II clinical data, we have selected cancer cachexia as the initial indication for Ostarine™ development. We plan to initiate a Phase IIb Ostarine™ clinical trial for cancer cachexia by the summer of 2007. We also plan to initiate a Phase IIb clinical trial of Ostarine™ for the treatment of muscle wasting in CKD/ESRD patients by the end of the year.

Our net loss for the year ended December 31, 2006 was $35.5 million. Our net loss included FARESTON® net product sales of $1.4 million and the recognition of collaboration revenue of $6.1 million. We have financed our operations and internal growth primarily through private placements of preferred stock and public offerings. On December 18, 2006, we completed an underwritten public offering of 3,799,600 shares of common stock and received net proceeds of approximately $57.4 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.

Sales and Marketing

We currently market FARESTON® (toremifene citrate 60 mg) tablets, which have been approved by the U.S. Food and Drug Administration, or FDA, for the treatment of metastatic breast cancer in postmenopausal women in the United States. In January 2005, we acquired from Orion the right to market FARESTON® tablets in the United States for the metastatic breast cancer indication. We also acquired from Orion a license to toremifene for all indications in humans worldwide, except breast cancer outside of the United States. The active pharmaceutical ingredient in FARESTON® is the same as in ACAPODENE®, but in a different dose. We plan to build specialized sales and marketing capabilities to promote our product candidates to urologists and medical oncologists in the United States and to seek partners to commercialize our product candidates in broader markets in the United States and in the rest of the world.

Research and Development

Since our inception in 1997, we have been focused on drug discovery and development programs. Research and development expenses represented 75% of our total operating expenses for the year ended December 31, 2006. 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® 80 mg for the treatment of multiple serious side effects of ADT for advance prostate cancer, (2) the continuation of the pivotal Phase III clinical trial of ACAPODENE® 20 mg for the prevention of prostate cancer in high risk men with high grade PIN, (3) the continued clinical and preclinical development of Ostarine™, (4) the continued preclinical development of other product candidates, including prostarine and andromustine and (5) the increase in research and development personnel.

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 our product candidates.

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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 achievement of certain milestone events under, and other matters related to, our collaboration and license agreement with Ipsen;
- The terms and timing of any future collaborative, licensing and other arrangements that we may establish;
- The cost and timing of regulatory approvals;
- Potential future licensing fees, milestone payments and royalty payments, including any milestone payments or royalty payments that we may receive under our collaboration and license agreement with Ipsen;
- 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.

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 Expenses

Our general and administrative expenses consist primarily of salaries and other related costs for personnel serving executive, finance, legal, human resources, information technology, investor 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

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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.

Critical Accounting Policies and Significant Judgments and Estimates

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. 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

Our revenues consist of product sales of FARESTON® and revenues derived from our collaboration and license agreements.

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 (SFAS) No. 48, *Revenue Recognition When Right of Return Exists* (SFAS No. 48) and Emerging Issues Task Force (EITF) Issue 00-21, *Revenue Arrangements with Multiple Deliverables* (EITF 00-21). Accordingly, revenues from licensing and collaboration 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 as collaboration revenue in the condensed statements of operations over the term of the performance obligation. We estimate the performance obligation period to be five years for the development of ACAPODENE® for both the high grade PIN and ADT indications in the European Territory with Ipsen. 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 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 No. 104 and SFAS No. 48 are satisfied. We account for rebates to certain governmental agencies as a reduction of product sales. We allow customers to return product within a specified time period prior to and subsequent to the product s labeled expiration date. As a result, we estimate an accrual for product returns, which is recorded as a reduction of product sales, based on factors which include historical product returns and estimated product in the distribution channel which is expected to exceed its expiration date. We retained substantially the same wholesale customers of, and the distribution channel that was used by, another pharmaceutical company that distributed FARESTON® for six years prior to our obtaining the rights to market FARESTON® in January 2005. We also obtained historical product return trend information that we continue to update with our own product return data. We estimate the amount of product in the distribution channel which is expected to exceed its expiration date and be returned by the customer by receiving information from our three largest wholesale customers about the levels of FARESTON® inventory held by these customers. These three largest wholesale customers accounted for 94% of the total sales of FARESTON® for the year ended December 31, 2006. Based on this information, and other factors, we estimate the number of months of product on

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hand. For the year ended December 31, 2006, actual product returns were approximately $287,000 and the provision for product returns was approximately $428,000 which resulted in an accrual for product returns at December 31, 2006 of $415,000. At December 31, 2005, our accrual for product returns was $274,000. During the three months ended December 31, 2006, we recorded a provision for product returns of approximately $375,000. If actual future results are different than our estimates, we may need to adjust our estimated accrual for product returns, which could have a material effect on earnings in the period of the adjustment.

Research and Development Expenses

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, development and clinical trial studies on our behalf.

Patent Costs

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

Share-Based Compensation

We have stock option plans that provide for the purchase our common stock by certain of its employees and directors. Effective January 1, 2006, we adopted SFAS 123(R), *Share-Based Payment* (SFAS 123R), and began recognizing compensation expense for our share-based payments based on the fair value of the awards. Share-based payments include stock option grants under our stock option plans. Prior to January 1, 2006, we accounted for share-based compensation expense using the intrinsic value recognition method prescribed by Accounting Principles Board Opinion (APB) No. 25 and SFAS 123. Since we adopted SFAS 123R under the modified prospective and the prospective transition methods, results from prior periods have not been restated. Under SFAS 123R, forfeitures are estimated at the time of valuation and reduce expense ratably over the vesting period. This estimate is adjusted periodically based on the extent to which actual forfeitures differ, or are expected to differ, from the previous estimate.

Total share-based compensation expense for the year ended December 2006 was $1.4 million, of which $540,000 and $861,000 were recorded in the statements of operations as research and development expenses and general and administrative expenses, respectively. Prior to the adoption of SFAS 123R, we accounted for share-based compensation expense under APB No. 25. Total share-based compensation expense for the years ended December 31, 2005 and 2004 was $819,000 and $804,000, respectively. Included in share-based compensation expense for all periods presented is share-based compensation expense related to deferred compensation arrangements for our directors, which was $140,000 and $180,000 for the years ended December 31, 2006 and 2005, respectively. On the date of adoption of SFAS 123R, the unamortized balance of deferred stock compensation of $1.7 million was reduced to zero with an offsetting adjustment to additional paid-in capital.

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, 2006, and 2005, net of the valuation allowance, the net deferred tax assets were reduced to zero.

