GTX INC /DE/
Form 10-K
March 15, 2010

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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, 2009**

**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.) |
| **175 Toyota Plaza**<br>**7th Floor**<br>**Memphis, Tennessee** | **38103** |
| (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 whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes o 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. þ

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act:

| Large accelerated filer o | Accelerated filer þ | Non-accelerated filer o (Do not check if a smaller reporting company) | Smaller reporting company 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, 2009 as reported on The NASDAQ Global Market was $179,881,356.

There were 36,420,901 shares of registrant s common stock issued and outstanding as of March 10, 2010.

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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 2010 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 that 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, including whether current and future clinical trials will achieve similar results to clinical trials that we have successfully concluded;
- the timing, scope and anticipated completion of current and future clinical trials;
- the timing of regulatory submissions and the timing, scope and anticipated outcome of related regulatory actions;
- potential future licensing fees, milestone payments and royalty payments including any milestone payments or royalty payments that we may receive under our collaborative arrangement with Ipsen Biopharm Limited (formerly known as Ipsen Developments Limited), or Ipsen;
- our and Ipsen s ability to obtain and maintain regulatory approvals of our product candidates and any related restrictions, limitations, and/or warnings in the label of an approved product candidate;
- our and Ipsen 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 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 loss and other serious medical conditions.

We are developing toremifene citrate, a selective estrogen receptor modulator, or SERM, in two separate clinical programs in men: first, toremifene 80 mg in a completed pivotal Phase III clinical trial to reduce fractures and treat other estrogen deficiency side effects of androgen deprivation therapy, or ADT, in men with prostate cancer, and second, toremifene 20 mg in an ongoing pivotal Phase III clinical trial for the prevention of prostate cancer in high risk men with precancerous prostate lesions called high grade prostatic intraepithelial neoplasia, or high grade PIN.

In our first clinical program, toremifene 80 mg is being developed to reduce fractures in men with prostate cancer on ADT. ADT is the most common treatment for advanced, recurrent, or metastatic prostate cancer, and we believe that it is currently used to treat approximately 700,000 men with prostate cancer in the United States. No treatments have been approved by the FDA to reduce fractures in men with prostate cancer on ADT. In the first quarter of 2008, we announced that the Phase III clinical trial results for toremifene 80 mg to reduce fractures and treat other estrogen deficiency side effects of ADT in men with prostate cancer showed that toremifene 80 mg reduced new morphometric vertebral fractures, met other key estrogen deficiency endpoints of bone mineral density, or BMD, lipid profiles and gynecomastia, and also showed that toremifene 80 mg demonstrated a reduction in hot flashes in a subset of patients. In December 2008, we submitted a New Drug Application, or NDA, for toremifene 80 mg to reduce fractures in men with prostate cancer on ADT to the U.S. Food and Drug Administration, or FDA. In October 2009, we received a Complete Response Letter from the FDA regarding our NDA for toremifene 80 mg notifying us that the FDA would not approve our NDA in its present form as a result of certain clinical deficiencies identified in the Complete Response Letter. We met with the FDA in December 2009 to better understand our options for addressing the deficiencies identified by the FDA in the Complete Response Letter. In 2010, we plan to submit to and discuss with the FDA a proposed protocol for a second pivotal Phase III clinical trial evaluating toremifene 80 mg to reduce fractures in men with prostate cancer on ADT to address in a single clinical trial the deficiencies identified by the FDA in the Complete Response Letter. Any decision to initiate another clinical trial for toremifene 80 mg to reduce fractures in men with prostate cancer on ADT will require us to obtain sufficient additional funding for the trial.

We are developing toremifene 20 mg to prevent prostate cancer in high risk men with high grade PIN. 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. We believe that more than 40% of men with high grade PIN detected on a prostate biopsy develop prostate cancer within three years. Currently, there are no treatments approved by the FDA to reduce the incidence of prostate cancer in high risk men with high grade PIN. In January 2005, we initiated a pivotal Phase III clinical trial of toremifene 20 mg for the prevention of prostate cancer in high risk men with high grade PIN, which is being conducted under a Special Protocol Assessment, or SPA, with the FDA. The last patient completed the high grade PIN Phase III clinical trial in February 2010. We plan to announce this year the results of the trial and, if the results from the trial are positive, our plans to submit a NDA for toremifene 20 mg to the FDA.

We licensed to Ipsen Biopharm Limited (formerly known as Ipsen Developments Limited), or Ipsen, exclusive rights in the European Union, Switzerland, Norway, Iceland, Lichtenstein and the Commonwealth of Independent States, which we collectively refer to as the European Territory, to develop and commercialize toremifene in all indications which we have licensed from Orion Corporation, or Orion, which include all indications in humans except the treatment and prevention of breast cancer outside of the United States.

Additionally, we are developing selective androgen receptor modulators, or SARMs, a new class of drugs with the potential to treat cancer cachexia (cancer induced muscle loss), chronic sarcopenia, which is the loss of skeletal muscle mass resulting in reduced physical strength and ability to perform activities of daily living, and other musculoskeletal wasting or muscle loss conditions. In December 2006, we announced that Ostarine met its

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primary endpoint in a Phase II proof of concept, double blind, randomized, placebo controlled clinical trial in 60 elderly men and 60 postmenopausal women. In October 2008, we announced that Ostarine met its primary endpoint in a Phase II clinical trial evaluating absolute change in total lean body mass (muscle) compared to placebo. In March 2010, we reacquired full rights to our SARM program, including Ostarine , following the termination by us and Merck & Co., Inc., or Merck, of the exclusive license and collaboration agreement for SARM compounds and related SARM products, which was entered into in December 2007. We plan to continue the development of Ostarine for the treatment of cancer cachexia and, in this regard, we anticipate conducting an end of Phase II meeting with the FDA to discuss a Phase III clinical development program for Ostarine . We do not anticipate significant development progress on Ostarine , or our SARM program in general, including the initiation of any additional clinical trials, unless and until we enter into one or more new collaborations with third parties or otherwise obtain additional funding.

We are also developing GTx-758, an oral luteinizing hormone, or LH, inhibitor for the first line treatment of advanced prostate cancer. In preclinical animal models, GTx-758 has demonstrated the potential to reduce testosterone concentrations in blood to castrate levels, increase BMD, and prevent hot flashes. In 2009, we completed two Phase I clinical trials, a single ascending dose clinical trial and a multiple ascending dose clinical trial, evaluating GTx-758 in healthy male volunteers. GTx-758 was well tolerated in both trials. In February 2010, we initiated a Phase II clinical trial evaluating the ability of GTx-758 to reduce testosterone to castrate levels, which is expected to be completed in the second half of 2010.

We market FARESTON® (toremifene citrate) 60 mg tablets, approved for the treatment of metastatic breast cancer in postmenopausal women in the United States. The active pharmaceutical ingredient in FARESTON® is the same as in our toremifene 80 mg and toremifene 20 mg product candidates. 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 the treatment and prevention of breast cancer outside of the United States.

We do not expect to obtain FDA or any other regulatory approvals to market any of our product candidates in the near future. Due to the termination of our collaboration with Merck and the expected recognition in the first quarter of 2010 of $49.9 million in deferred revenue and the final payment from Merck of $5.0 million of cost reimbursement for research and development expenses, we expect to report net income for the year ending December 31, 2010. However, while recognition of this revenue is expected to result in net income for 2010, we expect to incur significant operating losses in 2011 and for the foreseeable future. In addition, we expect that significant additional clinical development will be required in order to potentially obtain FDA approval of toremifene 80 mg, including an additional pivotal Phase III clinical trial of toremifene 80 mg.

**Scientific Background on Estrogens and Androgens**

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 slow bone turnover, improve bone quality, and reduce the risk of skeletal fractures. They may also have favorable effects 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 benign prostatic hyperplasia, or 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 function. Testosterone is converted into a more potent androgen, dihydrotestosterone, or 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 and in turn may result in osteoporosis and fractures, erectile dysfunction, decreased sexual interest, depression and mood changes.

Estrogens and androgens perform their physiologic functions by binding to and activating their respective hormone receptors located in various tissues. Once a hormone binds with its receptor, this activates a series of

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cellular events that results in estrogenic or androgenic tissue effects.

Pharmaceuticals that target estrogen or androgen receptors have been used medically for over 50 years. The drugs that have been used to stimulate androgen receptors are either natural or synthetic hormones, known as steroids. Steroids are generally believed to 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 lack of selectivity of testosterone and its conversion to DHT may result in unwanted side effects, such as the potential stimulation of latent clinical prostate cancer, worsening of BPH, development or worsening of acne and gynecomastia, or loss of hair in men. Hair growth, acne and masculinization are also of concern in women. To date, no orally available testosterone products have been approved for use in the United States. 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. 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 metastatic female breast cancer, and raloxifene, which is used to prevent and treat postmenopausal female 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 muscle and bone 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 androgen receptors in the brain to affect mood and sexual interest. Although no SARMs have been commercialized to date, we believe that SARMs, without the harmful side effects of testosterone or other exogenous anabolic steroid therapies, can potentially be developed to treat a range of medical conditions, including: (1) muscle loss conditions of chronic diseases, such as cancer, AIDS, chronic kidney disease, end-stage renal disease, neurodegenerative disorders, trauma and burns; (2) muscle loss conditions associated with aging such as frailty and chronic sarcopenia; (3) the prevention and/or treatment of osteoporosis; (4) prostate disorders, such as BPH; (5) disorders of the central nervous system, such as low libido, depression and other mood disorders; (6) low testosterone conditions, such as primary and secondary hypogonadism; (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 market FARESTON® (toremifene citrate) 60 mg tablets, approved for the treatment of metastatic breast cancer in postmenopausal women in the United States. Toremifene is a SERM owned and manufactured by Orion. Toremifene is the active pharmaceutical ingredient in FARESTON® and is currently being developed in two separate clinical programs for toremifene 80 mg and toremifene 20 mg. 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.

As part of our effort to complete the requirements for the submission of applications for regulatory approval of toremifene 80 mg and toremifene 20 mg, we have conducted a number of studies of toremifene in addition to our clinical trials, including a Thorough QT study. The results of the Thorough QT study of 250 healthy male volunteers showed that toremifene prolonged the QT interval in a dose dependent manner. Since we market FARESTON® in the United States under a license agreement with Orion, we notified the FDA of the Thorough QT study results and have

proposed modifications to the FARESTON® label in the United States. FDA action on the proposed label changes is pending. The study results could lead to the inclusion of restrictions, limitations and/or warnings in the label of FARESTON® or an approved product candidate, which may adversely affect the

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marketability of the product or limit the patients to whom the product is prescribed. Separately, Orion recommended label changes to the European Medicines Agency, or EMEA. In January 2009, the EMEA recommended that the FARESTON® label within the European Union reflect that toremifene should not be given to patients at risk of prolonged QT intervals or other certain heart problems.

We sell FARESTON® primarily through wholesale drug distributors. The top three distributors, McKesson Corporation, Cardinal Health, Inc. and AmerisourceBergen Corporation, accounted for approximately 95% of our product sales generated from the sale of FARESTON® for the year ended December 31, 2009. The loss of any of these three distributors could have a material adverse effect on continued FARESTON® sales. FARESTON® net product sales accounted for 22%, 8%, and 15% of our total revenue for the years ended December 31, 2009, 2008 and 2007, respectively.

## Product Candidates

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

| Program | Product Candidate/ Proposed Indication | Development Phase | Status |
|---|---|---|---|
| **SERM** | **Toremifene 80 mg** To reduce fractures in men with prostate cancer on ADT | Pivotal Phase III clinical trial; NDA pending | Received a Complete Response Letter from the FDA regarding the NDA in October 2009 and anticipate meeting with the FDA in 2010 to discuss protocol for a second pivotal Phase III clinical trial. |
| | **Toremifene 20 mg** Prevention of prostate cancer in high risk men with high grade PIN | Pivotal Phase III clinical trial | Results of the Phase III clinical trial to be announced in 2010. |
| **SARM** | **Ostarine™** Treatment of cancer cachexia | Phase II clinical trial | Phase II clinical trial completed in September 2008. |
| | **Ostarine™** Treatment of chronic sarcopenia | Phase II clinical trial | Phase IIa clinical trial completed in December 2006. |
| **LH inhibitor** | **GTx-758** Treatment of advanced prostate cancer | Phase II clinical trial | Phase II clinical trial expected to be completed in the second half of 2010. |

### Toremifene

Our most advanced product candidate, toremifene, is a SERM. Toremifene is being developed as a once-a-day oral tablet to (1) reduce fractures and treat other estrogen deficiency side effects of ADT in men with prostate cancer (80 mg dose) and (2) prevent prostate cancer in high risk men with high grade PIN (20 mg dose). In January 2005, we exclusively licensed toremifene from Orion for all indications in humans, except the treatment and prevention of

breast cancer outside of the United States. We licensed rights to toremifene based on toremifene s established record of safety in the treatment of postmenopausal women with metastatic breast cancer and our belief that SERMs can treat estrogen related complications resulting from ADT and reduce the incidence of prostate cancer in high risk men with high grade PIN. Under a license and supply agreement with Orion, Orion manufactures and supplies us with FARESTON®, the 60 mg dose of toremifene citrate, for sale in the United States to treat metastatic breast cancer in postmenopausal women, as well as toremifene 20 mg for our Phase III clinical trial for the prevention of prostate cancer in high risk men with high grade PIN. Additionally, Orion has agreed to manufacture our clinical

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supply and, if FDA approval of toremifene 80 mg is obtained, our commercial supply of toremifene 80 mg. In September 2006, we licensed to Ipsen exclusive rights to develop and commercialize toremifene in the European Territory in all indications that we have licensed from Orion.

***Toremifene 80 mg to Reduce Fractures and Treat Other Estrogen Deficiency Side Effects of ADT in Men with Prostate Cancer***

***Scientific Overview.*** ADT is the most common 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 LH releasing hormone agonists, or LHRH agonists. LHRH agonists work by shutting off LH 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), 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 men, aromatase converts testosterone to estrogen. By reducing testosterone to castrate levels, ADT depletes up to 80% of a man s estrogen, resulting in multiple estrogen deficiency side effects. Estrogen deficiency side effects associated with ADT include high risk of fractures, as well as accelerated and continuous bone loss, adverse lipid changes which may lead to higher risk of cardiovascular diseases, hot flashes, gynecomastia, depression, and memory loss. Increased risk of skeletal fractures is a significant clinical problem because clinical studies have shown that prostate cancer patients who develop skeletal fractures have 39 month shorter survival rates. 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 are the side effect most frequently mentioned by prostate cancer patients on ADT.

Based on the results of our Phase III clinical trial, our two Phase II clinical trials and our preclinical testing of toremifene 80 mg, as well as preclinical and clinical information known about toremifene, toremifene has shown estrogenic activity both in bone, which reduces fractures, 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 Phase III clinical trial, toremifene has been shown to improve lipid profiles in men with prostate cancer on ADT. Toremifene has also been shown to block estrogen s action in the male breast, which may prevent and treat gynecomastia. As a consequence, we believe that toremifene 80 mg has the potential to treat the following estrogen deficiency related side effects of LHRH agonists: fractures, hot flashes, adverse lipid changes and gynecomastia. Importantly, as evidenced by our two Phase II clinical trials and our Phase III clinical trial, toremifene has not been shown to stimulate prostate cancer growth or increase luteinizing hormone in men with prostate cancer on ADT.

***Potential Market.*** In the United States, we believe that approximately 700,000 prostate cancer patients are currently being treated with ADT, and approximately 100,000 new patients are started on this therapy each year. An increasing number of prostate cancer patients are being treated by androgen deprivation with LHRH agonists earlier than in the past because of two main factors: first, medical studies have shown that early ADT prolongs the survival of prostate cancer patients, and second, the serum test for prostate specific antigen, or PSA, is detecting advanced prostate cancer earlier than in the past. The net effect of prostate cancer being treated sooner and for longer periods is that the estrogen deficiency related 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 estrogen deficiency related 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. No treatments have been approved by the FDA to reduce fractures or treat other estrogen deficiency side effects in men with prostate cancer on ADT.

***Clinical Trials.*** In November 2003, we initiated a pivotal Phase III clinical trial of orally administered toremifene 80 mg dose in patients undergoing ADT for advanced, recurrent or metastatic prostate cancer. 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 was the reduction of new morphometric vertebral fractures measured by x-ray, and the secondary endpoints of the trial included BMD, hot flashes, lipid profile changes and gynecomastia. We reached our enrollment goal in the fall of

2005 and randomized approximately 1,400 patients into the trial with advanced, recurrent or metastatic prostate cancer who had been receiving ADT for at least six months and who had significant existing bone loss, or were greater than 70 years of age. The patients were randomized to receive either a placebo or a daily 80 mg dose of toremifene for 24 months. We conducted the trial in approximately 150 sites in the United States and Mexico.

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In December 2005, we completed a planned interim BMD analysis among the first 197 patients who completed one year of treatment. Patients treated with toremifene 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 ($p=0.009$).

The last patient completed the ADT Phase III clinical trial in November 2007. In February 2008, we announced that the results of the Phase III clinical trial showed that toremifene 80 mg reduced new morphometric vertebral fractures, met other key estrogen deficiency endpoints of BMD, lipid profiles and gynecomastia, and also demonstrated a reduction in hot flashes in a subset of patients. In the modified intent to treat analysis which included all patients with at least one evaluable study radiograph and a minimum of one dose of study drug or placebo, toremifene 80 mg demonstrated a 50% reduction in new morphometric vertebral fractures. In an intent to treat analysis, which included all patients randomized into the trial and who received a minimum of one dose of study drug, toremifene 80 mg demonstrated a 54% reduction in new morphometric vertebral fractures. In prespecified subset analyses, in study patients who were greater than 80% treatment compliant, toremifene 80 mg reduced new morphometric vertebral fractures by 61%. When study patients who had greater than 7% bone loss at one year and new morphometric vertebral fractures were considered as treatment failures, toremifene 80 mg compared to placebo demonstrated a 56% reduction.

Patients treated with toremifene 80 mg compared to placebo demonstrated statistically significant increases in BMD in the lumbar spine, hip, and femur skeletal sites (each site demonstrating $p<0.0001$). Toremifene 80 mg treatment compared to placebo also resulted in a decrease in total cholesterol ($p=0.011$), LDL ($p=0.018$), and triglycerides ($p<0.0001$), and an increase in HDL ($p=0.001$). There were also statistically significant improvements in gynecomastia ($p=0.003$). In March 2008, we announced that in an analysis of hot flashes in a subset of patients in the toremifene 80 mg Phase III clinical trial experiencing six or more hot flashes per day at baseline and not being treated with megestrol acetate (Megace®), toremifene 80 mg treatment reduced the number of hot flashes by an average of 4.7 hot flashes per day compared to placebo patients who had a reduction of 1.6 hot flashes per day ($p=0.03$). The reduction of hot flashes in patients treated with toremifene 80 mg was durable for at least 12 months.

Toremifene 80 mg had a favorable safety profile and was well tolerated. Among the most common adverse events that occurred in over 2% of study subjects were joint pain (treated 7.3%, placebo 11.8%), dizziness (treated 6.3%, placebo 6.2%), back pain (treated 6.0%, placebo 5.2%), and extremity pain (treated 5.0%, placebo 4.4%). Venous thromboembolic events, or VTEs, which included both deep venous thrombosis and pulmonary embolism, were 17 (2.6%) in the toremifene 80 mg treated group and 7 (1.1%) in the placebo group. The risk for VTE s was similar between the toremifene 80 mg treated group and the placebo group in the second year of treatment. The majority of VTEs occurred in men at high risk for a VTE (including: age greater than 80 years, history of VTEs, recent surgical procedure or immobilization). In men without major risk factors for VTE, there were 5 VTEs in the toremifene 80 mg treated group and 3 VTEs in the placebo group.

As part of our effort to complete the requirements for the submission of applications for regulatory approval of toremifene 80 mg, we have conducted a number of studies of toremifene in addition to our clinical trials, including a Thorough QT study, a bioequivalence study and a series of drug-drug interaction studies. The results of the Thorough QT study of 250 healthy male volunteers, with 5 parallel cohorts receiving 20 mg, 80 mg or 300 mg doses of toremifene, moxifloxacin, or placebo, showed that toremifene prolonged the QT interval in a dose dependent manner. The mean change in QTcB (a measurement of QT interval corrected by Bazett s formula) from baseline relative to placebo for toremifene 20 mg was 5.79 milliseconds, for toremifene 80 mg, it was 22.43 milliseconds, and for moxifloxacin, it was 8.83 milliseconds. Since we market FARESTON® in the United States under a license agreement with Orion, we notified the FDA of the Thorough QT study results and have proposed modifications to the FARESTON® label in the United States. FDA action on the proposed label changes is pending. The study results could lead to the inclusion of restrictions, limitations and/or warnings in the label of FARESTON or an approved product candidate, which may adversely affect the marketability of the product or limit the patients to whom the product is prescribed. Separately, Orion recommended label changes to the EMEA. In January 2009, the EMEA recommended that the FARESTON® label within the European Union reflect that toremifene should not be given to

patients at risk of prolonged QT intervals or other certain heart problems. Our Thorough QT study was designed to better understand the risk of Torsades de Pointes, or Torsades, a rare and potentially fatal arrhythmia. The degree of QT interval prolongation is recognized as an imperfect surrogate marker for the risk of Torsades. Moreover, it is well established that not all medicines which prolong the QT interval will result in Torsades and Torsades can occur in the absence of QT prolongation. The post marketing pharmacovigilance database of approximately 480,000 patient years of use of toremifene at doses up to 240 mg in women, who are more sensitive to develop Torsades than are men, and the extensive clinical development programs in women and now in men,

substantiate that there have been no reported cases of Torsades in patients taking toremifene. In our pivotal Phase III clinical trial, there was no increase in adverse events that have been associated with cardiac arrythmia in the toremifene group compared to placebo. The results of these completed studies were included as a part of the NDA submission to the FDA for our toremifene 80 mg product candidate to reduce fractures in men with prostate cancer on ADT and, subject to receipt of favorable results from our ongoing toremifene 20 mg Phase III clinical trial, will be included as a part of the NDA submission for our toremifene 20 mg product candidate for the prevention of prostate cancer in high risk men with high grade PIN, and will be used to update the label for FARESTON®. The study results could lead to the inclusion of restrictions, limitations and/or warnings in the label of FARESTON® or an approved product candidate, which may adversely affect the marketability of the product or limit the patients to whom the product is prescribed.

***NDA Filing.*** In December 2008, we submitted a NDA for toremifene 80 mg to reduce fractures in men with prostate cancer on ADT. In October 2009, we received a Complete Response Letter from the FDA regarding our NDA for toremifene 80 mg to reduce fractures in men with prostate cancer on ADT, notifying us that the FDA would not approve our NDA in its present form as a result of certain clinical deficiencies identified in the Complete Response Letter. The FDA identified two deficiencies in the Complete Response Letter and recommended that the following information be provided to the FDA to address these clinical deficiencies: (i) results of a second adequate and well-controlled Phase III clinical trial demonstrating the safety and efficacy of toremifene 80 mg to reduce fractures in men with prostate cancer on ADT and (ii) results from an adequate and well-controlled clinical trial demonstrating that toremifene 80 mg treatment to reduce fractures in men with prostate cancer on ADT does not have a detrimental effect on either time-to-disease progression or overall survival. We met with the FDA in December 2009 to better understand our options for addressing the deficiencies identified by the FDA in the Complete Response Letter. In 2010, we plan to submit to and discuss with the FDA a proposed protocol for a second pivotal Phase III clinical trial evaluating toremifene 80 mg to reduce fractures in men with prostate cancer on ADT to address in a single clinical trial the deficiencies identified by the FDA in the Complete Response Letter. Any decision to initiate another clinical trial for toremifene 80 mg to reduce fractures in men with prostate cancer on ADT will require us to obtain sufficient additional funding for the trial.

***Toremifene 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 15% of the patients who undergo prostate biopsies. Over a 17 year period, scientific evidence has established that men who have high grade PIN are at high risk for developing prostate cancer. We believe that more than 40% of these men will progress to prostate cancer within three years. 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 are no treatments approved by the FDA to reduce the incidence of prostate cancer in high risk men 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 toremifene blocks estrogen receptors in the prostate, we believe that it has the potential to reduce the incidence of prostate cancer in high risk men with high grade PIN.

***Potential Market.*** 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. There are approximately 192,000 new cases of prostate cancer diagnosed each year and 28,000 prostate cancer deaths annually in the United States. In addition, in the United States, there are over 115,000 new cases of high grade PIN diagnosed each year, with an estimated 14 million men under the age of 80 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.

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We have entered into separate collaboration agreements with several diagnostic companies to provide clinical samples to these companies from our Phase IIb clinical trial and/or our ongoing Phase III clinical trial of toremifene 20 mg for the prevention of prostate cancer in high risk men with high grade PIN. 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 toremifene in men diagnosed with high grade PIN to determine the efficacy and safety of a daily dose of toremifene 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 toremifene or placebo. A screening prostate biopsy was performed on each trial participant before enrollment into the trial, and eligibility was limited to participants who were diagnosed with high grade PIN and had no evidence of prostate cancer. A second biopsy was performed six months after enrollment in an effort to identify trial participants who had prostate cancer that was not detected by the initial biopsy. The intent to treat population consisted of all patients initially enrolled in the trial who returned for their six-month biopsy. We also analyzed trial results in a predefined subgroup of patients that excluded patients showing biopsy evidence of prostate cancer at six months and patients who did not complete the full course of therapy in the trial (completer s 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 toremifene 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 toremifene 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 toremifene 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 toremifene 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 toremifene 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 toremifene 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 toremifene dose groups and placebo. The results of the Phase IIb clinical trial may not be the same as or indicative of the results we obtain from the pivotal Phase III clinical trial, and we do not know if the results from our pivotal Phase III clinical trial will be sufficient for the FDA or any other regulatory authorities to approve toremifene 20 mg to prevent prostate cancer in high risk men with high grade PIN.

In January 2005, we initiated a randomized, double blind, placebo controlled pivotal Phase III clinical trial of orally administered toremifene 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. A SPA is designed to facilitate the FDA s review and approval of drug products by allowing the FDA 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 the NDA. However, there are circumstances under which we may not receive the benefits of a SPA, notably if the FDA subsequently identifies a substantial scientific issue essential to determining the product s safety and efficacy, and we may be required to conduct significant additional

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development in order to obtain regulatory approval notwithstanding a SPA with the FDA. Approximately 130 clinical sites across the United States and Canada are participating in this trial. We have randomized a total of 1,590 patients into the trial, 330 patients above our enrollment goal of 1,260 patients. These additional patients are also participating in bone and ocular substudies requested by the FDA under the SPA. A planned efficacy interim analysis conducted in the second quarter of 2008 did not reach the specified statistical outcome of $p<0.003$. A Data Safety Monitoring Board, or DSMB, meets every six months to review unblinded data from the toremifene 20 mg Phase III clinical trial. In September 2009, an independent DSMB conducted a planned, semi-annual review of unblinded safety data from the 1,590 patients participating in the toremifene 20 mg Phase III high grade PIN clinical trial and recommended the clinical trial continue as planned. The last patient completed the trial in February 2010. We plan to announce this year the results of the trial and, if the results from the trial are positive, our plans to submit a NDA for toremifene 20 mg to the FDA.

**SARMs**

SARMs are a new class of drugs with the potential to treat cancer cachexia (cancer induced muscle loss), chronic sarcopenia, which is the loss of skeletal muscle mass resulting in reduced physical strength and ability to perform activities of daily living, and other musculoskeletal wasting or muscle loss conditions.

***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 loss. 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 second, 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.

Ostarine is an oral nonsteroidal agent designed to have anabolic activity on muscle and bone without unwanted side effects on prostate and skin. 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.*** Approximately five million patients are treated by medical oncologists in the United States. Data has shown that two-thirds of patients with locally advanced or metastatic cancer may be at risk for cancer cachexia as measured by any of the following: actively losing weight, having functional limitations or losing muscle. The prevalence of precachexia at-risk patients is estimated to be up to 2.9 million. 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, Megace®, an appetite stimulant which has been used off-label for cancer patients, has not been shown to increase lean body mass in spite of increasing appetite.

***Clinical Trials.*** We have clinical data from two Phase I clinical trials and two 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 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 topline 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. Treatment with Ostarine also resulted in a dose dependent improvement in functional performance, a secondary endpoint, measured by a stair climb test. 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.

In July 2007, we initiated a Phase II randomized, double blind, placebo controlled clinical trial evaluating Ostarine for the treatment of cancer cachexia in 159 patients diagnosed with non-small cell lung cancer, colorectal cancer, non-Hodgkin s lymphoma, chronic lymphocytic leukemia, or breast cancer. In October 2008, we announced topline results of this clinical trial. In this analysis, the study met its primary endpoint of absolute change in total lean body mass (muscle) compared to placebo and the secondary endpoint of muscle function (performance) after 16 weeks of treatment in 159 cancer patients with reported weight loss. We plan to continue the development of Ostarine for the treatment of cancer cachexia and, in this regard, we anticipate conducting an end of Phase II meeting with the FDA to discuss a Phase III clinical development program for Ostarine . We do not anticipate significant development progress on Ostarine , or our SARM program in general, including the initiation of any additional clinical trials, unless and until we enter into one or more new collaborations with third parties or otherwise obtain additional funding.

***SARMs for the Treatment of Chronic Sarcopenia***

***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 20 and 80 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. 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. 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 SARMs 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 SARMs can increase muscle size and strength, resulting in improved function, quality of life and speed of recovery, and can prevent osteoporosis and fractures. SARMs have been designed to have anabolic properties in muscle and bone without unwanted side effects, such as the stimulation

of prostate cancer in men and masculinization in women. In preclinical studies of intact animals, SARMs have been shown to build muscle and bone while shrinking the prostate.

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***Potential Market.*** There are approximately 17.5 million people over the age of 65 in the United States who have age related loss of muscle mass. In the United States in 2006, there were approximately 13.1 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 loss 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.*** In December 2006, we announced that Ostarine , a SARM, 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 do not anticipate significant development progress on our SARM program, including the initiation of any additional clinical trials, unless and until we enter into one or more new collaborations with third parties or otherwise obtain additional funding.

**LH Inhibitor**

***GTx-758 for the Treatment of Advanced Prostate Cancer***

***Scientific Overview.*** GTx-758 is a small molecule that we are developing for the first line treatment of advanced prostate cancer. In animal models, GTx-758 rapidly suppressed secretion of luteinizing hormone, LH, by feedback inhibition on the pituitary, inhibiting the production of androgens by the testes.

ADT is the most common treatment for patients who have advanced prostate cancer. ADT reduces testosterone, a primary growth factor for prostate cancer, to castrate levels. ADT is accomplished either surgically by removal of the testes or chemically by LHRH therapy. LHRH agents work by shutting off LH secretion by the pituitary gland thereby stopping testosterone production by the testes. The reduction in testosterone by ADT also results in very low estrogen levels in men, because estrogen is derived from testosterone in men. Estrogen deficiency side effects associated with LHRH therapies may include bone loss and fractures, adverse lipid changes, hot flashes, gynecomastia and impaired cognitive function.

In preclinical animal models, GTx-758 has demonstrated the potential to reduce testosterone concentrations in blood to castrate levels, increase BMD, and prevent hot flashes.

***Potential Market.*** In the United States, we believe that approximately 700,000 prostate cancer patients are currently being treated with ADT, and approximately 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. In 2008, the annual U.S. sales of drugs for ADT, which include currently marketed LHRH agonists, were approximately $1.7 billion.

***Clinical Trials.*** In 2009, we evaluated GTx-758 in healthy male volunteers in two Phase I clinical trials, a single ascending dose clinical trial completed in the second quarter and a multiple ascending dose clinical trial completed in the fourth quarter. GTx-758 was well tolerated in both trials. In February 2010, we initiated a Phase II clinical trial evaluating the ability of GTx-758 to reduce testosterone to castrate levels in 70 subjects. We expect this trial to be completed in the second half of 2010.

**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 may be possible to design and develop classes of nonsteroidal small molecule drugs to modulate hormone receptors in addition to estrogen receptors.

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We have an extensive preclinical pipeline generated from our own discovery program, including estrogen receptor beta agonists and other novel compounds that are currently in preclinical development for the potential treatment of ophthalmic diseases, cancer, psoriasis and/or pain.

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 selectively modulate hormone receptors, inhibit cancer growth, or treat inflammatory conditions. Our in-house medicinal chemists and scientists provide us with significant discovery and development expertise. Using our capabilities in hormone receptor biology, cancer pharmacology and medicinal chemistry, we are able to target many hormone receptors or other cellular targets and generate compounds that are designed to address important unmet medical needs.

We design and synthesize new compounds based on computer, or *in silico,* models and crystal structures of a molecular target 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 continue to conduct research and development efforts focused on other SERM and SARM compounds, other hormone receptor modulator compounds and anticancer agents.

**Our Strategy**

Our objective is to discover, develop and commercialize small molecules that selectively target hormone pathways to treat cancer, osteoporosis and bone loss, muscle loss and other serious medical conditions. Key elements of our strategy to achieve this objective are to:

***Obtain Regulatory Approvals of Toremifene 80 mg and Toremifene 20 mg.*** We have completed our Phase III clinical trial of toremifene 80 mg to reduce fractures in men with prostate cancer on ADT and submitted a NDA to the FDA in December 2008. In October 2009, we received a Complete Response Letter from the FDA regarding our NDA for toremifene 80 mg to reduce fractures in men with prostate cancer on ADT, notifying us that the FDA would not approve our NDA in its present form as a result of certain clinical deficiencies identified in the Complete Response Letter. We met with the FDA in December 2009 to better understand our options for addressing the deficiencies identified by the FDA in the Complete Response Letter. In 2010, we plan to submit to and discuss with the FDA a proposed protocol for a second pivotal Phase III clinical trial evaluating toremifene 80 mg to reduce fractures in men with prostate cancer on ADT to address in a single clinical trial the deficiencies identified by the FDA in the Complete Response Letter. In addition, we are conducting our Phase III clinical trial of toremifene 20 mg for the prevention of prostate cancer in high risk men with high grade PIN under a SPA with the FDA. The last patient completed the trial in February 2010. We plan to announce this year the results of the trial and, if the results from the trial are positive, our plans to submit a NDA for toremifene 20 mg to the FDA. We remain focused on our efforts to continue the development of, and obtain regulatory approvals for our toremifene product candidates.

***Commercialize Toremifene 80 mg and Toremifene 20 mg in the United States and Establish a Sales and Marketing Infrastructure.*** We have licensed from Orion the commercial rights to toremifene in the United States. We believe that, if approved, we can effectively market toremifene to urologists and medical oncologists in the United States through a specialty sales force that we plan to build.

***Partner Additional Commercial Rights to Toremifene.*** In September 2006, we licensed to Ipsen exclusive rights in the European Territory to develop and commercialize toremifene in all indications which we have licensed from Orion. We are currently pursuing similar collaborations or partnerships for toremifene in Asia and other markets outside of the United States and the European Territory. We 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 toremifene 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 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

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more willing to be tested for high grade PIN if the diagnostic test were less invasive than a prostate biopsy. Given the large number of patients with undiagnosed high grade PIN, we believe that the development of a blood or urine test would increase the detection of high grade PIN and thereby expand the already large potential market for toremifene 20 mg.

***Pursue Clinical Development and Commercialization of SARMs***. As a result of the termination of our collaboration with Merck, we reacquired full rights to our SARM program, including Ostarine . We plan to continue the development of Ostarine for the treatment of cancer cachexia and, in this regard, we anticipate conducting an end of Phase II meeting with the FDA to discuss a Phase III clinical development program for Ostarine for which we will need additional funding. Accordingly, we are pursuing a global strategic partnership or collaboration for the clinical development and commercialization of our SARM product candidates.