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Purchased Intangible Assets

We account for our 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. 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, 2006 and 2005. If we are unsuccessful in obtaining regulatory approval for ACAPODENE®, we may not be able to recover the carrying amount of our license fee.

Results of Operations

Comparison of Years Ended December 31, 2006 and December 31, 2005

Revenues. Revenues for the year ended December 31, 2006 were $7.5 million as compared to $3.8 million for the same period of 2005. Revenues include net sales of FARESTON® marketed for the treatment of metastatic breast cancer and collaboration income from Ortho Biotech for andarine and Ipsen for ACAPODENE®. During the years ended December 31, 2006 and 2005, FARESTON® net sales were $1.4 million and $2.4 million, respectively, while costs of products sales were $773,000 and $1.6 million, respectively. During the year ended December 31, 2006, the sales price of FARESTON® increased by 10% while sales revenue and sales volume decreased by 32% and by 37%, respectively, as compared to the same period in 2005. Collaboration income was $6.1 million for the year ended December 31, 2006, of which $4.3 million and $1.8 million was from Ortho Biotech and Ipsen, respectively. In connection with the termination of the Ortho Biotech agreement, we recognized the associated $3.1 million balance of deferred revenue as additional collaboration revenue. Collaboration income from Ortho Biotech was $1.3 million for the year ended December 31, 2005.

Research and Development Expenses. Research and development expenses increased 9.7% to $33.9 million for the year ended December 31, 2006 from $30.9 million for the year ended December 31, 2005. The following table identifies the research and development expenses for each of our product candidates, as well as research and development expenses 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.

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Program	Product Candidate/ Indication	Years Ended December 31, 2006	2005	Increase (Decrease)
		(in thousands)		
SERM	**ACAPODENE® 80 mg** Multiple serious side effects of ADT	$ 8,446	$ 11,720	$ (3,274)
	ACAPODENE® 20 mg Prevention of prostate cancer in high risk men with high grade PIN	10,737	7,615	3,122
SARM	**Ostarine™** Cancer cachexia and CKD/ESRD muscle wasting	6,723	4,750	1,973
	Andarine	56	173	(117)
Other research and development		7,935	6,665	1,270
Total research and development expenses		$ 33,897	$ 30,923	$ 2,974

General and Administrative Expenses. General and administrative expenses increased 16% to $11.4 million for the year ended December 31, 2006 from $9.8 million for the year ended December 31, 2005. The increase of approximately $1.6 million was primarily the result of increased personnel related expenses of approximately $730,000, an increase in share-based compensation expense as a result of the adoption of SFAS No.123R effective January 1, 2006 of approximately $550,000, and a foreign currency transaction loss of $237,000 related to our Ipsen collaboration.

Interest Income. Interest income increased to $3.0 million for the year ended December 31, 2006 from $1.7 million for the year ended December 31, 2005. The increase of approximately $1.3 million was attributable to higher average interest rates in addition to higher average cash and cash equivalents balances during the year ended December 31, 2006, as compared to the prior year.

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 we 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

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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 following table identifies the research and development expenses for each of our product candidates, as well as research and development expenses pertaining to our other research and development efforts for each of the periods presented.

Program	Product Candidate/ Indication	Year Ended December 31, 2005	2004	Increase (Decrease)
		(in thousands)		
SERM	**ACAPODENE® 80 mg** Multiple serious side effects of ADT	$ 11,720	$ 6,484	$ 5,236
	ACAPODENE® 20 mg Prevention of prostate cancer in high risk men with high grade PIN	7,615	2,247	5,368
SARM	**Ostarine™** Cancer cachexia and CKD/ESRD muscle wasting	4,750	4,011	739
	Andarine	173	2,212	(2,039)
Other research and development		6,665	2,996	3,669
Total research and development expenses		$ 30,923	$ 17,950	$ 12,973

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.

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Liquidity and Capital Resources

Through December 31, 2006, we financed our operations and internal growth through private placements of preferred stock, the proceeds of our initial public offering, our follow-on offerings in October 2005 and December 2006 and proceeds from our collaboration agreements. 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, 2006, we had an accumulated deficit of $229.8 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® 80 mg for the treatment of multiple serious side effects of ADT, including two Phase II clinical trials and an ongoing pivotal Phase III clinical trial;

ACAPODENE® 20 mg for the prevention of prostate cancer in high risk 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/or bone loss in acute and chronic diseases;

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.

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, 2006, we had cash and cash equivalents of $119.6 million, compared to $74.0 million at December 31, 2005 and $64.5 million at December 31, 2004. 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. On December 18, 2006, we completed a public offering of 3,799,600 shares of common stock at an offering price to the public of $16.00 per share resulting in net proceeds of approximately $57.4 million.

Net cash used in operating activities was $11.5 million, $34.8 million and $15.7 million for the years ended December 31, 2006, 2005 and 2004, respectively. The use of cash in all periods resulted primarily from funding our net losses. Net cash used in operating activities for years ended December 31, 2006 and 2004 was reduced by up-front license fees and reimbursement of development expenses. In 2006, we received approximately $27.1 million in connection with our collaboration with Ipsen and in 2004, we received approximately $6.7 million in connection with our collaboration with Ortho Biotech. 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 Ostarine™ and our other product candidates.

Net cash used in investing activities for the year ended December 31, 2006 was $578,000 and was primarily for the purchase or research and development equipment, computer equipment and software. Net cash used in investing activities for 2005 was $1.4 million and was primarily for the purchase of research and development equipment, leasehold improvements, office and computer equipment, software and furniture and fixtures. Net cash used in investing activities in 2004 was primarily for the purchase of research and development equipment, office equipment and the purchase of an intangible asset (license fee) of $4.8 million. We currently expect to make expenditures for capital equipment and software of up to $1.2 million for the year ended December 31, 2007.

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Net cash provided by financing activities, was $57.6 million, $45.7 million and $71.4 million for the years ended December 31, 2006, 2005 and 2004, respectively. Net cash provided by financing activities for the year ended December 31, 2006 reflected net proceeds from our follow-on public offering, which closed on December 18, 2006. Net cash provided by financing activities for the year ended December 31, 2005 reflected net proceeds from our follow-on offering which closed October 17, 2005. 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.

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 quarter of 2009. This estimate does not include funding from milestone payments that we may receive under our existing collaboration with Ipsen, potential future collaboration agreements with pharmaceutical companies, or the potential future issuance and sale of our securities. This estimate also does not include any potential product launch costs for ACAPODENE® in the event that it is approved for marketing by the FDA.