***Build Upon Our Other Drug Discovery Capabilities to Sustain Our Small Molecule Product Candidate Pipeline***. While our clinical development efforts to date have focused on SERM and SARM technologies, we have the capability to discover and develop additional drug candidates for other important disease targets. We intend to develop new molecules to treat diseases that affect large numbers of patients and are underserved by available alternatives or for which there are no current alternatives. In 2009, we completed two Phase I clinical trials, a single ascending dose clinical trial and a multiple ascending dose clinical trial, evaluating GTx-758 in healthy male volunteers. GTx-758 was well tolerated in both trials. In February 2010, we initiated a Phase II clinical trial evaluating the ability of GTx-758 to reduce testosterone to castrate levels, which is expected to be completed in the second half of 2010.

***Increase Commercial Sales of FARESTON®.*** We market FARESTON® for the treatment of metastatic breast cancer in postmenopausal women in the United States. Our strategy is to increase commercial sales of FARESTON®. However, sales of pharmaceuticals for breast cancer in the SERM class have declined in recent years as aromatase inhibitors have gained market share.

## Licenses and Collaborative Relationships

In addition to our internally-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 product candidates. Our most significant license and collaboration relationships are as follows:

### *Orion Corporation*

In March 2000, we entered into a license and supply agreement with Orion to develop and commercialize products containing toremifene. 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 in January 2005 with Orion which replaced 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 for all human indications worldwide, except breast cancer outside of the United States. We are required to pay Orion a portion of certain types of upfront and milestone income that we receive from third-party sublicensees, after we recover our clinical development costs, and 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 toremifene 80 mg and toremifene 20 mg 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 toremifene globally and FARESTON® in the United States. Orion may terminate its supply obligations at its election at any time as a result of our failure to obtain regulatory approval of one of our toremifene product candidates in the United States prior to December 31, 2009, in which event we will have the right to enter into a contract manufacturing agreement with another supplier for toremifene-based products. However, any arrangements we make for an alternative supply would have to be made with a qualified alternative supplier with appropriate FDA approval in order for us to obtain our supply requirements for toremifene. The term of the amended and restated license and

supply agreement lasts, on a country-by-country basis, until the later of

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expiration of our own patents claiming the processes or the methods of use of toremifene for prostate cancer or the end of all marketing or regulatory exclusivity which we may obtain for toremifene-based products. The term of our method of use patents extend from 2019 to 2023. Orion may terminate the amended and restated license and supply agreement, on a country-by-country basis, as a result of our uncured material breach, including under certain circumstances if we decided not to commercially launch toremifene in any major country after we obtain regulatory approval in such country, or our bankruptcy. Following the termination of the amended and restated license and supply agreement by Orion for our material breach, we will grant a royalty-bearing license to Orion to enable Orion to continue the development and commercialization of toremifene-based products in the countries in which the agreement is terminated.

***University of Tennessee Research Foundation***

In July 2007, we and UTRF entered into a consolidated, amended and restated license agreement, or the SARM License Agreement, to consolidate and replace our two previously existing SARM license agreements with UTRF and to modify and expand certain rights and obligations of each of the parties under both license agreements. Pursuant to the SARM License Agreement, we were granted exclusive worldwide rights in all existing SARM technologies owned or controlled by UTRF, including all improvements thereto, and exclusive rights to future SARM technology that may be developed by certain scientists at the University of Tennessee or subsequently licensed to UTRF under certain existing inter-institutional agreements with The Ohio State University. Unless terminated earlier, the term of the SARM License Agreement will continue, on a country-by-country basis, for the longer of 20 years or until the expiration of the last valid claim of any licensed patent in the particular country in which a licensed product is being sold. UTRF may terminate the SARM License Agreement for our uncured breach or upon our bankruptcy.

In September 2007, we and UTRF entered into an amended and restated license agreement, or the SERM License Agreement, to replace our previously existing exclusive worldwide license agreement for toremifene. Pursuant to the SERM License Agreement, we were granted exclusive worldwide rights to UTRF s method of use patents relating to SERMs, including toremifene for chemoprevention of prostate cancer as well as future related SERM technologies that may be developed by certain scientists at the University of Tennessee. Unless terminated earlier, the term of the SERM License Agreement will continue, on a country-by-country basis, in a particular country for the longer of 20 years from the effective date of our previously existing exclusive worldwide license agreement with UTRF for toremifene or until the expiration of the last valid claim of any licensed patent in such country. UTRF may terminate the SERM License Agreement for our uncured breach or upon our bankruptcy.

Under the SARM License Agreement and the SERM License Agreement, or together, the UTRF License Agreements, we paid UTRF a one-time, upfront fee of $290,000 per UTRF License Agreement as consideration for entering into the UTRF License Agreements. We are also obligated to pay UTRF annual license maintenance fees and royalties on sublicense revenues and net sales of products. We also agreed to pay all expenses to file, prosecute and maintain the patents relating to the licensed SARM and SERM technologies, and are obligated to use commercially reasonable efforts to develop and commercialize products based on the licensed SARM and SERM technologies.

In December 2008, we and UTRF amended the UTRF License Agreements, or together, the License Amendments, to, among other things, clarify the treatment of certain payments that we may receive from our current and future sublicensees for purposes of determining sublicense fees payable to UTRF, including the treatment of payments made to us in exchange for the sale of our securities in connection with sublicensing arrangements. In consideration for the execution of the License Amendments, we paid UTRF an aggregate of $540,000.

***Ipsen***

In September 2006, we entered into a collaboration and license agreement with Ipsen, or the Ipsen Collaboration Agreement, pursuant to which we granted Ipsen exclusive rights in the European Territory to develop and commercialize toremifene in all indications which we have licensed from Orion, which include all indications in humans except the treatment and prevention of breast cancer outside of the United States. Under the Ipsen Collaboration 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 upon period of time subsequent to the time of the first commercial launch of toremifene within the European Territory. Also under the Ipsen Collaboration Agreement, 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.

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In accordance with the terms of the Ipsen Collaboration Agreement, Ipsen paid us 23.0 million as a license fee and expense reimbursement, of which 1.5 million was paid to us in equal installments over a three-year period. In October 2006, we received 21.5 million (approximately $27.1 million) from Ipsen as the initial payment for the license fee and expense reimbursement. In September 2009, 2008, and 2007, we received 500,000 (approximately $726,000, $711,000, and $688,000, respectively) from Ipsen for the three annual installment payments. Pursuant to the Ipsen Collaboration Agreement, we are also entitled to receive from Ipsen up to an aggregate of 39.0 million in milestone payments depending on the successful development and launch of toremifene in certain countries of the European Territory for the high grade PIN indication, subject to certain conditions, and the ADT indication. In February 2008, we earned a milestone of 1.0 million (approximately $1.5 million) with the achievement of the primary endpoint in the toremifene 80 mg ADT Phase III clinical trial.

Ipsen has agreed to be responsible for and to pay all clinical development, regulatory and launch activities to commercialize toremifene 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 toremifene development costs in the United States, if certain conditions are met. Under the Ipsen Collaboration Agreement, Ipsen must elect to retain its rights to commercialize toremifene 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 toremifene 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 toremifene for high grade PIN. If Ipsen does not exercise its election, 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 toremifene 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 toremifene 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 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 toremifene to both Orion and 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.

With respect to the development and commercialization of toremifene-based products, the term of the Ipsen Collaboration Agreement will continue until the parties are no longer developing and commercializing toremifene-based products. Ipsen may terminate the Ipsen Collaboration Agreement for our uncured breach, upon our bankruptcy, 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, or in the event that either the UTRF License Agreements or the license and supply agreement with Orion terminate early.

***Merck & Co., Inc.***

In December 2007, we entered into a global exclusive license and collaboration agreement, or the Merck Collaboration Agreement, governing our and Merck s joint research, development and commercialization of SARM compounds and related SARM products. In March 2010, following Merck s determination to discontinue internal development of Ostarine (previously designated by Merck as MK-2866), we and Merck mutually agreed to terminate our collaboration and, as a result, we reacquired full rights to our SARM program, including Ostarine .

Under the Merck Collaboration Agreement, we granted Merck an exclusive worldwide license under our SARM-related patents and know-how. In connection with entering into the Merck Collaboration Agreement, Merck paid us an upfront licensing fee of $40.0 million and purchased approximately $30.0 million of our common stock. In addition, Merck agreed to pay us $15.0 million in guaranteed cost reimbursements for research and development activities in equal annual installments over a three year period beginning on the first anniversary of the effective date of the Merck Collaboration Agreement. We received $5.0 million from Merck in both December 2008 and December 2009 as the first and second payments of cost reimbursements for research and development activities. Although the

Merck Collaboration Agreement has been terminated, Merck remains obligated to pay us the third and final payment of $5.0 million of cost reimbursements for research and development activities in late 2010.

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## Manufacturing

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.

We have agreed to purchase from Orion our worldwide requirements of toremifene in a finished tablet form at specified prices under a license and supply agreement. Similarly, Ipsen has agreed to purchase from Orion, toremifene tablets for clinical testing and commercial sale in 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 toremifene. 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. 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.

Orion may terminate its obligation to supply us and Ipsen at its election at any time. There are a number of circumstances in which Orion is required to grant manufacturing rights to us and Ipsen, including following termination of its supply obligation, 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. Also, under certain circumstances, if additional manufacturing capacity is needed to supply our increasing need for product, we have the right at certain sales levels to require Orion to qualify an additional manufacturing site at our expense. Under these circumstances, we and Ipsen would need to make arrangements for an alternative supply which would have to be made by a qualified alternative supplier with the appropriate FDA approval in order for us to obtain our supply requirements for toremifene. In addition, Orion may terminate its obligation to supply us or Ipsen with toremifene if we or Ipsen are in material breach of our respective supply agreements with Orion, or in connection with certain bankruptcy events involving us or Ipsen, respectively. If Orion elects to terminate its obligation to manufacture and supply us and Ipsen with toremifene, any arrangements we make for an alternative supply would have to be have to be made with a qualified alternative supplier with appropriate FDA approval in order for us to obtain our supply requirements for toremifene. In addition, although Orion s composition of matter patents have expired, and as such, neither we nor Ipsen would be prevented from manufacturing toremifene within the United States or European Territory, there is no obligation on the part of Orion to transfer its manufacturing technology to us or Ipsen or to assist us or Ipsen in developing manufacturing capabilities to meet our respective supply needs. We and Ipsen have mutually agreed to cooperate in the manufacture of toremifene in the event Orion ceases manufacture of toremifene for any of the above-mentioned reasons.

There are no complicated chemistries or unusual equipment required in the manufacturing process for our SARMs. The active ingredient in Ostarine and our other SARMs is manufactured using a four-step synthetic process that uses commercially available starting materials and raw materials for each step. Initially, we relied on third party vendors for the manufacture of Ostarine drug substance. During the term of our collaboration, Merck assumed primary manufacturing responsibilities for Ostarine and other SARM products developed under our collaboration. In connection with the termination of our collaboration, Merck agreed to return to us all remaining inventory of Ostarine drug substance.

## 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, 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. Our commercial opportunities will be

reduced or eliminated if our competitors develop and commercialize similar products that are safer, more effective, have fewer side effects or are less expensive than any products that we and/or our collaborators may develop.

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***Toremifene 80 mg to Reduce Fractures and Treat Other Estrogen Deficiency Side Effects of ADT in Men with Prostate Cancer***

Currently, there are no products that have been approved by the FDA to reduce fractures in men with prostate cancer. We are aware of a number of drugs that are marketed or prescribed off-label for the treatment of single estrogen deficiency related side effects. For example, Evista® (raloxifene hydrochloride), a SERM marketed by Eli Lilly & Co., 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. Prolia™ (denosumab), a monoclonal antibody developed by Amgen, is under regulatory review in the United States, Switzerland, Australia and Canada for the treatment and prevention of postmenopausal osteoporosis and for the treatment of bone loss in patients undergoing hormone ablation therapy for breast or prostate cancer and has received a positive opinion in Europe from the EMEA s Committee for Medicinal Products for Human Use. Effexor® (venlafaxine hydrochloride), marketed by Pfizer, Inc., Catapres® (clonidine hydrochloride), marketed by Boehringer Ingelheim, and Megace® (megestrol 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 treatments. In addition, most patients would need to take several different drugs and potentially receive radiation treatments to treat multiple estrogen deficiency side effects of ADT. In contrast, we believe that toremifene 80 mg as a single product candidate has the potential to treat multiple estrogen deficiency side effects of ADT.

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

Currently, there are no drug products approved by the FDA to reduce the incidence of prostate cancer in high risk men with high grade PIN. 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 toremifene 20 mg Phase III clinical trial and may not have enough clinical patients to show a statistically significant benefit. GlaxoSmithKline is expected to resubmit a supplemental NDA for Avodart® for prostate cancer risk reduction among men at increased risk of developing the disease. However, men with high grade PIN were excluded from the Avodart® Phase III clinical trial. Finasteride has been shown to reduce the risk of prostate cancer and in a retrospective ad hoc analysis the risk of high grade PIN in men with a PSA of 0-3 ng/dl. Because finasteride also increased the risk for high grade prostate cancer tumors (Gleason Grade 7-10) and sexual side effects, some physicians have not recommended the use of finasteride for prevention of prostate cancer.

***SARMs for the Treatment of Cancer Cachexia and Chronic Sarcopenia***

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, an oral steroid, 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. 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 also been prescribed off-label for cancer cachexia. Oxandrolone 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 loss. 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 loss. Pharmacopeia (now owned by Ligand Pharmaceuticals) in-licensed the Bristol Myers Squibb SARM program and has a product candidate in a Phase I clinical study. Abbott Laboratories and Ligand Pharmaceuticals have a collaboration to develop a SARM and have been conducting Phase I clinical studies. Other pharmaceutical companies are also developing SARMs. Pfizer, Inc., Eli Lilly & Co., and Amgen have myostatin inhibitors in development that may compete with Ostarine if approved for commercial sale. Megace® (megestrol acetate) and Marinol® (dronabinol) are appetite stimulants approved for AIDS patients that are used off-label for cancer cachexia. In addition, Cytokinetics, Inc. is developing a troponin activator with a muscle specific mechanism in a Phase I study. Moreover, there are other categories of drugs in development, including ghrelin

receptor agonists and growth hormone secretagogues, which may have some muscle activity.

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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 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. 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 which has shown efficacy and tolerability advantages for AIs compared to tamoxifen.

## Sales and Marketing

We market FARESTON® (toremifene citrate) 60 mg tablets, approved for the treatment of metastatic breast cancer in postmenopausal women in the United States. 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 specialty sales and marketing infrastructure to market toremifene 80 mg and toremifene 20 mg, if approved by the FDA, to the relatively small and concentrated community of urologists and medical oncologists in the United States. We have partnered with Ipsen to commercialize toremifene in the European Territory if approved for commercial sale. We are currently seeking partners to market toremifene in Asia and other markets outside of the United States and the European Territory.

## 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 toremifene 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 for all uses in humans in the United States, and for all human uses outside the United States other than the treatment and prevention of breast cancer. Orion s patent for toremifene expired in the United States in September 2009 and foreign counterparts of this patent also have expired. As a result, we will need to rely primarily on the protection afforded by the method of use patents that either have been already issued or may later issue from our owned or licensed patent applications.

We have licensed from UTRF method of use patents and pending patent applications for specific disease indications and doses in the United States, and issued and pending patent applications internationally related to the use of toremifene 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 toremifene for this indication will begin expiring in 2019.

We have our own method of use patents and applications in the United States and internationally related to the use of toremifene 80 mg for the treatment of osteoporosis and reduction of fractures in men with prostate cancer treated by ADT, as well as other side effects from ADT such as gynecomastia and hot flashes. A method of use patent related to the use of toremifene for the treatment of ADT-induced osteoporosis and fractures in men with prostate cancer is issued in the United States and will expire in 2023. Furthermore, with respect to the method of use of toremifene 80 mg for the treatment of osteoporosis and fractures and other side effects of ADT in men with prostate cancer worldwide and the method of use of toremifene 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 other pending patent applications.

Even though patents have issued in respect of our pending method of use patent applications, since patents covering the composition of matter of toremifene have expired, competitors could market and sell generic versions of toremifene at doses and in formulations that are bioequivalent to FARESTON® (toremifene citrate 60 mg) for uses other than the indications for toremifene covered by our issued and pending method of use patent applications, and individual physicians would be permitted to prescribe generic versions of toremifene 60 mg for indications that are protected by our or our licensors method of use patents and pending patent applications. Assuming toremifene receives appropriate marketing approval, if patents do not issue in particular countries on account of our pending

method of use patent applications related to the use of toremifene 80 mg for the treatment of osteoporosis and fractures and other side effects of ADT in men with prostate cancer and the use of toremifene 20 mg for the

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reduction in the incidence of prostate cancer in high risk men with high grade PIN outside the United States, competitors may be able to market and sell generic versions of toremifene tablets for these indications.

For Ostarine and our other SARMs, we have an exclusive license from 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 methods of synthesizing the active pharmaceutical ingredients. We have also licensed issued and pending patent applications in the United States and internationally related to methods for building muscle mass and bone in patients, for treating bone related disorders including bone frailty and osteoporosis, and for treating muscle wasting disorders including cancer cachexia using Ostarine and other SARMs.

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.

## 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 recently obtained authority to 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 the 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.

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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 Practices 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 typically considers, 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 a Phase I clinical trial is to establish initial data about the safety, tolerability and pharmacokinetic properties of the product candidates in humans. In Phase II clinical trials, controlled studies are conducted on an expanded population of patients with the targeted disease. The primary purpose of these tests is to evaluate the effectiveness of the drug candidate on the patients to determine if there are any side effects or other risks associated with the drug and to determine the optimal dose of the drug from the safety and efficacy profile developed from the clinical study. Phase III trials involve even larger patient populations, often with several hundred or even several thousand patients, depending on the use for which the drug is being studied. Phase III trials are intended to establish the overall risk-benefit ratio of the drug and provide, if appropriate, an adequate basis for product labeling. During all clinical trials, physicians monitor the patients to determine effectiveness and to observe and report any reactions or other safety risks that may result from use of the drug candidate.