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 achievement of certain milestone events under, and other matters related to, our collaboration and license agreement with Ipsen;

The terms and timing of any collaborative, licensing and other arrangements that we may establish;

The cost and timing of regulatory approvals;

Potential future licensing fees, milestone payments and royalty payments, including any milestone payments or royalty payments that we may receive under our collaboration and license agreement with Ipsen;

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 Ipsen, 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 Ipsen, we do not currently have any commitments for future external funding. We cannot be certain that additional funding will be

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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 Ipsen, 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, 2006, 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	$ 15	$ 5	$ 10	$	$
Operating lease obligations	806	806			
Purchase obligations	19	19			
Total	$ 840	$ 830	$ 10	$	$

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. The effect of a hypothetical decrease of one percentage point in the average interest rate earned on our cash equivalents would have resulted in a decrease in our interest income of approximately $655,000 for the year ended December 31, 2006.

We operate primarily in the United States. However, some of our clinical trial sites are located in Canada, Germany, Ireland, Mexico and the United Kingdom which requires us to make payments for certain clinical trial services in foreign currencies. In accordance with the terms of a collaboration and license agreement, Ipsen Limited is required to pay us 1.5 million as additional license fees over a three year period. We are also entitled to receive from Ipsen up to 39.0 million in milestone payments subject to the successful development and launch of ACAPODENE® in certain countries of the European Territory. Ipsen s obligation to make payments to us in Euros exposes us to potential foreign currency transaction losses. 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 is included in Item 15 below.

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

Not applicable.

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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, as amended (the Exchange Act)) that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act 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 disclosures.

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 Exchange Act) 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, 2006 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, 2006, our internal control over financial reporting was effective.

Attestation Report

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 2006 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

Not applicable.

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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 2007 Annual Meeting of Stockholders with the U.S. Securities and Exchange Commission pursuant to Regulation 14A (the 2007 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 2007 Proxy Statement is incorporated herein by reference.

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

(1) 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 2007 Proxy Statement. Such information is incorporated herein by reference.

(2) 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 2007 Proxy Statement. Such information is incorporated herein by reference.

(3) 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.

(4) 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 our website (www.gtxinc.com) under About GTx at Corporate Governance. We will provide a copy of these documents to any person, without charge, upon request, by writing to us at GTx, Inc. Director, Investor Relations, 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

(1) The information required by this Item concerning director and executive compensation is incorporated herein by reference to the information from the 2007 Proxy Statement under the sections entitled Compensation Discussion and Analysis, Executive Compensation, Potential Payments Upon Termination or Change in Control and Director Compensation.

(2) The information required by this Item concerning Compensation Committee interlocks and insider participation is incorporated herein by reference to the information from the 2007 Proxy Statement under the section entitled Compensation Committee Interlocks and Insider Participation.

(3) The information required by this Item concerning our Compensation Committee s review and discussion of the Compensation Discussion and Analysis section of the 2007 Proxy Statement is incorporated herein by reference to the information from the 2007 Proxy Statement under the section entitled Compensation Committee Report.

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

(1) 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 2007 Proxy Statement under the section entitled Security Ownership of Certain Beneficial Owners and Management.

(2) 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 2007 Proxy Statement under the section entitled Equity Compensation Plan Information.

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ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

(1) The information required by this Item concerning related party transactions is incorporated herein by reference to the information from the 2007 Proxy Statement under the section entitled Certain Relationships and Related Party Transactions.

(2) The information required by this Item concerning director independence is incorporated herein by reference to the information from the 2007 Proxy Statement under the section entitled Additional Information About the Board of Directors-Director Independence.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item is incorporated herein by reference to the information from the 2007 Proxy Statement under the section entitled Proposal No. 2 Ratification of Appointment of Independent Registered Public Accounting Firm.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)(1) Index to Financial Statements

Page	Description
F-2	Management s Report on Internal Control Over Financial Reporting
F-3	Reports of Independent Registered Public Accounting Firm
F-5	Balance Sheets at December 31, 2006 and 2005
F-6	Statements of Operations for the Years Ended December 31, 2006, 2005 and 2004
F-7	Statements of Cumulative Redeemable Convertible Preferred Stock and Stockholders Equity (Deficit) for the Years Ended December 31, 2006, 2005 and 2004
F-8	Statements of Cash Flows for the Years Ended December 31, 2006, 2005 and 2004
F-9	Notes 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)

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Number	Description
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)
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, 2002, between Registrant and University of Tennessee Research Foundation(3)
10.22	Amended and Restated Exclusive License Agreement dated August 30, 2002, 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	Purchase Agreement dated December 13, 2004, between Registrant and Orion Corporation(4)
10.25	Amended and Restated License and Supply Agreement effective January 1, 2005, between Registrant and Orion Corporation(5)
10.26	Sublease Agreement dated April 1, 2005, as amended, between Registrant and TriStar Enterprises, Inc.(6)
10.27*	Employment Agreement dated January 1, 2005, between Registrant and James T. Dalton(7)

10.28*	Compensation Information for Registrant s Executive Officers, effective as of January 1, 2006[8]
10.29*	Employment Agreement dated August 26, 2005, between Registrant and K. Gary Barnette[9]
10.30*	Employment Agreement dated August 26, 2005, between Registrant and Gregory A. Deener[10]
10.31*	Amended and Restated 2004 Non-Employee Directors Stock Option Plan[16]
10.32	Amendment dated May 23, 2006 to the Amended and Restated License and Supply Agreement effective January 1, 2005, between Registrant and Orion Corporation[11]
10.33	Amendment dated June 30, 2006 to the Amended and Restated License and Supply Agreement effective January 1, 2005, between Registrant and Orion Corporation[12]
10.34*	Form of Stock Option Agreement under the Amended and Restated 2004 Non-Employee Directors Stock Option Plan[13]
10.35	Partial Assignment Agreement among Registrant, Orion Corporation and Ipsen Limited dated September 7, 2006[14]
10.36	Collaboration and License Agreement between Registrant and Ipsen Limited dated September 7, 2006[15]
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)[17]
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)[17]

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

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Confidential treatment extension 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.

Revised redacted agreement filed herewith.

(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 3.2 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 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.

(5) 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.

(6) Filed as Exhibit 10.27 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.

(7) Filed as Exhibit 10.28 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 Currrent 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) Filed as Exhibit 10.33 to the Registrant s Quarterly Report on Form 10-Q (File No. 000-50549), filed with the SEC on August 9, 2006, and incorporated herein by reference.

(12) Filed Exhibit 10.34 to the Registrant s Quarterly Report on Form 10-Q (File No. 000-50549), filed with the SEC on August 9, 2006, and incorporated herein by reference.

(13) Filed Exhibit 10.35 to the Registrant s Quarterly Report on Form 10-Q (File No. 000-50549), filed with the SEC on November 3, 2006, and incorporated herein by reference.

(14) Filed Exhibit 10.36 to the Registrant s Quarterly Report on Form 10-Q (File No.

000-50549), filed with the SEC on November 3, 2006, and incorporated herein by reference.

(15) Filed Exhibit 10.37 to the Registrant s Quarterly Report on Form 10-Q (File No. 000-50549), filed with the SEC on November 3, 2006, and incorporated herein by reference.

(16) Filed Exhibit 10.1 to the Registrant s Quarterly Report on Form 8-K (File No. 000-50549), filed with the SEC on April 27, 2006, and incorporated herein by reference.

(17) 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.

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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 9, 2007

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 9, 2007
/s/ Mitchell S. Steiner Mitchell S. Steiner, M.D., F.A.C.S.	Chief Executive Officer, Vice Chairman and Director	March 9, 2007
/s/ Mark E. Mosteller Mark E. Mosteller, CPA	Vice President, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	March 9, 2007
/s/ Marc S. Hanover Marc S. Hanover	President, Chief Operating Officer and Director	March 9, 2007
/s/ Andrew M. Clarkson	Director	March 9, 2007

Andrew M. Clarkson		
/s/ J. Kenneth Glass	Director	March 9, 2007
J. Kenneth Glass		
/s/ Robert W. Karr	Director	March 9, 2007
Robert W. Karr, M.D.		
/s/ Rosemary Mazanet	Director	March 9, 2007
Rosemary Mazanet, M.D., Ph.D.		

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		Date
/s/ John H. Pontius	Director	March 9, 2007
John H. Pontius		
/s/ Timothy R. G. Sear	Director	March 9, 2007
Timothy R. G. Sear		
/s/ Michael G. Carter	Director	March 9, 2007
Michael G. Carter, M. D.		

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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, 2006 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, 2006, 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
Memphis, Tennessee
February 21, 2007

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

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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 report on management s assessment of internal control over financial reporting, that GTx, Inc. maintained effective internal control over financial reporting as of December 31, 2006, 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, 2006, 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, 2006, 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, 2006 and 2005, 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, 2006, of GTx, Inc. and our report dated February 20, 2007, expressed an unqualified opinion thereon.

Memphis, Tennessee
February 21, 2007

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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, 2006 and 2005, 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, 2006. 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, 2006 and 2005, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2006, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 2 to the financial statements, effective January 1, 2006, the Company adopted Statement of Financial Accounting Standards No. 123 R, *Share Based Payment*, to account for stock based compensation.

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, 2006, 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 20, 2007 expressed an unqualified opinion thereon.

Memphis, Tennessee
February 21, 2007

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

	December 31, 2006	December 31, 2005
ASSETS		
Current assets:		
Cash and cash equivalents	$ 119,550	$ 74,014
Accounts receivable, net	61	153
Inventory	207	135
Prepaid expenses and other current assets	1,882	1,702
Total current assets	121,700	76,004
Property and equipment, net	1,448	1,746
Purchased intangible assets:		
License fee, net	4,226	4,524
Other, net	488	454
Other assets	1,393	83
Total assets	$ 129,255	$ 82,811
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 1,336	$ 1,407
Accrued expenses	3,149	3,230
Deferred revenue current portion	5,852	1,337
Total current liabilities	10,337	5,974
Deferred revenue, less current portion	21,554	2,958
Capital lease obligation	15	20
Other long-term liability	300	280
Commitments and contingencies		
Stockholders equity:		
Common stock, $0.001 par value: 60,000,000 shares authorized; 34,822,362 shares issued and outstanding at December 31, 2006 and 30,993,967 shares issued and outstanding at December 31, 2005	35	31
Deferred stock compensation		(1,725)
Additional paid-in capital	326,793	269,542
Accumulated deficit	(229,779)	(194,269)
Total stockholders equity	97,049	73,579
Total liabilities and stockholders equity	$ 129,255	$ 82,811

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

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

	Years Ended December 31,		
	2006	**2005**	**2004**
Revenues:			
Product sales, net	$ 1,357	$ 2,445	$
Collaboration revenue	6,148	1,337	1,055
Reimbursement of development costs			812
Total revenues	7,505	3,782	1,867
Costs and expenses:			
Cost of product sales	773	1,573	
Research and development expenses	33,897	30,923	17,950
General and administrative expenses	11,352	9,845	7,211
Total costs and expenses	46,022	42,341	25,161
Loss from operations	(38,517)	(38,559)	(23,294)
Interest income	3,007	1,720	946
Net loss	(35,510)	(36,839)	(22,348)
Accrued preferred stock dividends			(455)
Adjustment to preferred stock redemption value			17,125
Net loss attributable to common stockholders	$ (35,510)	$ (36,839)	$ (5,678)
Net loss per share attributable to common stockholders:			
Basic	$ (1.14)	$ (1.42)	$ (0.25)
Diluted	$ (1.14)	$ (1.42)	$ (0.93)
Weighted average shares used in computing net loss per share attributable to common stockholders:			
Basic	31,150,035	25,982,478	22,993,221
Diluted	31,150,035	25,982,478	24,062,271

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

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GTx, Inc.
STATEMENTS OF CUMULATIVE REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (DEFICIT)
For the Years Ended December 31, 2006, 2005 and 2004
(in thousands, except share and per share data)

	Cumulative Redeemable Convertible Preferred Stock		Stockholders Equity (Deficit)					
			Common Stock		Deferred Stock	Additional Paid-in		Total Stockholders Equity
	Shares	Amount	Shares	Amount	Compensation	Capital	(Accumulated Deficit)	(Deficit)
Balances at January 1, 2004	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
					489	(489)		

Forfeitures of stock-based compensation						
Directors deferred compensation				180		180
Share-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
Issuance of common stock	3,799,600	4		57,422		57,426
Exercise of employee stock options	28,795			153		153
Directors deferred compensation				140		140
Share-based compensation				1,261		1,261
Reversal of deferred stock compensation			1,725	(1,725)		
Net loss and comprehensive loss					(35,510)	(35,510)
Balances at December 31, 2006	$ 34,822,362	$ 35	$	$ 326,793	$ (229,779)	$ 97,049