***Product Formulation and Manufacture***

Concurrent with clinical trials and preclinical studies, companies must develop information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product. In addition, manufacturers, including contract manufacturers, are required to comply with current applicable FDA 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 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.

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, the 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. The FDA initially 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.

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 a complete response letter at the end of the review period. A complete response letter will be issued to let a company know that the review period for a drug is complete and that the application is not yet ready for approval. The letter will describe specific deficiencies and, when possible, will outline recommended actions the applicant might take to

get the application ready for approval.

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***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.

In accordance with newly-gained authority pursuant to the Food and Drug Administration Amendments Act of 2007, the FDA may impose risk evaluation mitigation strategies, or REMS, on a product if the FDA believes there is a reason to monitor the safety of the drug in the marketplace. REMS are a new tool for the FDA that became effective in March 2008, and the agency has begun to implement this new authority on a case-by-case assessment as to whether a REMS is needed. Since the effective date, the FDA has used its new REMS enforcement authority more than 60 times and it is anticipated the agency will continue to use this authority on a regular basis going forward. REMS could add training requirements for healthcare professionals, safety communications efforts, and limits on channels of distribution, among other things. The sponsor would be required to evaluate and monitor the various REMS activities and adjust them if need be. The financial impact of REMS is uncertain at this time.

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, or ANDAs.

Patent term extension 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 extensions, however, are subject to a maximum extension of five years, and the patent term extension 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 generally 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 ANDA or a NDA submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetics Act, 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 (505(b)(2) NDA), 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 ANDA or 505(b)(2) NDA, 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, and any use of the drug for which marketing approval is sought could not violate another NDA holder s patent claims.

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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 ANDA or 505(b)(2) NDA 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 ANDAs or 505(b)(2) NDAs 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 ANDAs for generic versions of their drugs assuming the approval would not violate another NDA holder s patent claims. The ANDA 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 ANDA applicant needs only to submit data demonstrating that its product is bioequivalent to the innovator product as well as relevant chemistry, manufacturing and product data. The Hatch-Waxman Act also instituted a third type of drug application that requires the same information as a NDA, including full reports of clinical and preclinical studies, except that some of the information from the reports required for marketing approval comes from studies which the applicant does not own or have a legal right of reference. This type of application, a 505(b)(2) NDA, 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.

If a competitor submits an ANDA or 505(b)(2) NDA for a compound or use of any compound covered by another NDA holder s patent claims, the Hatch-Waxman Act requires, in some circumstances, the applicant to notify the patent owner and the holder of the approved NDA of the factual and legal basis of the applicant s opinion that the patent is not valid or will not be infringed. Upon receipt of this notice, the patent owner and the NDA holder have 45 days to bring a patent infringement suit in federal district court and obtain a 30-month stay against the company seeking to reference the NDA. The NDA holder could still file a patent suit after the 45 days, but if they miss the 45-day deadline, 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 ANDA or 505(b)(2) NDA. 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 ANDA or 505(b)(2) NDA. Once the applicant of the ANDA or 505(b)(2) NDA 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

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pharmaceutical pricing. Currently, our only marketed product, FARESTON® for the treatment of metastatic breast cancer, is eligible for coverage and reimbursement by third-party payors.

**Research and Development**

Since our inception in 1997, we have been focused on drug discovery, preclinical development and clinical development programs. Research and development expenses include, but are not limited to, 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 and medical affairs activities, quality assurance activities and license fees. Our research and development expenses were $32.3 million for the year ended December 31, 2009, $44.3 million for the year ended December 31, 2008, and $38.5 million for the year ended December 31, 2007.

**Employees**

As of December 31, 2009, we had 120 employees, 32 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 electronically with the U.S. Securities and Exchange Commission, or SEC, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934. We make available on our Web site at www.gtxinc.com, free of charge, copies of these reports as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Further, copies of these reports are located at the SEC s Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. Information on the operation of the Public Reference Room can be obtained by calling the SEC at 1-800-SEC-0330. The SEC maintains a Web site that contains reports, proxy statements, and other information regarding our filings at www.sec.gov. 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 of the Registrant**

The following table sets forth information about our executive officers as of March 10, 2010.

| Name | Age | Position(s) |
|---|---|---|
| Mitchell S. Steiner, M.D., F.A.C.S. | 49 | Chief Executive Officer and Vice Chairman of the Board of Directors |
| Marc S. Hanover | 47 | President, Chief Operating Officer and Director |
| Ronald A. Morton, Jr., M.D., F.A.C.S. | 51 | Vice President, Chief Medical Officer |
| Henry P. Doggrell | 61 | Vice President, General Counsel and Secretary |
| Mark E. Mosteller | 47 | Vice President, Chief Financial Officer and Treasurer |
| James T. Dalton, Ph.D. | 47 | Vice President, Preclinical Research and Development |
| Gregory A. Deener | 48 | Vice President, Sales and Marketing |

***Mitchell S. Steiner, M.D., F.A.C.S.,*** a co-founder of GTx, has served as our Chief Executive Officer and Vice Chairman of our Board of Directors since our inception in September 1997. From 1995 to 2003, Dr. Steiner held numerous academic appointments, including Chairman and Professor of Urology, Director of Urologic Oncology and Research and the Chair of Excellence in Urologic Oncology at the University of Tennessee. Since 2003, Dr. Steiner has continued to serve on the faculty at the University of Tennessee. Dr. Steiner holds a B.A. in Molecular Biology from Vanderbilt University and an M.D. from the University of Tennessee, and performed his surgery and urologic training at The Johns Hopkins Hospital.

***Marc S. Hanover,*** a co-founder of GTx, has served as our President and Chief Operating Officer and a director since our inception in September 1997. Prior to joining GTx, Mr. Hanover was a founder of Equity Partners

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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.

***Ronald A. Morton, Jr., M.D., F.A.C.S.,*** was appointed Vice President and Chief Medical Officer in April 2007. He joined GTx from the University of Medicine & Dentistry of New Jersey Robert Wood Johnson Medical School, where he served as Professor of Surgery, Chief of Urology and Director of Urologic Oncology for the Cancer Institute of New Jersey from January 2004 until April 2007. Dr. Morton also held the Conzen Chair for Clinical Research and was the Director of the New Jersey Center for Clinical and Translational Sciences. Prior to joining Robert Wood Johnson Medical School in 2004, Dr. Morton held a dual faculty appointment at the Baylor College of Medicine in the Scott Department of Urology and in the Department of Molecular and Cell Biology (May 1994 to December 2003), was Clinical Director of the Baylor Adult Urology Program (July 2000 to December 2003), Chief of Urology at the Houston Veterans Administration Medical Center (January 1999 to December 2003), and Director of the Baylor Prostate Cancer Center Research Laboratories (July 1996 to December 2003). He received his bachelor and medical degrees from The Johns Hopkins University and completed his urology training and postdoctoral fellowship and was an AFUD Scholar at The Johns Hopkins Brady Urological Institute.

***Henry P. Doggrell*** has served as our General Counsel and Secretary since October 2001 and was appointed Vice President on January 20, 2005. From April 1998 to August 2001, Mr. Doggrell was Senior Vice President, Corporate Affairs at Buckeye Technologies, Inc., a specialty cellulose company, where he was responsible for matters including corporate finance, investor relations, mergers and acquisitions, intellectual property and licensing and strategic development. From 1996 to 1998, Mr. Doggrell served as General Counsel and Secretary of Buckeye Technologies. Prior to joining Buckeye Technologies, Mr. Doggrell was a partner of the Baker, Donelson, Bearman, Caldwell and Berkowitz law firm from 1988 to 1996, where he served as a member of the law firm management committee and Chair of the firm s Corporate Securities department. Mr. Doggrell holds a B.S. in Commerce from the University of Virginia and a JD from Vanderbilt University.

***Mark E. Mosteller*** 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 by Ernst & Young LLP. Mr. Mosteller is a Certified Public Accountant and holds a B.S. in Accounting from the University of Tennessee.

***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 25 years of experience in Marketing and Sales and has launched a urology medicine within the U.S. From 1996 to December 2003, Mr. Deener served as a Marketing Director for GlaxoSmithKline in various roles within the U.S. and Europe. Most recently Mr. Deener was responsible for the launch of Avodart, a urology medicine for BPH. From 1983 to 1996, Mr. Deener worked for Procter & Gamble in Brand Management and Sales. Mr. Deener holds a B.S. in Business Administration from the University of North Carolina at Chapel Hill.

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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 we anticipate that we will incur continued losses for the foreseeable future.***

We have a limited operating history. As of December 31, 2009, we had an accumulated deficit of $368.2 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 $46.3 million for the year ended December 31, 2009, $51.8 million in 2008, and $40.4 million in 2007. Due to the termination of our collaboration with Merck & Co., Inc., or Merck, and the expected recognition in the first quarter of 2010 of $49.9 million in deferred revenue and the final payment from Merck of $5.0 million of cost reimbursement for research and development expenses, we expect to report net income for the year ending December 31, 2010. However, while recognition of this revenue is expected to result in net income for 2010, we expect to incur significant operating losses in 2011 and for the foreseeable future. In addition, we do not expect to obtain FDA or any other regulatory approvals to market any of our product candidates in the near future. These losses have had and will continue to have an adverse effect on our stockholders equity and working capital.

In October 2009, we received a Complete Response Letter from the U.S. Food and Drug Administration, or FDA, regarding our New Drug Application, or NDA, for toremifene 80 mg to reduce fractures in men with prostate cancer on ADT notifying us that the FDA would not approve our NDA in its present form as a result of certain clinical deficiencies identified in the Complete Response Letter. As a result, FDA approval of toremifene 80 mg, if it occurs, will be substantially delayed. In addition, we expect that significant additional clinical development will be required in order to potentially obtain FDA approval of toremifene 80 mg, including an additional pivotal Phase III clinical trial. We do not currently have the cash resources sufficient to fund such additional clinical development, and if we are unable to obtain funding sufficient to continue or complete the development of toremifene 80 mg, we may be required to further delay or eliminate our toremifene 80 mg development program, which would have a material adverse effect on our business and growth prospects.

Because of the numerous risks and uncertainties associated with developing and commercializing small molecule drugs, we are unable to predict the extent of any future losses or when we will become profitable, if at all. We have financed our operations and internal growth primarily through public offerings and private placement of our common stock, as well as payments from our current and former collaborators which include $40.0 million in upfront license fees from Merck received in January 2008, a $1.5 million milestone payment from Ipsen Biopharm Limited, or Ipsen, received in April 2008, and $5.0 million received from Merck in guaranteed cost reimbursements for research and development activities in both December 2009 and December 2008. In March 2010, we and Merck agreed to terminate our collaboration and, as a result, we will not receive any milestone payments or royalties for the development or sale of selective androgen receptor modulators, or SARMs, from Merck. Although the collaboration with Merck was terminated, Merck remains obligated to pay us the third and final payment of $5.0 million of cost reimbursements for research and development activities in late 2010. We do not anticipate significant development progress on Ostarine , or our SARM program in general, including the initiation of any additional clinical trials, unless and until we enter into one or more new collaborations with third parties or otherwise obtain additional funding. FARESTON® is currently our only commercial product and, until such time that we receive regulatory approval to market any of our product candidates, we expect that FARESTON® will account for all of our product revenue. For the year ended December 31, 2009, we recognized $3.3 million in net revenues from the sale of FARESTON®. If we, Ipsen, and/or any potential future collaborators are unable to develop and commercialize any of our product

candidates, if development is delayed or if sales revenue from any product candidate that receives marketing approval is insufficient, we may never become profitable and we will not be successful.

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***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 substantial additional capital to:

- fund our operations and conduct clinical trials, including any additional clinical trial that we may undertake in an effort to obtain FDA approval of toremifene 80 mg or any of our SARM product candidates;
- 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 and cash equivalent balances, short-term investments, interest income and product revenue from the sale of FARESTON® will be sufficient to meet our projected operating requirements for at least the next twelve months. This estimate does not include any costs related to additional clinical development of our toremifene 80 mg product candidate or SARM program that we may undertake in an effort to obtain FDA approval. 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. Our future funding requirements will depend on many factors, including:

- whether and to what extent we determine to continue the development of toremifene 80 mg following discussion with the FDA, including an additional clinical trial to address the deficiencies identified by the FDA in the Complete Response Letter for toremifene 80 mg;
- the scope, rate of progress and cost of our, Ipsen s and/or any potential future collaborators clinical trials and other research and development activities;
- future clinical trial results;
- the terms and timing of any future collaborative, licensing and other arrangements that we may establish;
- the cost and timing of regulatory filings and/or approvals to commercialize our product candidates and any related restrictions, limitations, and/or warnings in the label of an approved product candidate;
- potential future licensing fees, milestone payments and royalty payments, including any milestone payments or royalty payments that we may receive under our collaborative arrangement with Ipsen;
- the cost and timing of establishing medical education, sales, marketing and distribution capabilities;
- the cost of establishing clinical and commercial supplies of our product candidates and any products that we, Ipsen, and/or any potential future collaborators 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 cost of defending any other litigation claims; 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 short-term investments, 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. In December 2009, we announced a reduction of approximately 26% of our workforce in order to reduce our operating expenses in connection with the receipt of the Complete Response Letter regarding our NDA for toremifene 80 mg and the associated delay in the potential regulatory approval of toremifene 80 mg. If we are unable to raise additional funds when needed, we may need to further reduce our expenditures, perhaps significantly, to preserve our cash. The cost-cutting measures we have

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taken and may take in the future may not be sufficient to enable us to meet our cash requirements, and they may negatively affect our business and growth prospects.

If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Debt financing, if available, may involve restrictive covenants. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. If we raise additional funds through collaboration and/or licensing arrangements with third parties, it may be necessary to relinquish rights to some of our technologies or product candidates, or we may be required to grant licenses on terms that are not favorable to us. Our ability to raise additional funds may be adversely impacted by our receipt of the Complete Response Letter from the FDA in October 2009 regarding our NDA for toremifene 80 mg and the related uncertainty regarding the continued development of, and prospects for FDA approval of, toremifene 80 mg, as well as current economic conditions, including the effects of the disruptions to and continuing volatility in the credit and financial markets in the United States and worldwide. As a result of these and other factors, we cannot be certain that additional funding will be available on acceptable terms, or at all. If adequate funds are not available when we need them, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs or 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.

**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 if our or our collaborators 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.

In clinical studies, the efficacy and/or safety results from the trial may be insufficient to support the submission or approval of a NDA with the FDA. For example, we received a Complete Response Letter in October 2009 from the FDA regarding our NDA for toremifene 80 mg to reduce fractures in men with prostate cancer on ADT, notifying us that the FDA would not approve our NDA in its present form as a result of certain clinical deficiencies identified in the Complete Response Letter, which deficiencies may only be addressed by conducting an additional pivotal Phase III clinical trial of toremifene 80 mg. In 2010, we plan to submit to and discuss with the FDA a proposed protocol for a second pivotal Phase III clinical trial evaluating toremifene 80 mg to reduce fractures in men with prostate cancer on ADT to address in a single clinical trial the deficiencies identified by the FDA in the Complete Response Letter. Any decision to initiate another clinical trial for toremifene 80 mg to reduce fractures in men with prostate cancer on ADT will require us to obtain sufficient additional funding for the trial. In addition, in connection with our pivotal Phase III clinical trial of toremifene 20 mg for the prevention of prostate cancer in high risk men with high grade PIN, a planned efficacy interim analysis was conducted in the second quarter of 2008, which concluded that the efficacy results did not reach the specified statistical outcome, and we were therefore unable to submit a NDA to the FDA based on this efficacy interim analysis. Until such time as we conclude the clinical trial and analyze the data, which we expect will occur in 2010, we will not be able to determine if the clinical trial successfully demonstrated a statistically significant positive outcome to allow us to submit a NDA to the FDA to seek marketing approval for this product candidate.

We, Ipsen, or any potential future collaborators may experience numerous unforeseen events during, or as a result of, preclinical testing and the clinical trial process that could delay or prevent our or our collaborators ability to commercialize our product candidates, including:

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

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

promising;

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

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we, Ipsen, or any potential future collaborators may suspend or terminate 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, Ipsen, or any potential future collaborators 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 currently 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. Our, Ipsen s or any potential future collaborators preclinical or clinical trials may produce negative or inconclusive results that would not support our beliefs regarding the potential effectiveness of our product candidates.

***If we, Ipsen, or any potential future collaborators 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, Ipsen, or any potential future collaborators 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.***

In our Phase III clinical trial for toremifene 20 mg for the prevention of prostate cancer in high risk men with high grade PIN, some patients have experienced venous thromboembolic events, or VTEs, such as deep vein thromboses and pulmonary embolisms, as well as myocardial infarctions, or heart attacks, which have been considered by investigators as possibly related to treatment with toremifene 20 mg. Because this trial is blinded, we do not know whether these patients received placebo or toremifene 20 mg in this trial. In addition, although the results from our Phase III clinical trial for toremifene 80 mg to reduce fractures and treat other estrogen deficiency side effects of ADT in men with prostate cancer showed that the drug had a generally favorable safety profile compared to placebo and was well tolerated, there were a higher number of subjects experiencing a VTE in the toremifene 80 mg treatment group, 17 (2.6%) versus 7 (1.1%) in the placebo group. Even though the majority of VTEs recorded in the clinical trial occurred in men who were at high risk for a VTE (including: age greater than 80 years, history of VTEs, recent surgical procedure or immobilization) and data from the clinical trial showed that the number of men without any of these independent risk factors for VTEs in whom a VTE occurred during the clinical trial was 5 in the toremifene 80 mg treatment group versus 3 in the placebo group, the FDA will consider the overall safety profile from the clinical trial when making its determination to grant marketing approval and to require potential warnings in the label if approval is granted.