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

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

	Years Ended December 31,		
	2006	**2005**	**2004**
Cash flows from operating activities:			
Net loss	$ (35,510)	$ (36,839)	$ (22,348)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,140	1,038	475
Share-based compensation	1,261	639	804
Directors deferred compensation	140	180	
Deferred revenue amortization	(6,148)	(1,337)	(1,055)
Foreign currency transaction loss	237		
Loss on retirement of property and equipment		33	
Changes in operating assets and liabilities:			
Accounts receivable, net	92	(153)	
Inventory	(72)	313	(448)
Prepaid expenses and other assets	(1,727)	(93)	(1,488)
Accounts payable	(71)	507	439
Accrued expenses and other long-term liability	(61)	893	1,263
Deferred revenue	29,259		6,687
Net cash used in operating activities	(11,460)	(34,819)	(15,671)
Cash flows from investing activities:			
Purchase of property and equipment	(338)	(935)	(1,174)
Purchase of intangible assets	(240)	(446)	(4,826)
Net cash used in investing activities	(578)	(1,381)	(6,000)
Cash flows from financing activities:			
Proceeds from issuance of common stock	57,426	45,663	71,836
Deferred initial public offering costs			(433)
Payments on capital lease obligation	(5)	(4)	
Proceeds from exercise of employee stock options	153	27	27
Net cash provided by financing activities	57,574	45,686	71,430
Net increase in cash and cash equivalents	45,536	9,486	49,759
Cash and cash equivalents, beginning of year	74,014	64,528	14,769
Cash and cash equivalents, end of year	$ 119,550	$ 74,014	$ 64,528
Supplemental schedule of non-cash investing and financing activities:			
Preferred stock dividends	$	$	$ 455

Preferred stock adjustment to redemption value	$	$	$ (17,125)
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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GTx, Inc.
NOTES TO FINANCIAL STATEMENTS
(in thousands, except share and per share data)

1. Business and Basis of Presentation

GTx, Inc. (GTx, the Company, or we), a Delaware Corporation incorporated on September 24, 1997 and headquartered in Memphis, Tennessee, is a biopharmaceutical company dedicated to the discovery, development and commercialization of small molecules that selectively target hormone pathways to treat cancer, osteoporosis and bone loss, muscle wasting and other serious medical conditions. GTx operates in one business segment.

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 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. GTx has licensed to Ipsen Limited (Ipsen) exclusive rights in the European Union, Switzerland, Norway, Iceland, Lichtenstein, and the Commonwealth of Independent States to develop and commercialize ACAPODENE® and other products containing toremifene for all indications which we have licensed from Orion Corporation. GTx is also developing Ostarine™, a selective androgen receptor modulator, or SARM for the treatment of cancer wasting, which is known as cancer cachexia and for chronic kidney disease and end state renal disease.

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.

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GTx, Inc.
NOTES TO FINANCIAL STATEMENTS
(in thousands, except share and per share data)

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 6 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, 2006 and 2005. 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 6. 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, 2006 and 2005.

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 84% and 92% of accounts receivable as of December 31, 2006, and 2005, respectively.

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GTx, Inc.
NOTES TO FINANCIAL STATEMENTS
(in thousands, except share and per share data)

Revenue Recognition

The Company recognizes net product sales revenue from the sale of FARESTON® less deductions for estimated sales discounts and sales returns. Revenue from product sales is recognized when the goods are shipped and title and risk of loss pass to the customer and the other criteria outlined in Staff Accounting Bulletin (SAB) No. 101, *Revenue Recognition in Financial Statements* as amended by SAB No. 104 (together, SAB No. 104) and SFAS No. 48, *Revenue Recognition When Right of Return Exists* are satisfied. The Company accounts for rebates to certain governmental agencies as a reduction of product sales. The Company allows customers to return product within a specified time period prior to and subsequent to the product s labeled expiration date. The Company estimates an accrual for product returns, which is recorded as a reduction of product sales, based on factors which include historical product returns and estimated product in the distribution channel which is expected to exceed its expiration date. At December 31, 2006 and 2005, the Company s accrual for product returns was $415 and $274, respectively. If actual future results are different than the Company s estimates, the Company may need to adjust its estimated accrual for product returns, which could have a material effect on results of operations in the period of the adjustment.

Collaboration revenue consists of non-refundable up-front payments and license fees associated with the Company s collaboration and license agreements discussed in Note 8. The Company recognized revenue in accordance with SAB No. 104. 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 sheets and amortized as collaboration revenue in the statements of operations over the term of the performance obligation.

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, 2006 and 2005, net of the valuation allowance, the net deferred tax assets were reduced to zero.

Stock Options

The Company has stock option plans that provide for the purchase of the Company s Common Stock by certain of its employees and directors, which are described more fully in Note 3 Share-Based Compensation. Effective January 1, 2006, the Company adopted SFAS No. 123(R), *Share-Based Payment* (SFAS 123R) and began recognizing compensation expense for its share-based payments based on the fair value of the awards. See Note 3 Share-Based Compensation for further discussion.

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GTx, Inc.
NOTES TO FINANCIAL STATEMENTS
(in thousands, except share and per share data)

Deferred Stock Compensation

In anticipation of the Company s initial public offering 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 amortized the related expense on a straight-line basis over the estimated service period, which was generally five years. The Company recorded amortization of deferred stock compensation of $487 and $804 for years ended December 31, 2005 and 2004, respectively. 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. At January 1, 2006 upon adoption of SFAS 123R the unamortized balance was reduced to zero with an offsetting adjustment to additional paid-in capital.

Basic and Diluted Net Loss Per Share

The Company computed net loss per share attributable to common stockholders according to SFAS 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 potential of 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, 2006, 2005 and 2004:

	Years Ended December 31,		
	2006	**2005**	**2004**
Basic net loss per share attributable to common stockholders			
Numerator:			
Net loss attributable to common stockholders	$ (35,510)	$ (36,839)	$ (5,678)
Denominator:			
Common stock outstanding at beginning of period	30,993,967	24,664,716	7,735,848
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	145,738	1,316,986	
Exercise of employee stock options	10,330	776	666
Weighted average shares used in computing basic net loss per share	31,150,035(1)	25,982,478(2)	22,993,221
Basic net loss per share attributable to common stockholders	$ (1.14)	$ (1.42)	$ (0.25)

	Years Ended December 31,		
	2006	**2005**	**2004**
Diluted net loss per share attributable to common stockholders			
Numerator:			
Net loss	$ (35,510)	$ (36,839)	$ (22,348)(3)

Denominator:			
Common stock outstanding at beginning of period	30,993,967	24,664,716	7,735,848
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	145,738	1,316,986	
Exercise of employee stock options	10,330	776	666
Weighted average shares used in computing diluted net loss per share	31,150,035(1)	25,982,478(2)	24,062,271
Diluted net loss per share attributable to common stockholders	$ (1.14)	$ (1.42)	$ (0.93)

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GTx, Inc.
NOTES TO FINANCIAL STATEMENTS
(in thousands, except share and per share data)

(1) The weighted average shares used in computing basic and diluted net loss per share attributable to common stockholders for the year ended December 31, 2006 include 145,738 shares, which represent the weighted average effect during the period of the Company s issuance of 3,799,600 shares of common stock on December 18, 2006. At December 31, 2006, the Company had outstanding 34,822,362 shares of common stock.
(2) The weighted average shares used in computing basic and diluted 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.
(3) 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.