As part of our effort to complete the requirements for the submission of applications for regulatory approval to commercialize toremifene 80 mg and 20 mg, we have conducted a number of studies of toremifene in addition to our clinical trials, including a Thorough QT study (toremifene 80 mg and toremifene 20 mg), a bioequivalence study (toremifene 80 mg), a series of drug-drug interaction studies (toremifene 80 mg and toremifene 20 mg), and a semen quality study (toremifene 20 mg) to assess the effect of toremifene. The results of the Thorough QT study of 250 healthy male volunteers, with 5 parallel cohorts receiving 20 mg, 80 mg or 300 mg doses of toremifene, moxifloxacin, or placebo, showed that toremifene prolonged the QT interval in a dose dependent manner. The mean change in QTcB (a measurement of QT interval corrected by Bazett s formula) from baseline relative to placebo for toremifene 20 mg was 5.79 milliseconds, for toremifene 80 mg, it was 22.43 milliseconds, and for moxifloxacin, it was 8.83 milliseconds. Since we market FARESTON® in the United States under a license agreement with Orion Corporation, or Orion, we notified the FDA of the Thorough QT study results and have proposed modifications to the FARESTON® label in the United States. FDA action on the proposed label changes is pending. Separately, Orion

recommended label changes to the European Medicines Agency, or EMEA. In January 2009, the EMEA recommended that the FARESTON® label within the European Union reflect that toremifene should not be given to patients at risk of prolonged QT intervals or other certain heart problems. The results of these completed studies have been included as a part of the NDA submission to the FDA for our toremifene 80 mg product candidate to

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reduce fractures in men with prostate cancer on ADT and, subject to receipt of favorable results from our ongoing toremifene 20 mg Phase III clinical trial, will be included as a part of the NDA submission for our toremifene 20 mg product candidate for the prevention of prostate cancer in high risk men with high grade PIN, and will be used to update the label for FARESTON®. The study results could lead to the inclusion of restrictions, limitations and/or warnings in the label of FARESTON® or an approved product candidate, which may adversely affect the marketability of the product or limit the patients to whom the product is prescribed.

In addition, in our Phase II clinical trial for Ostarine for the treatment of cancer cachexia (cancer induced muscle loss), we observed mild elevations of hepatic enzymes in a few patients, and in our preclinical studies for Ostarine , only at the highest doses, we observed expected selective effects on the reproductive and other target organs in the male population consistent with the stimulating and inhibiting effects on the androgen receptor which is located in these organs.

If the incidence of the events described above increases in number or severity, if a regulatory authority believes that these or other 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, Ipsen, or any potential future collaborators may conduct in the future or after any of our product candidates are approved and marketed:

- we, Ipsen, or any potential future collaborators 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 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**

***We are dependent upon our collaborative arrangement with Ipsen to further develop and commercialize toremifene 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 toremifene, any dispute over the terms of our collaboration with Ipsen, or any other adverse developments in our relationship with Ipsen could materially harm our business and would 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 toremifene within the European Territory. Any failure on the part of Ipsen to initiate these studies could delay the commercialization of toremifene within the European Territory. In addition, the receipt of the Complete Response Letter from the FDA in October 2009 has delayed Ipsen s plans to seek marketing approval of toremifene 80 mg in the European Territory.

We may not be successful in entering into additional collaborative arrangements with other third parties, and even if we do enter into collaborative arrangements with other parties, such arrangements may not be successful. 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 collaborative arrangement with Ipsen for the development and commercialization of toremifene subjects us to a number of risks, including:

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we are not able to control either the amount and timing of resources that Ipsen devotes to toremifene;

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

Ipsen or any potential future collaborations may experience financial difficulties or changes in business focus;

we may be required to relinquish important rights such as marketing and distribution rights;

under certain circumstances, Ipsen may not be required to commercialize toremifene in certain countries of the European Territory if Ipsen determines 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 toremifene 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 the 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;

under certain circumstances, a collaborator could move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors; and

collaborative arrangements are often terminated or allowed to expire, such as our former collaboration with Merck, which would delay the development and may increase the cost of developing our product candidates.

***We may not realize the anticipated benefits from our collaborative arrangement with Ipsen, and may not receive the anticipated benefits from any future collaboration arrangements that we might establish.***

We may not receive any future milestone payments provided for under our collaborative arrangement with Ipsen if our agreement with Ipsen is terminated, if certain clinical development and regulatory milestones under our agreement with Ipsen are not achieved or if Ipsen fails to develop and commercialize toremifene in the European Territory. In addition, even if required regulatory approvals to market toremifene are obtained, it is possible that Ipsen will not successfully market and sell any toremifene products in which case we would not receive royalties to the extent that we currently anticipate. Furthermore, our royalty rates under our collaboration and license 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, and Ipsen may be entitled to offset a portion of any royalties due to us if Ipsen licenses patent rights from a third party that would otherwise be infringed by Ipsen s use, manufacture, sale or import of toremifene compounds.

Under our agreement with Ipsen, 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 toremifene 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. However, there can be no assurance that we will be able to reach an agreement with Ipsen on reasonable terms, or at all, for any new SERM-based products.

Ipsen may terminate the license and collaboration agreement for our uncured breach, upon our bankruptcy, 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, or in the event that either the UTRF License Agreements or the license and supply agreement with Orion terminate early. If our agreement with Ipsen is terminated, the anticipated future benefits to us from this agreement would be eliminated and the development and commercialization of toremifene in the European Territory would be delayed. In any such or similar events, we may not realize the anticipated benefits from our collaborative arrangement with Ipsen.

Besides Ipsen, we have established and intend to continue to establish collaborations with third parties to develop and commercialize some of our current and future product candidates, and these collaborations may not be

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successful or we may otherwise not realize the anticipated benefits from these collaborations. For example, in March 2010, following Merck s determination to discontinue internal development of Ostarine (previously designated by Merck as MK-2866), we and Merck mutually agreed to terminate our collaboration and, as a result, we will not receive any milestone payments or royalties for the development or sale of SARMs from Merck. In the future, we may not be able to locate third-party collaborators to develop and market our product candidates, and we may lack the capital and resources necessary to develop our product candidates alone.

***If third parties do not manufacture our product candidates in sufficient quantities, in the required timeframe, 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, if any, 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 in a finished tablet form at specified prices under a license and supply agreement. Similarly, Ipsen has agreed to purchase from Orion toremifene 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 toremifene.

Orion may terminate its supply obligations at its election at any time as a result of our failure to obtain regulatory approval of one of our toremifene product candidates in the United States prior to December 31, 2009. If Orion elects to terminate its obligation to manufacture and supply us and Ipsen with toremifene, any arrangements we make for an alternative supply would have to be made with a qualified alternative supplier with appropriate FDA approval in order for us to obtain our supply requirements for toremifene. In addition, although Orion s composition of matter patents have expired, and as such, neither we nor Ipsen would be prevented from manufacturing toremifene within the United States or European Territory, there is no obligation on the part of Orion to transfer its manufacturing technology to us or Ipsen or to assist us or Ipsen in developing manufacturing capabilities to meet our respective supply needs. We and Ipsen have mutually agreed to cooperate in the manufacture of toremifene in the event Orion ceases manufacture of toremifene for any of the above-mentioned reasons. Although we and Ipsen have agreed to cooperate with each other in the event either of our supply rights are terminated by Orion for any reason, a disruption in the supply of toremifene could delay the development of and impair our and Ipsen s ability to commercialize toremifene.

We also rely on Orion to cooperate with us in the filing and maintenance of regulatory filings with respect to the manufacture of toremifene, and Orion may terminate its obligation to assist us in obtaining and maintaining regulatory approval of toremifene at its election at any time. 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 further delay or prevent regulatory approval of toremifene.

Historically, we have relied on third party vendors for the manufacture of Ostarine drug substance. However, Merck assumed primary manufacturing responsibilities for Ostarine under our exclusive license and collaboration agreement with Merck, which agreement was terminated in March 2010. In connection with the termination of the agreement with Merck, Merck agreed to return to us all remaining inventory of Ostarine drug substance. If this supply of Ostarine becomes unusable or if we are unsuccessful in identifying a contract manufacturer or negotiating a manufacturing agreement on a timely basis for our Ostarine or other SARM product candidates supply needs, we could experience a delay in conducting any additional clinical trials of Ostarine or other SARM product candidates. 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 the relationship with Orion for toremifene, or to do so at an acceptable cost, or other suppliers fail to meet our requirements for Ostarine or other SARM product candidates for any reason, we would be required to obtain alternate suppliers. 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.

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***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;
- drug product supplies not meeting the requisite requirements for clinical trial use; and
- the possible exercise by Orion of its right to terminate its obligation to supply us with toremifene, which it may do at its election at any time.

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, Ipsen and/or our potential future collaborators may develop may compete with other product candidates and products for access to manufacturing facilities. For example, the active pharmaceutical ingredient in our toremifene 80 mg and toremifene 20 mg product candidates is also the active pharmaceutical ingredient in FARESTON®. Further, Orion has agreed to supply toremifene 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 metastatic 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 successfully 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.

## Risks Related to Our Intellectual Property

***If we lose our licenses from the University of Tennessee Research Foundation, or UTRF, we may be unable to continue a substantial part of our business.***

We have licensed intellectual property rights and technology from UTRF used in a substantial part of our business. These license agreements may be terminated by UTRF 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 a substantial part of our business and may result in a

serious adverse effect on our financial condition, results of operations and any prospects for growth. Additionally, the termination of our UTRF license for chemoprevention of prostate cancer could lead to a termination of our license and collaboration agreement with Ipsen, which would result in a loss of any potential

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milestone or royalty payments from Ipsen related to the high grade PIN indication.

***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 result in issued patents or result in patents with narrow or unenforceable claims, or if we are prevented 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 toremifene within a substantial portion of the European Territory may depend on having 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 inter-institutional agreements with The Ohio State University, or 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. In addition, under the terms of some of our agreements with diagnostic companies to which we provided clinical samples from our clinical trials of toremifene 20 mg, 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 has expired in the United States and abroad. As a result, we will need to rely primarily on the protection afforded by method of use patents relating to the use of toremifene for the relevant prescribed indications that have been issued or may be issued from our owned or licensed patent applications. Also, within the European Territory, Ipsen may need to rely primarily on the protection afforded by marketing and data exclusivity for the toremifene products that may be sold within the countries comprising the European Territory. To date, many of our applications for method of use patents filed for toremifene outside of the United States are still pending and have not yielded issued patents. Loss of marketing and data exclusivity for any toremifene products that may be commercialized within the European Territory could adversely affect Ipsen s ability to successfully commercialize these products.

Our and our licensors ability to obtain patents can be highly uncertain and involve complex and in some cases unsettled legal issues and factual questions. Furthermore, different countries have different procedures for obtaining patents, and patents issued in different countries provide different degrees of protection against the use of a patented invention by others. Therefore, if the issuance to us or our licensors, in a given country, of a patent covering an invention is not followed by the issuance, in other countries, of patents covering the same invention, or if any judicial interpretation of the validity, enforceability or scope of the claims in a patent issued in one country is not similar to the interpretation given to the corresponding patent issued in another country, our ability to protect our intellectual property in those countries may be limited. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection.

Even if patents are issued to us or our licensors regarding our product candidates or methods of using them, those patents can be challenged by our competitors who can argue such patents are invalid or unenforceable or that the claims of the issued patents should be limited or narrowly construed. Patents also will not protect our product candidates if competitors devise ways of making or using these product candidates without legally infringing our patents. The Federal Food, Drug, and Cosmetic Act and FDA regulations and policies create a regulatory environment that encourages companies to challenge branded drug patents or to create non-infringing 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

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event of unauthorized disclosure of confidential information. Enforcing a claim that a third party illegally obtained and is using our trade secrets is expensive and time-consuming, and the outcome is unpredictable. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. Failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

***Off-label sale or use of toremifene products could decrease sales of toremifene 80 mg and toremifene 20 mg tablets if approved for commercial sale, 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 toremifene.***

In all countries in which we hold or have licensed rights to patents or patent applications related to toremifene, the composition of matter patents we license from Orion have expired. As a result, we will need to rely primarily on the protection afforded by method of use patents. Our method of use patents may not protect toremifene from the risk of off-label sale or use of other toremifene products in place of toremifene 80 mg and toremifene 20 mg tablets. 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 other toremifene products may adversely affect our or Ipsen s ability to generate revenue from the sale of toremifene 80 mg and 20 mg tablets, if approved for commercial sale.

Even in the event that patents are issued from our pending method of use patent applications, 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 method of use 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 or potential 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 toremifene 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 toremifene in the countries outside of the United States where these applications are currently pending, we would not have as extensive patent coverage to prevent competitors from marketing and selling generic versions of toremifene at doses and in formulations equivalent to toremifene 80 mg and toremifene 20 mg tablets for the indications covered by our pending method of use patent applications. Also, regulatory authorities may not recognize marketing and data exclusivity for toremifene in the European Territory for the treatment of prostate cancer and estrogen deficiency side effects resulting from ADT. If generic versions of toremifene are able to be sold in countries within the European Territory for the indications for which Ipsen anticipates marketing toremifene, 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 generic sales thresholds are reached.

***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 toremifene for human uses outside the United States.***

Our exclusive license and supply agreement from Orion excludes the use of toremifene for the treatment of metastatic breast cancer in postmenopausal women 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 toremifene 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 toremifene.

***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, development, and manufacture and process synthesis efforts. Others might have

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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, synthesis, commercialization, formulation or use of our product candidates. In addition, the production, manufacture, synthesis, 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, Ipsen and/or our potential future collaborators 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 that it does not infringe, which may not be possible or could require substantial funds and time.

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 product sales to pay for costs incurred by Ipsen to obtain a license to any dominant intellectual property rights that are infringed by the products at issue.

## Risks Related to Regulatory Approval of Our Product Candidates

***If we, Ipsen, or any potential future collaborators are not able to obtain required regulatory approvals, we or such 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, 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 or any collaborator from commercializing the product candidate. We have not received regulatory approval to market any of our product candidates in any jurisdiction, and we do not expect to obtain FDA or any other regulatory approvals to market any of our product candidates in the near future. 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 toremifene 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. For example, the FDA announced in 2008 that, due to staffing and resource limitations, it has given its managers discretion to miss certain timing goals for completing reviews of NDAs set forth under the Prescription Drug User Fee Act, or PDUFA. Although the FDA has since publicly expressed a recommitment to meeting PDUFA deadlines, it remains unclear whether and to what extent the FDA will adhere to PDUFA deadlines in the future. If the FDA were to miss a PDUFA timing goal for one of our product candidates, the development and commercialization of the product candidate could be delayed. In addition, the Food and Drug Administration Amendments Act of 2007, or the FDA Amendments Act, which was enacted in September 2007, expands the FDA s authority to regulate drugs throughout the product life cycle, including enhanced authority to require post-approval studies and clinical trials. Other proposals have been made to impose additional requirements on drug approvals, further expand post-approval requirements and restrict sales and promotional activities. This new legislation, and the additional proposals if enacted, may make it more difficult or burdensome for us or our potential future collaborators to obtain approval of our product candidates. 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 approval may also impose risk evaluation mitigation strategies, or REMS, on a product if the FDA believes

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there is a reason to monitor the safety of the drug in the market place. REMS may include requirements for additional training for health care professionals, safety communication efforts and limits on channels of distribution, among other things. The sponsor would be required to evaluate and monitor the various REMS activities and adjust them if need be. 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, in October 2009, we received a Complete Response Letter from the FDA regarding our NDA for toremifene 80 mg to reduce fractures in men with prostate cancer on ADT notifying us that the FDA would not approve our NDA in its present form as a result of certain clinical deficiencies identified in the Complete Response Letter. As a result, FDA approval of toremifene 80 mg, if it occurs, will be substantially delayed. In addition, we completed our Phase III clinical trial of toremifene 80 mg to reduce fractures and treat other estrogen deficiency side effects of ADT in men with prostate cancer and are conducting our Phase III clinical trial of toremifene 20 mg for the prevention of prostate cancer in high risk men with high grade PIN, under Special Protocol Assessments, or SPAs, with the FDA. A SPA is designed to facilitate the FDA s review and approval of drug products by allowing the FDA 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 if the FDA subsequently identifies a substantial scientific issue essential to determining the product s safety or efficacy, and we may be required to conduct significant additional development in order to obtain regulatory approval notwithstanding a SPA with the FDA. For example, even though our Phase III clinical trial of toremifene 80 mg to reduce fractures in men with prostate cancer on ADT was completed under a SPA, we were unable to obtain approval of our NDA for toremifene 80 mg that we submitted in December 2008. 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 submit an application to 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, including toremifene 80 mg in the near future. In October 2009, we received a Complete Response Letter from the FDA regarding our NDA for toremifene 80 mg to reduce fractures in men with prostate cancer on ADT identifying two deficiencies in our application and requesting that clinical trials be conducted to address the deficiencies. Furthermore, it is not anticipated that Ipsen will receive the appropriate regulatory approvals to market toremifene within the European Territory any sooner than we will achieve regulatory approval in the United States, and it likely will be thereafter. The inability to obtain FDA approval or approval from comparable authorities in other countries for our product candidates would prevent us, Ipsen, or any potential future collaborators from commercializing these product candidates in the United States or other countries. See the section entitled Business Government Regulation under Part I, Item 1 of this Annual Report on Form 10-K for additional information regarding risks associated with marketing approval, as well as risks related to post-approval requirements.

**Risks Related to Commercialization**

***The commercial success of any products that we, Ipsen, and/or any potential future collaborators may develop, including any toremifene products, will depend upon the market and the degree of market acceptance among physicians, patients, healthcare payors and the medical community.***

Any products that we, Ipsen, and/or any potential future collaborators 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 or receive royalties to the extent we currently anticipate, 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:

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efficacy and safety results in clinical trials;

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.