Weighted average options outstanding to purchase shares of common stock of 1,462,842, 1,244,232, and 997,059 were excluded from the calculation of diluted net loss per share attributable to common stockholders for the years ended December 31, 2006, 2005 and 2004, 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 year ended December 31, 2004.

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 July 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes-an interpretation of FASB Statement No. 109 (FIN 48)*, which clarifies the accounting for uncertainty in tax positions.

FIN 48 requires the recognition in the financial statements, the impact of a tax position, if that position is more likely than not of being sustained on audit, based on the technical merits of the position. The provisions of FIN 48 are effective as of January 1, 2007, with the cumulative effect of the change in accounting principle recorded as an adjustment to opening retained earnings. The adoption of the standard did not have a material effect on the Company s financial condition.

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GTx, Inc.
NOTES TO FINANCIAL STATEMENTS
(in thousands, except share and per share data)

3. Share-Based Compensation

Effective January 1, 2006, the Company adopted SFAS 123R and began recognizing compensation expense for its share-based payments based on the fair value of the awards. Share-based payments include stock option grants under the Company s stock option plans. Prior to January 1, 2006, the Company accounted for share-based compensation expense using the intrinsic value recognition method prescribed by APB No. 25 and SFAS No.123.

SFAS 123R requires share-based compensation expense recognized since January 1, 2006 to be based on the following: a) grant date fair value estimated using the minimum value method in accordance with the original provisions of SFAS 123, *Accounting for Share-based Compensation* for unvested options granted prior to the Company s initial public offering (IPO) in February 2004; b) grant date fair value estimated using the intrinsic value method for unvested options granted prior to the Company s IPO and previously accounted for using Accounting Principles Board Opinion (APB) No. 25, *Accounting for Stock Issued to Employees*; c) grant date fair value estimated in accordance with the original provisions of SFAS No.123 for unvested options granted after the Company s IPO and prior to the adoption date and d) grant date fair value estimated in accordance with the provisions of SFAS 123R for unvested options granted on or after the adoption date.

The adoption of SFAS 123R has resulted in increased share-based compensation expense and net loss of $626 and increased net loss per share of $0.02 for the year ended December 31, 2006. Since the Company adopted SFAS 123R under the modified prospective and the prospective transition methods, results from prior periods have not been restated. On the date of adoption of SFAS 123R, the unamortized balance of deferred stock compensation of $1,725 was reduced to zero with an offsetting adjustment to additional paid-in capital (See Note 2 Deferred Stock Compensation). SFAS 123R also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as required prior to the adoption of SFAS 123R. The impact of adopting SFAS 123R on future results will depend on, among other things, levels of share-based options granted in the future, actual forfeiture rates and the timing of option exercises.

The following table illustrates the effect on net loss and net loss per share if the Company had not adopted SFAS 123R and applied the fair value recognition provisions of SFAS No.123 and the intrinsic value recognition provisions of APB No. 25 to options granted under the Company s stock option plans in all periods presented. For purposes of this pro forma disclosure, the fair value of the options granted is estimated using the Black-Scholes-Merton option pricing model, the minimum value method and the intrinsic value method.

	Years Ended December 31,		
	2006	**2005**	**2004**
Net loss attributable to common stockholders, as reported	$ (35,510)	$ (36,839)	$ (5,678)
Add: Share-based compensation expense included in reported net loss	1,401	819	804
Deduct: Share-based compensation expense determined under the fair value based method	(1,401)	(2,034)	(1,319)
Pro forma net loss attributable to common stockholders	$ (35,510)	$ (38,054)	$ (6,193)
Net loss per share attributable to common stockholders:			
Basic as reported	$ (1.14)	$ (1.42)	$ (0.25)
Basic pro forma	$ (1.14)	$ (1.46)	$ (0.27)
Diluted as reported	$ (1.14)	$ (1.42)	$ (0.93)

Diluted pro forma	$ (1.14)	$ (1.46)	$ (0.95)

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Under SFAS 123R forfeitures are estimated at the time of valuation and reduce expense ratably over the vesting period. This estimate is adjusted periodically based on the extent to which actual forfeitures differ, or are expected to differ, from the previous estimate. Under SFAS 123 and APB No. 25, the Company elected to account for forfeitures when awards were actually forfeited, at which time all previous pro forma expense was reversed to reduce pro forma expense for that period.

Total share-based compensation expense for the year ended December 31, 2006 was $1,401, of which $540 and $861 were recorded in the statements of operations as research and development expenses and general and administrative expenses, respectively. Prior to the adoption of SFAS 123R, the Company accounted for share-based compensation expense under APB No. 25. Total share-based compensation expense for the years ended December 31, 2005, and 2004 was $819 and $804, respectively. Share-based compensation expense for the years ended December 31, 2006 and 2005 included share-based compensation expense related to deferred compensation arrangements for the Company s directors of $140 and $180, respectively.

The Company grants options to purchase common stock to certain employees and directors under various plans at prices equal to the market value of the stock on the dates the options are granted. The options have a term of ten years from the grant date and vest three years from the grant date for director options and in periods up to five years from the grant date for employee options. Employees have 90 days after the employment relationship ends to exercise all vested options except in the case of retirement, permanent disability or death, where exercise periods are generally longer. The Company issues new shares of common stock upon the exercise of options. The fair value of each option grant is separately estimated for each vesting date. The fair value of each option is amortized into compensation expense on a straight-line basis between the grant date for the award and each vesting date. The Company estimates the fair value of certain stock option awards as of the date of the grant by applying the Black-Scholes-Merton option pricing valuation model. The application of this valuation model involves assumptions that are judgmental and highly sensitive in the determination of compensation expense. The weighted average for key assumptions used in determining the fair value of options granted in 2006, 2005 and 2004 and a summary of the methodology applied to develop each assumption are as follows:

	Years Ended December 31,		
	2006	**2005**	**2004**
Expected price volatility	70.3%	61.6%	59.7%
Risk-free interest rate	4.6%	4.0%	3.9%
Weighted average expected life in years	6.0 years	5.7 years	6.0 years
Dividend yield	0%	0%	0%
Forfeiture rate	14.0%	n/a	n/a

Expected Price Volatility This is a measure of the amount by which a price has fluctuated or is expected to fluctuate. We use an average expected price volatility of other publicly traded biopharmaceutical companies as it is management s belief that this is the best indicator of future volatility due to the limited period of time the Company s stock has been publicly traded. An increase in the expected price volatility will increase compensation expense.