As part of our effort to complete the requirements for the submission of applications for regulatory approval to commercialize toremifene 80 mg and toremifene 20 mg, we have conducted a number of studies of toremifene in addition to our clinical trials, including a Thorough QT study (toremifene 80 mg and toremifene 20 mg), a bioequivalence study (toremifene 80 mg), a series of drug-drug interaction studies (toremifene 80 mg and toremifene 20 mg), and a semen quality study (toremifene 20 mg) to assess the effect of toremifene. The results of the Thorough QT study of 250 healthy male volunteers, with 5 parallel cohorts receiving 20 mg, 80 mg or 300 mg doses of toremifene, moxifloxacin, or placebo, showed that toremifene prolonged the QT interval in a dose dependent manner. The mean change in QTcB (a measurement of QT interval corrected by Bazett s formula) from baseline relative to placebo for toremifene 20 mg was 5.79 milliseconds, for toremifene 80 mg, it was 22.43 milliseconds, and for moxifloxacin, it was 8.83 milliseconds. Since we market FARESTON® in the United States under a license agreement with Orion, we notified the FDA of the Thorough QT study results and have proposed modifications to the FARESTON® label in the United States. FDA action on the proposed label changes is pending. Separately, Orion recommended label changes to the European Medicines Agency, or EMEA. In January 2009, the EMEA recommended that the FARESTON® label within the European Union reflect that toremifene should not be given to patients at risk of prolonged QT intervals or other certain heart problems. The results of these completed studies were included as a part of the NDA submission to the FDA for our toremifene 80 mg product candidate to reduce fractures in men with prostate cancer on ADT and, subject to receipt of favorable results from our ongoing toremifene 20 mg Phase III clinical trial, will be included as a part of the NDA submission for our toremifene 20 mg product candidate for the prevention of prostate cancer in high risk men with high grade PIN, and will be used to update the label for FARESTON®. The study results could lead to the inclusion of restrictions, limitations and/or warnings in the label of FARESTON® or an approved product candidate, which may adversely affect the marketability of the product or limit the patients to whom the product is prescribed.

***Our only marketed product generating revenue is FARESTON®, which is subject to a number of risks. These risks may cause sales of FARESTON® to continue to decline.***

FARESTON® is currently our only marketed product. FARESTON® is indicated for the treatment of metastatic breast cancer in postmenopausal women. FARESTON® competes against tamoxifen, fulvestrant, and several aromatase inhibitors, including anastrozole, letrozole, and exemestane, for hormonal treatment of breast cancer. Sales of pharmaceuticals for breast cancer in the SERM class have declined in recent years as aromatase inhibitors have gained market share and we believe this trend will continue. Further, the branded competitors have greater resources and generic competitors are preferred by insurers. Continued sales of FARESTON® also could be impacted by many other 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 together accounted for approximately 95% of our product sales of FARESTON® for the year ended December 31, 2009;

any restrictions, limitations, and/or warnings added to the FARESTON® label as a result of our studies of toremifene, including a Thorough QT study and drug interaction studies, or otherwise;

the continued success of competing products, including aromatase inhibitors;

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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 introduction of generic toremifene products that compete with FARESTON® for the treatment of breast cancer; and

the loss of Orion, upon which we rely as a single source, as our supplier of FARESTON®.

***If we are unable to expand our sales and marketing capabilities or establish 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. We currently plan to build a specialty sales force to market our product candidates, if approved for commercial sale, to urologists and medical oncologists in the United States. In the event we are unable to hire a sufficient number of qualified sales personnel consistent with our plans, this could delay the commercialization of any of our product candidates if approved for commercial sale. We are relying on Ipsen to market and distribute our toremifene 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 toremifene 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 toremifene product candidates in the European Territory. Currently, we do not have a partner outside of the European Territory and our success in regions other than the European Territory may be dependent on our ability to find suitable partners in other regions of the world. 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, Ipsen, and/or any potential future collaborators 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, Ipsen, and/or any potential future collaborators 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, Ipsen, and/or any potential future collaborators may develop, our revenues and prospects for profitability may suffer. For example, the Medicare Prescription Drug, Improvement and Modernization Act of 2003 created a prescription drug benefit program for Medicare recipients. The prescription drug program established by this legislation may have the effect of reducing the prices that we, Ipsen, or any potential future collaborators are able to charge for products we, Ipsen, and/or any potential future collaborators develop and sell through the program. This 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, Ipsen, and/or any potential future collaborators may develop or to lower the amount that they pay. In addition, members of the United States Congress have stated their desire to reduce the government s cost for reimbursements of prescription drugs by amending this legislation.

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 twelve months or longer after the receipt of regulatory marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we, Ipsen, or any potential future collaborators may be

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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 or our collaborators commercialization efforts. 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, Ipsen, and/or any potential future collaborators may develop or sell. Cost-control initiatives could decrease the price we might establish for products that we, Ipsen, or any potential future collaborators may develop or sell, which would result in lower product revenues or royalties payable to us.

Another development that may affect the pricing of drugs is proposed congressional action regarding drug reimportation into the United States. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 gives discretion to the Secretary of Health and Human Services to allow drug reimportation into the United States under some circumstances from foreign countries, including countries where the drugs are sold at a lower price than in the United States. Proponents of drug reimportation may attempt to pass legislation which would directly allow reimportation under certain circumstances. If legislation or regulations were passed allowing the reimportation of drugs, they could decrease the price we, Ipsen, or any potential future collaborators receive for any products that we, Ipsen, and/or any potential future collaborators may develop, negatively affecting our revenues and prospects for profitability.

***Healthcare reform measures could hinder or prevent our product candidates commercial success.***

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in health care systems to contain health care costs and improve quality. While reform proposals often involve expanding coverage to more individuals, health care reform may also involve increased government price controls, additional regulatory mandates and other measures designed to lower medical and pharmaceutical costs which could have an adverse impact on our business.

***If product liability lawsuits are brought against us, we may 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 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, Ipsen, and/or any potential future collaborators may develop, our commercial opportunity will be reduced or eliminated.***

We face competition from commercial pharmaceutical and biotechnology enterprises, 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, Ipsen, and/or any potential future collaborators may develop. In addition, significant delays in the development of our product candidates could allow our

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competitors to bring products to market before us and impair any 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 in our pipeline, and a number of companies are or may be developing new treatments. These product uses, as well as promotional efforts by competitors and/or clinical trial results of competitive products, could significantly diminish any ability to market and sell any products that we, Ipsen, and/or any potential future collaborators may develop. For example, although there are no products that have been approved by the FDA to reduce fractures or treat estrogen deficiency related side effects of ADT, we are aware of a number of drugs, including drugs marketed by Eli Lilly & Co. (Evista®), Merck (Fosamax®), Sanofi-Aventis and Warner Chilcott (Actonel®), Pfizer Inc. (Effexor®), Boehringer Ingelheim (Catapres®), Novartis (Zometa®) and Bristol Myers Squibb (Megace®), that are prescribed to treat single side effects of ADT; that external beam radiation and tamoxifen are used to treat breast pain and enlargement, or gynecomastia. Prolia™ (denosumab), a monoclonal antibody developed by Amgen, is under regulatory review in the United States, Switzerland, Australia and Canada for the treatment and prevention of postmenopausal osteoporosis and for the treatment of bone loss in patients undergoing hormone ablation therapy for breast or prostate cancer, and has received a positive opinion in Europe from the EMEA s Committee for Medicinal Products for Human Use. While we have the only pharmaceutical product in clinical development to prevent prostate cancer in high risk men with high grade PIN, GlaxoSmithKline is expected to resubmit a supplemental NDA for Avodart® for prostate cancer risk reduction among men at increased risk of developing the disease. Additionally, recent literature has suggested that finasteride and dutasteride may be effective in reducing the risk of prostate cancer progression. Testosterone and other anabolic agents are used to treat involuntary weight loss in patients who have acute muscle loss. There are other SARM product candidates in development that may compete with our product candidates. Pfizer Inc, Eli Lilly & Co., and Amgen have myostatin inhibitors in development that may compete with Ostarine if approved for commercial sale. In addition, Cytokinetics, Inc. is developing a troponin activator with a muscle specific mechanism in a Phase I study. Moreover, there are other categories of drugs in development, including ghrelin receptor agonists and growth hormone secretagogues that may have some muscle activity. Other appetite stimulants such as megestrol acetate and dronabinol are also used off-label for cancer cachexia. Competition 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.

In December 2009, we announced a reduction of approximately 26% of our workforce in order to reduce our operating expenses in connection with the receipt of the Complete Response Letter regarding our NDA for toremifene 80 mg and the associated delay in the potential regulatory approval of toremifene 80 mg. This and any future workforce reductions may negatively affect our ability to retain or attract talented employees.

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***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 100 and 150 additional employees in order to commercialize toremifene 80 mg or toremifene 20 mg, including approximately 65 sales consultants. The competition for qualified personnel in the biotechnology field is intense.

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

## Risks Related to Our Common Stock

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

The market prices for securities of biotechnology companies in general have been highly volatile and may continue to be 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:

the results of our discussions with the FDA regarding the actions necessary to address the deficiencies identified by the FDA in the Complete Response Letter we received in October 2009 regarding our NDA for toremifene 80 mg, our ability to obtain the funding necessary for further clinical development of toremifene 80 mg, and any related announcements by us with respect to the same;

adverse results or delays in our clinical trials;

the timing of achievement of, or failure to achieve, our, Ipsen s and any potential future collaborators 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, including regulatory actions requiring or leading to restrictions, limitations and/or warnings in the label of FARESTON® or an approved product candidate;

the commercial success of any product approved by the FDA or its foreign counterparts;

developments with respect to our collaborations with Ipsen;

introductions or announcements of technological innovations or new products by us, Ipsen, potential future collaborators, or our competitors, and the timing of these introductions or announcements;

market conditions for equity investments in general, or the biotechnology or pharmaceutical industries in particular;

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 or reimbursement policies of health care payment systems;

any intellectual property infringement lawsuit involving us;

actual or anticipated fluctuations in our results of operations;

changes in financial estimates or recommendations by securities analysts;

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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. Recently, the financial markets have faced almost unprecedented turmoil, resulting in a decline in investor confidence and concerns about the proper functioning of the securities markets, which decline in general investor confidence has resulted in depressed stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. These broad market fluctuations may adversely affect the trading price of our common stock.

In the past, class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Any such litigation brought against us could result in substantial costs, which would hurt our financial condition and results of operations and divert management s attention and resources, which could result in delays of our clinical trials or commercialization efforts.

***Our executive officers, directors and largest stockholders have the ability to control all matters submitted to stockholders for approval.***

As of January 31, 2010, our executive officers, directors and holders of 5% or more of our outstanding common stock beneficially owned approximately 59.3% of our outstanding common stock, and our executive officers and directors alone beneficially owned approximately 46.5% of our outstanding common stock. As a result, these stockholders, acting together, may or will have the ability 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.

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***If there are substantial sales of our common stock, the market price of our common stock could drop substantially, even if our business is doing well.***

For the 12-month period ended December 31, 2009, the average daily trading volume of our common stock on the NASDAQ Global Market was approximately 372,346 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, 2009, we had 36,420,901 shares of common stock outstanding.

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. If any of these large stockholders were to sell large blocks of shares in a short period of time, the market price of our common stock could drop substantially.

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

**ITEM 2. PROPERTIES**

Effective October 1, 2009, we terminated our sublease agreement dated April 1, 2005 with the University of Tennessee Research Foundation ( UTRF ) and entered into a new sublease agreement with UTRF for the lease of approximately 53,000 square feet of laboratory and office space located at 3 North Dunlap Street, Memphis, Tennessee. The new sublease expires on December 31, 2012, unless sooner terminated in accordance with the terms of this sublease. We have an option to extend the new sublease for an additional two years.

In December 2007, we entered into a sublease for approximately 31,000 square feet of office space located at 175 Toyota Plaza, Memphis, Tennessee, under an operating lease which expires on April 30, 2015. We have an option to terminate this sublease beginning December 31, 2010. In July 2008, we amended the sublease to add approximately 22,000 square feet of additional office space through April 30, 2015. We have an option to terminate the sublease for this additional space effective December 31, 2012.

**ITEM 3. LEGAL PROCEEDINGS**

We are not currently involved in any material legal proceedings.

**ITEM 4. (REMOVED AND RESERVED)**

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## 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. The following table presents, for the periods indicated, the high and low intraday sales prices per share of our common stock as reported on The NASDAQ Global Market.

| | 2009 | | 2008 | |
|---|---|---|---|---|
| | High | Low | High | Low |
| First Quarter | $ 18.00 | $ 8.06 | $ 20.00 | $ 10.75 |
| Second Quarter | 11.24 | 8.07 | 19.00 | 13.98 |
| Third Quarter | 13.59 | 7.72 | 20.20 | 14.14 |
| Fourth Quarter | 12.70 | 3.22 | 19.63 | 12.54 |

On March 10, 2010, the closing price of our common stock as reported on The NASDAQ Global Market was $3.66 per share and there were approximately 72 holders of record of our common stock.

### Performance Graph[1]

The rules of the SEC require that we include in our annual report to stockholders a line-graph presentation comparing cumulative stockholder returns on our 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 us. We have elected to use The NASDAQ Composite Index (which tracks the aggregate price performance of equity securities of companies traded on NASDAQ Stock Market) and The NASDAQ Biotechnology Index (consisting of a group of approximately 130 companies in the biotechnology sector, including us) 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 December 31, 2004 on The NASDAQ Global Market for: (1) our common stock; (2) The NASDAQ Composite Index and (3) The NASDAQ Biotechnology Index. All values assume reinvestment of the full amounts of all dividends. No dividends have been declared on our common stock. The closing sale price of our common stock on December 31, 2009 as reported on The NASDAQ Global Market was $4.20.

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

**COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN***

Among GTx Inc., The NASDAQ Composite Index
And The NASDAQ Biotechnology Index



* $100 invested on 12/31/04 in stock or index, including reinvestment of dividends.

Fiscal year ending December 31.

[1] 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 GTx, Inc. under the Securities Act of 1933 or the Securities Exchange Act of 1934 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.

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**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, 2009, 2008 and 2007, and the balance sheet data as of December 31, 2009 and 2008, 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, 2006 and 2005, and the consolidated balance sheet data as of December 31, 2007, 2006 and 2005, 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, | | | | |
|---|---|---|---|---|---|
| | 2009 | 2008 | 2007 | 2006 | 2005 |
| | (in thousands, except per share data) | | | | |
| **Statement of Operations Data:** | | | | | |
| Revenues: | | | | | |
| Product sales, net | $ 3,289 | $ 1,088 | $ 1,076 | $ 1,357 | $ 2,445 |
| Collaboration revenue | 11,441 | 12,440 | 6,050 | 6,148 | 1,337 |
| Total revenues | 14,730 | 13,528 | 7,126 | 7,505 | 3,782 |
| Cost and expenses: | | | | | |
| Cost of product sales | 1,290 | 649 | 621 | 773 | 1,573 |
| Research and development expenses | 32,344 | 44,259 | 38,508 | 33,897 | 30,923 |
| General and administrative expenses | 27,749 | 23,105 | 13,501 | 11,352 | 9,845 |
| Total costs and expenses | 61,383 | 68,013 | 52,630 | 46,022 | 42,341 |
| Loss from operations | (46,653) | (54,485) | (45,504) | (38,517) | (38,559) |
| Interest income | 159 | 2,705 | 5,145 | 3,007 | 1,720 |
| Loss before income taxes | (46,494) | (51,780) | (40,359) | (35,510) | (36,839) |
| Income tax benefit | 238 | | | | |
| Net loss | $ (46,256) | $ (51,780) | $ (40,359) | $ (35,510) | $ (36,839) |
| Net loss per share: | | | | | |
| Basic and diluted | $ (1.27) | $ (1.43) | $ (1.16) | $ (1.14) | $ (1.42) |

| | As of December 31, | | | | |
|---|---|---|---|---|---|
| | 2009 | 2008 | 2007 | 2006 | 2005 |
| | (in thousands) | | | | |
| **Balance Sheet Data:** | | | | | |
| Cash, cash equivalents and short-term investments | $ 49,044 | $ 97,667 | $ 100,178 | $ 119,550 | $ 74,014 |
| Working capital | 34,723 | 79,047 | 132,932 | 111,363 | 70,030 |
| Total assets | 57,721 | 108,109 | 159,730 | 129,255 | 82,811 |
| Accumulated deficit | (368,174) | (321,918) | (270,138) | (229,779) | (194,269) |
| Total stockholders (deficit) equity | (8,750) | 32,018 | 78,917 | 97,049 | 73,579 |

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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 contains 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 Part I, Item 1A Risk Factors and elsewhere in this Annual Report on Form 10-K. See Special Note Regarding Forward-Looking Statements 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 loss and other serious medical conditions.

We are developing toremifene citrate, a selective estrogen receptor modulator, or SERM, in two separate clinical programs in men. We commenced a pivotal Phase III clinical trial of toremifene 80 mg to reduce fractures and treat other estrogen deficiency related side effects of androgen deprivation therapy, or ADT, in men with prostate cancer in November 2003. In the first quarter of 2008, we announced that the Phase III clinical trial results for toremifene 80 mg to reduce fractures and treat other estrogen deficiency side effects of ADT in men with prostate cancer showed that toremifene 80 mg reduced new morphometric vertebral fractures, met other key endpoints of bone mineral density, or BMD, lipid profiles and gynecomastia, and also showed that toremifene 80 mg demonstrated a reduction in hot flashes in a subset of patients. In December 2008, we submitted a New Drug Application, or NDA, for toremifene 80 mg to reduce fractures in men with prostate cancer on ADT to the U.S. Food and Drug Administration, or FDA. In October 2009, we received a Complete Response Letter from the FDA regarding our NDA for toremifene 80 mg notifying us that the FDA would not approve our NDA in its present form as a result of certain clinical deficiencies identified in the Complete Response Letter. The FDA identified two deficiencies in the Complete Response Letter and recommended that the following information be provided to the FDA to address these clinical deficiencies: (i) results of a second adequate and well-controlled Phase III clinical trial demonstrating the safety and efficacy of toremifene 80 mg to reduce fractures in men with prostate cancer on ADT and (ii) results from an adequate and well-controlled clinical trial demonstrating that toremifene 80 mg treatment to reduce fractures in men with prostate cancer on ADT does not have a detrimental effect on either time-to-disease progression or overall survival. We met with the FDA in December 2009 to better understand our options for addressing the points made by the FDA in the Complete Response Letter. In 2010, we plan to submit to and discuss with the FDA a proposed protocol for a second pivotal Phase III clinical trial evaluating toremifene 80 mg to reduce fractures in men with prostate cancer on ADT to address in a single clinical trial the deficiencies identified by the FDA in the Complete Response Letter. Any decision to initiate another clinical trial for toremifene 80 mg to reduce fractures in men with prostate cancer on ADT will require us to obtain sufficient funding for the trial.