Risk-Free Interest Rate This is the U.S. Treasury rate for the week of the grant having a term approximating the expected life of the option. An increase in the risk-free interest rate will increase compensation expense.

Expected Life This is the period of time over which the options granted are expected to remain outstanding and is based on management s estimate, taking into consideration vesting term, contractual term and historical actual life. Options granted have a maximum term of ten years. An increase in the expected life will increase compensation expense.

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Dividend Yield The Company has not made any dividend payments nor does it have plans to pay dividends in the foreseeable future. An increase in the dividend yield will decrease compensation expense.

Forfeiture Rate This is the estimated percentage of options granted that are expected to be forfeited or canceled before becoming fully vested. This estimate is based on historical experience. An increase in the forfeiture rate will decrease compensation expense.

The following is a summary of stock option transactions for all of the Company s stock option plans for the three years ended December 31, 2006:

	Number of Shares	Weighted Average Exercise Price Per Share
Options outstanding at January 1, 2004	828,750	$ 6.18
Options granted	323,250	11.35
Options forfeited	(1,000)	8.90
Options exercised	(7,793)	3.48
Options outstanding 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
Options outstanding at December 31, 2005	1,301,750	8.27
Options granted	225,834	8.50
Options forfeited	(40,500)	9.42
Options exercised	(28,795)	5.32
Options outstanding at December 31, 2006	1,458,289	8.33

The following table summarizes information about stock options outstanding at December 31, 2006:

	Options Outstanding			Options Exercisable	
Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life(years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$2.24 - $ 2.24	35,375	3.89	$ 2.24	35,375	$ 2.24
$6.24 - $ 7.85	826,330	6.52	6.64	406,182	6.57
$8.51 - $14.50	596,584	8.06	11.03	74,504	13.16
	1,458,289	7.08	8.33	516,061	7.22

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At December 31, 2006, the aggregate intrinsic value of all outstanding options was $13,871 with a weighted average remaining contractual term of 7.08 years, of which 516,061 of the outstanding options are currently exercisable with an aggregate intrinsic value of $5,480, a weighted average exercise price of $7.22 and a weighted average remaining contractual term of 5.79 years. For the years ended December 31, 2006, 2005 and 2004, the weighted average grant date fair values of options granted was $5.67, $6.23, and $6.58, respectively. There were 28,795 options exercised during the year ended December 31, 2006. The total intrinsic value of options exercised during the year ended December 31, 2006 was $204. At December 31, 2006, the total compensation cost related to non-vested awards not yet recognized was $2,644 with a weighted average expense recognition period of 1.78 years. Options available for future issuance under the Company s stock option plans were 1,550,672 at December 31, 2006. On January 1, 2007, options available for future issuance increased to 2,304,453 in accordance with the provisions of the Company s stock option plans.

4. Property and Equipment, Net

Property and equipment, net consist of the following:

	December 31,	
	2006	**2005**
Equipment	$ 3,146	$ 2,813
Leasehold improvements	669	669
Furniture and fixtures	312	307
	4,127	3,789
Less: accumulated depreciation	(2,679)	(2,043)
	$ 1,448	$ 1,746

Depreciation expense for the years ended December 31, 2006, 2005 and 2004 was $636, $639 and $454, respectively. Of these amounts, $377, $468 and $396, respectively, were included in research and development expenses in the statements of operations.

5. Accrued Expenses

Accrued expenses consist of the following:

	December 31,	
	2006	**2005**
Clinical trial	$ 1,117	$ 893
Other	924	745
Research and development	627	1,148
Professional fees	481	444
	$ 3,149	$ 3,230

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6. Purchased Intangible Assets

Purchased intangible assets consist of the following:

	December 31,	
	2006	**2005**
License fee	$ 4,826	$ 4,826
Less: accumulated amortization	(600)	(302)
	$ 4,226	$ 4,524
Other purchased intangible assets	$ 832	$ 592
Less: accumulated amortization	(344)	(138)
	$ 488	$ 454

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 8). 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, 2006, 2005 and 2004 was $504, $400, and $21, respectively.

Estimated future amortization expense for purchased intangible assets at December 31, 2006 is as follows:

Years Ending December 31,	
2007	$ 529
2008	473
2009	357
2010	320
2011	298
Thereafter	2,737
Total	$ 4,714

7. 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 October 17, 2005, the Company completed an underwritten public offering of 6,325,000 shares of 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.

On December 18, 2006, the Company completed an underwritten public offering of 3,799,600 shares of common stock at a price to the public of $16.00 per share. Net cash proceeds from this offering were $57,426 after deducting underwriting discounts and other offering expenses.

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8. Collaboration and License Agreements

Ipsen Collaboration and License Agreement

In September 2006, the Company entered into a collaboration and license agreement with Ipsen pursuant to which the Company granted Ipsen exclusive rights in the European Union, Switzerland, Norway, Iceland, Lichtenstein and the Commonwealth of Independent States (collectively, the European Territory) to develop and commercialize ACAPODENE® and other products containing toremifene in all indications which the Company has licensed from Orion Corporation, (Orion), which include all indications in humans except the treatment and prevention of breast cancer outside of the United States. In accordance with the terms of the license agreement, Ipsen has agreed to pay the Company 23,000 as a license fee and expense reimbursement, of which 1,500 will be paid in equal installments over a three year period. In October 2006, the Company received 21,500 (approximately $27,100) from Ipsen as the initial payment for the license fee and expense reimbursement. Pursuant to the agreement, GTx is also entitled to receive from Ipsen up to an aggregate of 39,000 in milestone payments depending on the successful development and launch of ACAPODENE® in certain countries of the European Territory for the high grade PIN indication, subject to certain conditions, and the ADT indication. Ipsen has agreed to be responsible for and to pay all clinical development, regulatory and launch activities to commercialize ACAPODENE® in the European Territory for both the high grade PIN indication and ADT indication. Ipsen has agreed to pay the Company a royalty equal to a graduating percentage of aggregate net sales of products containing toremifene (including ACAPODENE®) which rates will be dependent on whether such sales are for the high grade PIN indication or the ADT indication. GTx will remain responsible for paying upstream royalties on ACAPODENE® to both Orion and the University of Tennessee Research Foundation (UTRF) for the PIN indication and to Orion only for the ADT indication. Ipsen will purchase the bulk drug product supply directly from Orion and is responsible for the packaging and labeling of the final product.