We are also developing toremifene 20 mg in an ongoing pivotal Phase III clinical trial for the prevention of prostate cancer in high risk men with precancerous prostate lesions called high grade prostatic intraepithelial neoplasia, or high grade PIN. In January 2005, we initiated a pivotal Phase III clinical trial of toremifene 20 mg for the prevention of prostate cancer in high risk men with high grade PIN, which is being conducted under a Special Protocol Assessment, or SPA, with the FDA. The last patient completed the trial in February 2010. We plan to announce this year the results of the trial and, if the results from the trial are positive, our plans to submit a NDA for toremifene 20 mg to the FDA.

We have licensed to Ipsen Biopharm Limited (formerly known as Ipsen Developments Limited), or Ipsen, exclusive rights in the European Union, Switzerland, Norway, Iceland, Lichtenstein and the Commonwealth of Independent States, which we collectively refer to as the European Territory, to develop and commercialize toremifene in all indications which we have licensed from Orion Corporation, or Orion, which include all indications in humans except the treatment and prevention of breast cancer outside of the United States.

Additionally, we are developing selective androgen receptor modulators, or SARMs, a new class of drugs with the potential to treat cancer cachexia (cancer induced muscle loss), chronic sarcopenia, which is the loss of skeletal

muscle mass resulting in reduced physical strength and ability to perform activities of daily living, and other musculoskeletal wasting or muscle loss conditions. 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. In October 2008, we announced that Ostarine met its primary

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endpoint in a Phase II clinical trial evaluating absolute change in total lean body mass (muscle) compared to placebo. In March 2010, we reacquired full rights to our SARM program, including Ostarine (previously designated by Merck & Co., Inc., or Merck, as MK-2866), following the termination by us and Merck of the exclusive license and collaboration agreement for SARM compounds and related SARM products, which was entered into in December 2007. We plan to continue the development of Ostarine for the treatment of cancer cachexia and, in this regard, we anticipate conducting an end of Phase II meeting with the FDA to discuss a Phase III clinical development program for Ostarine. We do not anticipate significant development progress on Ostarine, or our SARM program in general, including the initiation of any additional clinical trials, unless and until we enter into one or more new collaborations with third parties or otherwise obtain additional funding.

We are also developing GTx-758, an oral luteinizing hormone, or LH, inhibitor for the first line treatment of advanced prostate cancer. In preclinical animal models, GTx-758 has demonstrated the potential to reduce testosterone concentrations in blood to castrate levels, increase BMD, and prevent hot flashes. In 2009, we completed two Phase I clinical trials, a single ascending dose clinical trial and a multiple ascending dose clinical trial, evaluating GTx-758 in healthy male volunteers. GTx-758 was well tolerated in both trials. In February 2010, we initiated a Phase II clinical trial evaluating the ability of GTx-758 to reduce testosterone to castrate levels in 70 subjects. We expect this trial to be completed in the second half of 2010.

We market FARESTON® (toremifene citrate) 60 mg tablets, approved for the treatment of metastatic breast cancer in postmenopausal women in the United States. Part of our strategy is to increase commercial sales of FARESTON®. However, sales of pharmaceuticals for breast cancer in the SERM class have declined in recent years as aromatase inhibitors have gained market share. The active pharmaceutical ingredient in FARESTON® is the same as in our toremifene 80 mg and toremifene 20 mg product candidates.

Our net loss for the year ended December 31, 2009 was $46.3 million. Our net loss included FARESTON® net product sales of $3.3 million and the recognition of collaboration revenue of $11.4 million. We have financed our operations and internal growth primarily through public offerings and private placements of our common stock, as well as payments from our current and former collaborations. In December 2009, we announced a reduction of approximately 26% of our workforce in order to reduce our operating expenses in connection with the receipt of the Complete Response Letter regarding our NDA for toremifene 80 mg and the associated delay in the potential regulatory approval of toremifene 80 mg. We expect to continue to incur significant net losses as we continue our clinical development and research and development activities, apply for and address issues related to potential regulatory approvals and, subject to regulatory approval of our product candidates, expand our sales and marketing capabilities. Due to the termination of our collaboration with Merck and the expected recognition of $49.9 million in deferred revenue and the final payment from Merck of $5.0 million of cost reimbursement for research and development expenses, we expect to report net income for the year ending December 31, 2010. However, while recognition of this revenue is expected to result in net income for 2010, we expect to incur significant operating losses in 2011 and for the foreseeable future. In addition, we do not expect to obtain FDA or any other regulatory approvals to market any of our product candidates in the near future. In addition, we expect that significant additional clinical development will be required in order to potentially obtain FDA approval of toremifene 80 mg, including an additional pivotal Phase III clinical trial of toremifene 80 mg.

**Sales and Marketing**

We market FARESTON® (toremifene citrate) 60 mg tablets, approved 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 in postmenopausal women indication. We also acquired from Orion a license to toremifene for all indications in humans worldwide, except breast cancer outside of the United States. 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 specialty sales and marketing infrastructure to market toremifene 80 mg and toremifene 20 mg, if approved by the FDA, to the relatively small and concentrated community of urologists and medical oncologists in the United States. We have partnered with Ipsen to commercialize toremifene in the European Territory if approved for commercial sale. We are currently seeking partners to market toremifene in Asia and other markets outside of the United States and the

European Territory.

**Research and Development**

Since our inception in 1997, we have been focused on drug discovery and development programs. Research and development expenses include, but are not limited to, our expenses for personnel, supplies, and facilities associated with our research activities, screening and identification of product candidates, formulation and synthesis

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activities, manufacturing, preclinical studies, toxicology studies, clinical trials, regulatory and medical affairs activities, quality assurance activities and license and royalty fees.

We expect that research and development expenditures for fiscal year 2010 will be less than fiscal year 2009 due to the completion of the pivotal Phase III clinical trial for the prevention of prostate cancer in high risk men with high grade PIN. This expectation does not consider the impact of additional expenses for toremifene 80 mg and Ostarine that we may incur for further clinical development of these programs. Future research and development expenses will be focused on the following:

- activities relating to our efforts to obtain regulatory approvals of toremifene 80 mg to reduce fractures and treat other estrogen deficiency side effects of ADT in men with prostate cancer, including potentially an additional pivotal Phase III clinical trial of toremifene 80 mg;
- the completion of the pivotal Phase III clinical trial of toremifene 20 mg for the prevention of prostate cancer in high risk men with high grade PIN;
- our ongoing SARM research and development efforts; and
- the continued preclinical and clinical development of other product candidates, including GTx-758.

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 Part I, 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.

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 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 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. Even if the FDA grants marketing approval, the FDA may impose restrictions, limitations and/or warnings in the label of an approved product candidate, which may adversely affect the marketability of the product or limit the patients to whom the product is prescribed.

The successful development and commercialization 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 and commercialization of, or the period in which material net cash inflows are expected to commence from, any of our product candidates, including any product candidates developed and/or commercialized through our collaboration with Ipsen, due to the numerous risks and uncertainties associated with developing and commercializing drugs, including the uncertainty of:

- whether and to what extent we determine to continue the development of toremifene 80 mg following discussion with the FDA, including an additional clinical trial to address the deficiencies identified by the FDA in the Complete Response Letter for toremifene 80 mg;
- the scope, rate of progress and cost of our, Ipsen s, and/or any potential future collaborators clinical trials and other research and development activities;
- future clinical trial results;
- the terms and timing of any future collaborative, licensing and other arrangements that we may establish;

the cost and timing of regulatory filings and/or approvals to commercialize our product candidates, and any related restrictions, limitations, and/or warnings in the label of an approved product candidate;

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potential future licensing fees, milestone payments and royalty payments, including any milestone payments or royalty payments that we may receive under our collaborative arrangement with Ipsen;

the cost and timing of establishing medical education, sales, marketing and distribution capabilities;

the cost of establishing clinical and commercial supplies of our product candidates and any products that we, Ipsen, and/or any potential future collaborators may develop;

the effect of competing technological and market developments; and

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

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 development and commercialization efforts on schedule, or at all, and some consequences of failing to do so, are set forth under Part I, 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, sales and marketing functions. General and administrative expenses also include facility costs, insurance costs, and professional fees for legal, accounting, public relations, marketing services, and FARESTON® selling and distribution expenses. We expect our general and administrative expenses for fiscal year 2010 to be less than fiscal year 2009 since fiscal year 2009 general and administrative expenses included spending on sales and marketing, medical education and other supporting activities in anticipation of regulatory approval of our toremifene product candidates that we do not expect to incur in 2010, as well as the December 2009 reduction in our workforce.

**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, share-based compensation, 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.

Collaboration revenue consists of non-refundable upfront payments, license fees, reimbursements for research and development activities, and milestone payments associated with our collaboration and license agreements and is based on the performance requirements of the specific agreements. We have analyzed our agreements with multiple element arrangements to determine whether the deliverables under the agreement, including license and

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performance obligations such as joint steering committee participation and research and development activities, can be separated or whether all of the deliverables must be accounted for as a single unit of accounting. For these arrangements, we were not able to identify evidence of fair value for the undelivered elements and therefore recognize any consideration for a single unit of accounting in the same manner as the revenue is recognized for the final deliverable, which is ratable over the performance period. The performance period is estimated at the inception of the agreement and is reevaluated at each reporting period. Cost reimbursements for research activities are recognized as collaboration revenue if amounts are determinable and collection of the related receivable is reasonably assured. Revenues from milestone payments for which we have no continuing performance obligations are recognized upon achievement of the performance milestone, as defined in the related agreement, provided the milestone is substantive and a culmination of the earnings process has occurred. Performance obligations typically consist of significant milestones in the development life cycle of the related product candidates and technology, such as initiation of clinical trials, achievement of specified clinical trial endpoints, filing for approval with regulatory agencies and approvals by regulatory agencies.

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 continually monitor these factors for indications of appropriate revisions. We estimated the performance obligation period to be six years for the development of toremifene for both the high grade PIN and ADT indications under our collaboration agreement with Ipsen. We estimated the performance obligation period to be ten years for our collaboration agreement with Merck. However, due to the termination of the license and collaboration agreement with Merck in March 2010, we expect to recognize as collaboration revenue all of the remaining $49.9 million unamortized revenue that was deferred as of December 31, 2009, as well as the final payment of $5.0 million for cost reimbursement for research and development expense that we will receive from Merck in late 2010, during the first quarter of 2010.

We recognize revenue from net product sales of FARESTON® less deductions for estimated sales discounts and sales returns. We recognize revenue from product sales when persuasive evidence of an arrangement exists, title passes, the price is fixed or determinable, and collectability is reasonably assured. 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. We consider historical product return trend information that we continue to update each period. We estimate the number of months of product on hand and the amount of product 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 approximately 95% of our product sales of FARESTON® for the year ended December 31, 2009. Based on this information, and other factors, we estimate an accrual for product returns. At December 31, 2009 and 2008, our accrual for product returns was $494,000 and $815,000, respectively.

***Research and Development Expenses***

Research and development expenses include, but are not limited to, our expenses for personnel, supplies, and facilities associated with research activities, screening and identification of product candidates, formulation and synthesis activities, manufacturing, preclinical studies, toxicology studies, clinical trials, regulatory and medical affairs, quality assurance activities and license and royalty fees. We expense these costs in the period in which they are incurred. We estimate our liabilities for research and development expenses in order to match the recognition of expenses to the period in which the actual services are received. As such, accrued liabilities related to third party research and development activities are recognized based upon our estimate of services received and degree of completion of the services in accordance with the specific third party contract.

***Share-Based Compensation***

We have stock option and equity incentive plans that provide for the purchase of our common stock by certain of our employees and non-employee directors. We recognize compensation expense for our share-based payments based on the fair value of the awards on the grant date and recognize the expense over the period during which an employee

or non-employee director is required to provide service in exchange for the award.

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The determination of the fair value of share-based payment awards on the date of grant include the expected life of the award, the expected stock price volatility over the expected life of the awards, expected dividend yield, and risk-free interest rate. We estimate the expected life of options by calculating the average of the vesting term and contractual term of the options. We estimate the expected stock price volatility based on the historical volatility of our common stock. The risk-free interest rate is determined using U.S. Treasury rates where the term is consistent with the expected life of the stock options. Expected dividend yield is not considered as we have not made any dividend payments and have no plans of doing so in the foreseeable future. The amount of share-based compensation expense recognized is reduced ratably over the vesting period by an estimate of the percentage of options granted that are expected to be forfeited or canceled before becoming fully vested. 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 31, 2009 was $5.4 million, of which approximately $2.1 million and approximately $3.2 million were recorded in the statements of operations as research and development expenses and general and administrative expenses, respectively. Total share-based compensation expense for the years ended December 31, 2008 and 2007 was $3.7 million and $2.2 million, 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 $178,000, $178,000 and $183,000 for the years ended December 31, 2009, 2008 and 2007, respectively. At December 31, 2009, the total compensation cost related to non-vested awards not yet recognized was approximately $12.5 million with a weighted average expense recognition period of 2.23 years.

***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. Accordingly, at December 31, 2009 and 2008, net of the valuation allowance, the net deferred tax assets were reduced to zero.

***Intangible Assets***

We amortize our purchased intangible assets with finite lives over their estimated economic lives. Our purchased intangible assets, license fees, represent license fees paid to Orion in connection with entering into an amended and restated license and supply agreement and to the University of Tennessee Research Foundation, or UTRF, in connection with entering into two amended and restated license agreements. The Orion license fee is being amortized on a straight-line basis over the term of the agreement which we estimate to be 16 years. The UTRF license fees are being amortized on a straight-line basis over the term of each agreement with UTRF, which we estimate to be approximately 14 years and 11.5 years, respectively. We review long-lived assets for impairment whenever 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. An impairment loss would be recognized when estimated future cash flows is less than the carrying amount. The cash flow estimates would be based on management s best estimates, using appropriate and customary assumptions and projections at the time.

***Recent Accounting Pronouncements***

In October 2009, the Financial Accounting Standards Board ( FASB ) issued Accounting Standards Update No. 2009-13, *Revenue Recognition (Topic 605): Multiple-Deliverable Revenue Arrangements (a consensus of the FASB Emerging Issues Task Force)* ( ASU No. 2009-13 ). ASU No. 2009-13 amends revenue recognition guidance related to multiple deliverable arrangements to provide new guidance concerning the determination of whether an arrangement involving multiple deliverables contains more than one unit of accounting and the manner in which arrangement consideration should be allocated to such deliverables. The amended guidance is effective for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010 and may be applied prospectively or retroactively. We do not expect the adoption of ASU No. 2009-13 to have a material impact on our financial position or results of operations.

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## Results of Operations

***Comparison of Years Ended December 31, 2009 and December 31, 2008***

***Revenues.*** Revenues for the year ended December 31, 2009 were $14.7 million as compared to $13.5 million for the same period of 2008. Revenues for the year ended December 31, 2009 included net sales of FARESTON® marketed for the treatment of metastatic breast cancer in postmenopausal women and collaboration income from Ipsen and Merck. During the years ended December 31, 2009 and 2008, FARESTON® net product sales were $3.3 million and $1.1 million, respectively, while cost of products sales were $1.3 million and $649,000, respectively. FARESTON® net product sales for the year ended December 31, 2009 increased from the same period in the prior year as a result of a price increase instituted in the fourth quarter of 2008, partially offset by a decrease of approximately 22% in sales volume of FARESTON® as compared to the year ended December 31, 2008. The increase in cost of product sales was due to an increase in royalty expense which is based on our net sales of FARESTON®. Collaboration income was $11.4 million for the year ended December 31, 2009, which consisted of approximately $5.8 million and $5.6 million from the amortization of deferred revenue from Ipsen and Merck, respectively. For the year ended December 31, 2008, collaboration income was $12.4 million, of which $5.9 million and $5.1 million was from the amortization of deferred revenue from Ipsen and Merck, respectively, and approximately $1.5 million was from an earned milestone from Ipsen with the achievement of the primary endpoint in the toremifene 80 mg Phase III clinical trial. As a result of the termination of our collaboration with Merck in March 2010, collaboration income in 2010 is expected to increase substantially as compared to 2009. This is a result of the recognition of previously deferred collaboration income that was being recognized over our ten year expected obligation period under the agreement. As of December 31, 2009, we had $49.9 million in deferred revenue related to this collaboration that we expect to recognize as revenue, along with the final payment from Merck of $5.0 million of research and development cost reimbursement that will be received from Merck in late 2010, in the first quarter of 2010.

***Research and Development Expenses.*** Research and development expenses decreased 27% to $32.3 million for the year ended December 31, 2009 from $44.3 million for the year ended December 31, 2008. The decrease in research and development expenses during the year ended December 31, 2009 compared to the year ended December 31, 2008 was due primarily to the completion of the toremifene 80 mg Phase III clinical trial, a decreased number of subject visits in the toremifene 20 mg Phase III clinical trial due to a portion of the subjects having completed the trial prior to or during the year ended December 31, 2009, and the completion of the Ostarine Phase II cancer cachexia clinical trial during 2008. Research and development expenses for the year ended December 31, 2008 included payment of a $1.2 million fee to the FDA for the submission of the NDA for toremifene 80 mg and a payment to UTRF of $540,000 for the execution of amendments to our existing SARM and SERM license agreements. These amounts are included in Toremifene 80 mg and Other research and development , respectively, for the year ended December 31, 2008 in the table below. Research and development expenses were also lower in the year ended December 31, 2009 as a result of our decision to not pay cash bonuses to employees for 2009. Research and development expenses included employee bonus expense of $967,000 for the year ended December 31, 2008.