The Company recorded deferred revenue of $29,259 related to the Ipsen upfront license fee and expense reimbursement which is expected to be amortized into revenue on a straight-line basis over the estimated five year development period for ACAPODENE® in the European Territory. The Company recognized as collaboration revenue $1,853 for the year ended December 31, 2006 from the amortization of the Ipsen deferred revenue.

University of Tennessee Research Foundation License Agreement

In August 2002, the Company executed an Amended and Restated Exclusive License Agreement with the UTRF granting the Company a worldwide exclusive license under its method of use patents relating to ACAPODENE® 20 mg for the treatment and/or prevention of prostate cancer and PIN that may develop into prostate cancer. Under the terms of the agreement, the Company is required (1) to make annual maintenance fee payments and (2) 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 and Ostarine™, to market, distribute and sell licensed products. Under the terms of the license agreements, the Company is required (1) to make annual maintenance fee payments and (2) 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.

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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.

In December 2006, the Company and UTRF entered into a letter of intent agreeing to modify each of the above referenced license agreements existing between the parties. The revised license agreements, when executed by the Company and UTRF, are intended to address certain provisions of the agreements pertaining to license maintenance fees and royalty fees. Upon execution of the revised license agreements, the Company will pay to UTRF an aggregate consideration of $600 which will be allocated among the license agreements.

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 license and supply agreement will survive for the term of the Company s patents, including the Company s patents to treat complications arising from ADT and the patents it licenses from UTRF for the treatment and/or prevention of PIN and prostate cancer. The term of the Company s method of use patents extend from 2019 to 2023.

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 and 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 and License Agreement

In March 2004, the Company entered into a joint collaboration and license agreement with Ortho Biotech Products, L.P., a subsidiary of Johnson & Johnson (Ortho Biotech) for andarine, and specified backup SARM compounds. Under the terms of the agreement, the Company received in April 2004 an up-front licensing fee and expense reimbursement totaling $6,687. The up-front licensing fee and expense reimbursement were deferred and amortized into revenue on a straight-line basis over the estimated five year andarine development period. In December 2006, the Company reacquired full rights to develop and commercialize andarine and all backup compounds previously licensed to Ortho Biotech and the joint collaboration and license agreement was terminated by mutual agreement of the parties. In connection with the termination of the Ortho Biotech agreement, the Company recognized the associated $3.1 million balance of deferred revenue as additional collaboration revenue. The Company recognized revenue of $4,295, $1,337 and $1,055 for the years ended December 31, 2006, 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.

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9. Income Taxes

We have incurred net losses since inception and, consequently, have not recorded any U.S. federal and state 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,	
	2006	**2005**
Deferred income tax assets:		
Net federal and state operating loss carryforwards	$ 38,921	$ 34,246
Research and development credits	4,614	3,229
Cash basis method	641	1,185
Deferred stock compensation	1,185	744
Deferred revenue	10,319	1,622
Total deferred tax assets	55,680	41,026
Deferred income tax liabilities:		
Depreciation	84	120
Total deferred tax liabilities	84	120
Net deferred income tax assets	55,596	40,906
Valuation allowance	(55,596)	(40,906)
	$	$

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by $14.7 million, $15.0 million and $8.9 million in 2006, 2005 and 2004, respectively.

At December 31, 2006, the Company had net federal operating loss carryforwards of approximately $101.3 million, which expire from 2018 to 2026 if not utilized. The Company had state operating loss carryforwards of approximately $82.3 million, which expire from 2013 to 2021 if not utilized. The company also had research and development credits of $4.6 million, which expire from 2018 to 2026 if not utilized.

Utilization of the net operating loss and tax credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations provided by the Internal Revenue Code of 1986, as amended and similar state provisions. The annual limitations may result in the expiration of net operating loss carryforwards before utilization.

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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.

For the years ended December 31, 2006, 2005, and 2004, the Company incurred board of director fee expense of $163, $137, and $98, respectively, of which $140, $125, and $55 was deferred and will be paid in common stock. At December 31, 2006, 32,638 stock units had been credited to individual director stock unit accounts.

11. 401(k) Plan

The Company sponsors a 401(k) retirement savings plan that is available to all eligible employees. 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 $15 for employees under age 50 and $20 for employees 50 and older in calendar year 2006. 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. In 2006, the Company elected to match a portion of employee s contributions to the plan in the amount of $89.

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. Rent expense was approximately $712, $599 and $219 for the years ended December 31, 2006, 2005 and 2004, respectively.

Purchase Commitments

The Company had outstanding contractual purchase obligations of $19 and $104 at December 31, 2006 and 2005, 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, 2006 and 2005, 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, 2006 and 2005.

	Quarters Ended Year 2006			
	March 31	June 30	September 30	December 31
Revenues:				
Product sales, net	$ 876	$ 288	$ 348	$ (155)(a)
Collaboration revenue	334	335	724	4,755(b)
Total revenues	1,210	623	1,072	4,600
Costs and expenses:				
Cost of product sales	467	170	118	18
Research and development expenses	8,441	8,444	9,614	7,398
General and administrative expenses	2,950	2,692	2,867	2,843
Total costs and expenses	11,858	11,306	12,599	10,259
Loss from operations	(10,648)	(10,683)	(11,527)	(5,659)
Interest income	724	699	638	946
Net loss	$ (9,924)	$ (9,984)	$ (10,889)	$ (4,713)
Net loss per share:				
Basic	$ (0.32)	$ (0.32)	$ (0.35)	$ (0.15)
Diluted	$ (0.32)	$ (0.32)	$ (0.35)	$ (0.15)

	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 per share:				
Basic	$ (0.37)	$ (0.41)	$ (0.40)	$ (0.26)
Diluted	$ (0.37)	$ (0.41)	$ (0.40)	$ (0.26)

(a) Decrease in net product sales reflects the increase during the quarter to the Company s reserve for FARESTON® product returns. See Note 2, Revenue Recognition.

(b) Increase reflects amortization of Ipsen deferred revenue for the entire quarter and recognition of the remaining balance of Ortho Biotech deferred revenue in connection with the termination of the Ortho Biotech agreement. See Note 8, Collaboration and License Agreements.