The decrease in research and development expenses in the year ended December 31, 2009 was partially offset by increased research and development spending on our Phase I clinical trials for GTx-758 and by approximately $290,000 of severance costs incurred related to our workforce reduction that occurred in December 2009. Additionally, toremifene 80 mg tablets purchased at a cost of approximately $941,000 were recorded as research and development expense in the fourth quarter due to the receipt of the Complete Response Letter regarding our NDA for toremifene 80 mg and the associated delay in the potential regulatory approval of toremifene 80 mg to reduce fractures in men with prostate cancer on ADT. This expense is included in Toremifene 80 mg in the table below.

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The following table identifies the research and development expenses for each of our clinical product candidates, as well as research and development expenses pertaining to our other research and development efforts, for each of the periods presented. Other research and development expenses in the table below represent the cost of personnel, supplies and facilities associated with preclinical and discovery research and development activities. Research and development spending for past periods is not indicative of spending in future periods.

| Program | Product Candidate/ Proposed Indication | Years Ended December 31, 2009 | 2008 | Increase/ (Decrease) |
|---|---|---|---|---|
| | | (in thousands) | | |
| **SERM** | **Toremifene 80 mg** To reduce fractures in men with prostate cancer on ADT | $ 3,377 | $ 11,724 | $ (8,347) |
| | **Toremifene 20 mg** Prevention of prostate cancer in high risk men with high grade PIN | 5,881 | 9,338 | (3,457) |
| **SARM** | **Ostarine™** Treatment of cancer cachexia | 679 | 5,973 | (5,294) |
| **LH inhibitor** | **GTx-758** Treatment of advanced prostate cancer | 10,074 | 3,786 | 6,288 |
| **Other research and development** | | 12,333 | 13,438 | (1,105) |
| **Total research and development expenses** | | $ 32,344 | $ 44,259 | $ (11,915) |

***General and Administrative Expenses.*** General and administrative expenses increased 20% to $27.7 million for the year ended December 31, 2009 from $23.1 million for the year ended December 31, 2008. The increase of approximately $4.6 million was primarily the result of increased personnel and personnel related expenses of approximately $5.3 million, severance costs and legal fees of $656,000 related to the workforce reduction that occurred in December 2009, and an increase of approximately $630,000 in intellectual property and other legal expenses. These increases were slightly offset by a decrease in marketing expenses of approximately $950,000 due to lower spending on marketing expositions and public relation activities in the current year. General and administrative expenses were also lower in the year ended December 31, 2009 as compared to the prior year as a result of our decision to not pay cash bonuses to employees for 2009. General and administrative expenses for the year ended December 31, 2008 included employee bonus expense of approximately $1.3 million.

***Interest Income.*** Interest income decreased to $159,000 for the year ended December 31, 2009 from $2.7 million for the year ended December 31, 2008. The decrease of approximately $2.5 million was attributable to lower average interest rates and lower average cash balances during the year ended December 31, 2009, as compared to the prior

year.

***Comparison of Years Ended December 31, 2008 and December 31, 2007***

***Revenues.*** Revenues for the year ended December 31, 2008 were $13.5 million as compared to $7.1 million for the same period of 2007. Revenues for the year ended December 31, 2008 included net sales of FARESTON® marketed for the treatment of metastatic breast cancer in post menopausal women and collaboration income from Ipsen and Merck. During the years ended December 31, 2008 and 2007, FARESTON® net product sales were $1.1 million for both periods, while cost of products sales were $649,000 and $621,000, respectively. Although FARESTON® net product sales for the year ended December 31, 2008 were consistent with the prior year, the 2008 net product sales included an increase in the average price of FARESTON® of 44% as a result of a price increase in the fourth quarter of 2008. The sales volume of FARESTON® also increased 4% for the year ended December 31,

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2008 as compared to year ended December 31, 2007. The increase in net product sales due to the increase in price and volume in 2008 was offset by an increase in the provision for product returns. While we did not estimate a material increase in the volume of product returns as a result of the price increase in the fourth quarter of 2008, the price increase did result in an increase in the amount of the estimated product returns accrual since certain product returns are accepted at or near the current sales price of FARESTON®. Collaboration income was $12.4 million for the year ended December 31, 2008, which consisted of approximately $5.9 million and $5.1 million from the amortization of deferred revenue from Ipsen and Merck, respectively, and approximately $1.5 million from an earned milestone from Ipsen with the achievement of the primary endpoint in the toremifene 80 mg Phase III clinical trial. For the year ended December 31, 2007, collaboration income was $6.1 million, of which $5.9 million and $198,000 was from the amortization of deferred revenue Ipsen and Merck, respectively.

***Research and Development Expenses*.** Research and development expenses increased 15% to $44.3 million for the year ended December 31, 2008 from $38.5 million for the year ended December 31, 2007. The following table identifies the research and development expenses for each of our clinical 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 expenses for the year ended December 31, 2008 included payment of a $1.2 million fee to the FDA for the submission of the NDA for toremifene 80 mg to reduce fractures in men with prostate cancer on ADT. This amount is included in Toremifene 80 mg in the table below. Additionally, research and development expenses for the year ended December 31, 2008 included a payment to UTRF of $540,000 for the execution of amendments to our existing SARM and SERM license agreements. This amount is included in Other research and development in the table below. Included in Other research and development for the year ended December 31, 2007 is a sublicense royalty of approximately $1.9 million paid to UTRF as a result of our collaboration with Merck.

| Program | Product Candidate/ Proposed Indication | Years Ended December 31, 2008 | 2007 | Increase/ (Decrease) |
|---|---|---|---|---|
| | | (in thousands) | | |
| **SERM** | **Toremifene 80 mg** To reduce fractures in men with prostate cancer on ADT | $ 11,724 | $ 9,422 | $ 2,302 |
| | **Toremifene 20 mg** Prevention of prostate cancer in high risk men with high grade PIN | 9,338 | 8,694 | 644 |
| **SARM** | **Ostarine™** Treatment of cancer cachexia | 5,973 | 7,056 | (1,083) |
| **LH inhibitor** | **GTx-758** Treatment of advanced prostate cancer | 3,786 | | 3,786 |
| **Other research and development** | | 13,438 | 13,336 | 102 |
| | | $ 44,259 | $ 38,508 | $ 5,751 |

**Total research and development expenses**

***General and Administrative Expenses.*** General and administrative expenses increased 71% to $23.1 million for the year ended December 31, 2008 from $13.5 million for the year ended December 31, 2007. The increase of approximately $9.6 million was primarily the result of increased personnel and personnel related expenses of approximately $4.5 million, marketing expenses of approximately $1.9 million in connection with the planned commercialization of our toremifene product candidates, medical education expenses of approximately $1.6 million, and $460,000 in losses from our investment in the Bank of America s Columbia Strategic Cash Portfolio.

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***Interest Income.*** Interest income decreased to $2.7 million for the year ended December 31, 2008 from $5.1 million for the year ended December 31, 2007. The decrease of approximately $2.4 million was attributable to lower average interest rates offset by slightly higher average cash and cash equivalents balances during the year ended December 31, 2008, as compared to the prior year.

**Liquidity and Capital Resources**

Through December 31, 2009, we have financed our operations and internal growth primarily through public offerings and private placements of our common stock, as well as payments from our current and former collaborations. 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, 2009, we had an accumulated deficit of $368.2 million, which resulted primarily from:

our research and development activities associated with:

the development of toremifene 80 mg to reduce fractures and treat other estrogen deficiency side effects of ADT in men with prostate cancer, including two Phase II clinical trials, a pivotal Phase III clinical trial, and the preparation and submission of a NDA to the FDA;

the development of toremifene 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;

the preclinical and clinical development of our SARM compounds;

the continued preclinical and clinical development of other product candidates, including GTx-758;

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, which was converted to common stock in conjunction with our initial public offering.

We expect to continue to incur significant net losses as we continue our clinical development and research and development activities, apply for regulatory approvals, and, subject to regulatory approval of our product candidates, expand our sales and marketing capabilities. Due to the termination of our collaboration with Merck and the expected recognition in the first quarter of 2010 of $49.9 million in deferred revenue and the final payment from Merck of $5.0 million of cost reimbursement for research and development expenses, we expect to report net income for the year ending December 31, 2010. However, while recognition of this revenue is expected to result in net income for 2010, we expect to incur significant operating losses in 2011 and for the foreseeable future. In addition, we expect that significant additional clinical development will be required in order to potentially obtain FDA approval of toremifene 80 mg, including an additional pivotal Phase III clinical trial of toremifene 80 mg.

At December 31, 2009, we had cash, cash equivalents and short-term investments of $49.0 million, compared to $97.7 million at December 31, 2008 and $110.0 million at December 31, 2007. As of December 31, 2009, our cash and cash equivalents consisted of bank deposits, certificates of deposit with original maturities of 90 days or less, and money market mutual funds which are required to comply with Rule 2a-7 under the Investment Company Act of 1940. Our short-term investments consisted of investments in certificates of deposit with original maturities greater than three months and less than one year.

In September 2006, we entered into a collaboration and license agreement with Ipsen, under which Ipsen paid us 21.5 million (approximately $27.1 million) as a license fee and expense reimbursement and paid us 1.5 million in equal installments over a three year period from the date of the agreement. In September of 2009, 2008, and 2007, we received 500,000 (approximately $726,000, $711,000, and $688,000, respectively) from Ipsen for the three annual installment payments. Pursuant to the agreement, we are also entitled to receive from Ipsen up to a total of 39.0 million in milestone payments depending on the successful development and launch of toremifene in certain countries of the European Territory for the high grade PIN indication, subject to certain conditions, and the ADT indication. In February 2008, we earned a milestone of 1.0 million (approximately $1.5 million) with the

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achievement of the primary endpoint in the toremifene 80 mg Phase III clinical trial. Ipsen has agreed to pay a portion of our toremifene development costs in the United States if certain conditions are met. Under the collaboration agreement, Ipsen must elect to retain its rights to commercialize toremifene and other products containing toremifene for the high grade PIN indication.

In December 2007, we entered into an exclusive license and collaboration agreement with Merck, or the Merck Collaboration Agreement, which was terminated in March 2010. In connection with entering into this agreement, we received an upfront licensing fee of $40.0 million in January 2008, and Merck purchased approximately $30.0 million of our common stock in December 2007. Under our collaboration with Merck, we were entitled to receive up to $422.0 million in future milestone payments, and Merck also agreed to pay us $15.0 million in guaranteed cost reimbursements for research and development activities in equal annual installments over a three year period beginning on the first anniversary of the effective date of the agreement. We received the first and second $5.0 million payments in December 2009 and 2008, respectively. As a result of the termination of our collaboration with Merck, we will not receive any of the $422.0 million in milestone payments or royalties for the development or sale of SARMs from Merck provided for under our former collaboration with Merck. We do not anticipate significant development progress on Ostarine™, or our SARM program in general, including the initiation of any additional clinical trials, unless and until we enter into one or more new collaborations with third parties or otherwise obtain additional funding. Although the Merck Collaboration Agreement was terminated, Merck remains obligated to pay us the third and final payment of $5.0 million of cost reimbursements for research and development activities in late 2010.

Net cash used in operating activities was $46.0 million, $2.9 million and $37.6 million for the years ended December 31, 2009, 2008 and 2007, respectively. The use of cash in all periods resulted primarily from funding our net losses. In 2009, this was reduced by approximately $726,000 related to the third and final annual license fee and expense reimbursement installment payment from Ipsen in conjunction with our collaboration and license agreement, $5.0 million from Merck related to the second annual installment cost reimbursement payment in conjunction with our exclusive license and collaboration agreement, and approximately $2.3 million in distributions from our investment in Bank of America Corporation s Columbia Strategic Cash Portfolio. In 2008, this was substantially offset by the receipt of $40.0 million in conjunction with our exclusive license and collaboration agreement with Merck, approximately $1.5 million from Ipsen due to the achievement of the primary endpoint in the toremifene 80 mg Phase III clinical trial, approximately $711,000 related to the second annual license fee and expense reimbursement installment payment from Ipsen in conjunction with our collaboration and license agreement, $5.0 million from Merck related to the first annual installment payment in conjunction with our exclusive license and collaboration agreement, and approximately $7.1 million in distributions from our investment in Bank of America Corporation s Columbia Strategic Cash Portfolio. Net cash used in operating activities for the year ended December 31, 2007 was reduced by the receipt of approximately $688,000 from Ipsen related to the first annual license fee and expense reimbursement installment payment in conjunction with our collaboration and license agreement with Ipsen.

Net cash used in investing activities for the year ended December 31, 2009 was $9.4 million and was for the purchase of short-term investments in certificates of deposit of approximately $11.3 million and the purchase of information technology equipment, research and development equipment, and software totaling approximately $600,000. This was reduced by the maturities of certificates of deposit of approximately $2.5 million. Net cash used in investing activities for the year ended December 31, 2008 was $2.9 million and was primarily for the purchase of furniture and fixtures, leasehold improvements, office equipment, software and information technology equipment related to the addition of office space. Additionally, investing activities in 2008 included the purchase of research and development equipment. Net cash used in investing activities for the year ended December 31, 2007 was $1.7 million and was primarily for the purchase of research and development equipment, office equipment, computer equipment and software and the purchase of intangible assets (license fees) of $513,000. We currently expect to make capital expenditures of approximately $226,000 for the year ending December 31, 2010.

Net cash provided by financing activities was $131,000, $1.2 million and $20.0 million for the years ended December 31, 2009, 2008 and 2007, respectively. For the years ended December 31, 2009 and 2008, the net cash was provided primarily from proceeds from the exercises of employee stock options. Net cash provided by financing

activities for the year ended December 31, 2007 reflected proceeds of approximately $30.0 million from our private placement of 1,285,347 shares of common stock to Merck in December 2007 and proceeds of $826,000 from the exercise of employee stock options.

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We estimate that our current cash and cash equivalent balances, short-term investments, interest income and product revenue from the sale of FARESTON® will be sufficient to meet our projected operating requirements for at least the next twelve months. This estimate does not include costs related to additional clinical development of our toremifene 80 mg product candidate or SARM program that we may undertake in an effort to obtain FDA approval. 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.

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 Part I, 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 and potential commercialization 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, other research and development activities, and potential commercialization activities. Our future funding requirements will depend on many factors, including:

- whether and to what extent we determine to continue the development of toremifene 80 mg following discussion with the FDA, including an additional clinical trial to address the deficiencies identified by the FDA in the Complete Response Letter for toremifene 80 mg;
- the scope, rate of progress and cost of our, Ipsen s and/or any potential future collaborators clinical trials and other research and development activities;
- future clinical trial results;
- the terms and timing of any future collaborative, licensing and other arrangements that we may establish;
- the cost and timing of regulatory filings and/or approvals to commercialize our product candidates, and any related restrictions, limitations, and/or warnings in the label of an approved product candidate;
- potential future licensing fees, milestone payments and royalty payments, including any milestone payments or royalty payments that we may receive under our collaborative arrangement with Ipsen;
- the cost and timing of establishing medical education, sales, marketing and distribution capabilities;
- the cost of establishing clinical and commercial supplies of our product candidates and any products that we, Ipsen, and/or any potential future collaborator 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 cost of defending any other litigation claims; 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 short-term investments 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. In December 2009, we announced a reduction of approximately 26% of our workforce in order to reduce our operating expenses in connection with the receipt of the Complete Response Letter regarding our NDA for toremifene 80 mg and the associated delay in the potential regulatory approval of toremifene 80 mg. If we are unable to raise additional funds when needed, we may need to further reduce our expenditures, perhaps significantly, to preserve our cash. The cost-cutting measures we have taken and may take in the future may not be sufficient to enable us to meet our cash requirements, and they may

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negatively affect our business and growth prospects. 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. Our ability to raise additional funds may be adversely impacted by the receipt of the Complete Response Letter from the FDA in October 2009 regarding our NDA for toremifene 80 mg and the related uncertainty regarding the continuing development of, and prospects for FDA approval of toremifene 80 mg, as well as current economic conditions, including the effects of the disruptions to and continuing volatility in the credit and financial markets in the United States and worldwide. As a result of these and other factors, we cannot be certain that additional funding will be available on acceptable terms, or at all. If adequate funds are not available when we need them, 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.

At December 31, 2009, 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 | $ 31 | $ 7 | $ 22 | $ 2 | $ |
| Operating lease obligations | 4,053 | 1,653 | 2,400 | | |
| Equipment financing obligation | 254 | 85 | 169 | | |
| Purchase obligations | 40 | 40 | | | |
| Total | $ 4,378 | $ 1,785 | $ 2,591 | $ 2 | $ |

Our long-term commitments under the operating leases shown above consist of payments relating to a sublease for laboratory and office space at 3 North Dunlap Street, Memphis, Tennessee and a sublease for office space at 175 Toyota Plaza, Memphis, Tennessee. Our sublease agreement for the premises located at 3 North Dunlap Street expires on December 31, 2012, with an option to extend for two additional years. We amended our original sublease agreement for the premises located at 175 Toyota Plaza to add additional office space. The amended sublease includes escalating rental payments and expires on April 30, 2015. We have the ability to cancel the original sublease beginning on December 31, 2010 and to cancel the sublease for additional space on December 31, 2012. 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 and investments in certificates of deposit. 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 ten percent in the average yield earned on our cash equivalents and short-term investments would have resulted in a decrease in our interest income of approximately $15,000 for the year ended December 31, 2009.

We operate primarily in the United States. However, some of our clinical trial sites are located in Canada and the United Kingdom which requires us to make payments for certain clinical trial services in foreign currencies. We are also entitled to receive from Ipsen up to a total of 39.0 million in milestone payments subject to the successful development and launch of toremifene 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 if we initiate future clinical trials outside the United States and to the extent we are able to commercialize toremifene 80 mg and toremifene 20 mg because we are obligated to pay Orion Corporation, our supplier of toremifene, in Euros. However, we do not expect that our total exposure to changes in foreign currencies will be material to our operating results in 2010. We do not currently use derivative financial instruments to mitigate this exposure.

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## ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our financial statements and the reports of our independent registered public accounting firm are included in this Annual Report on Form 10-K beginning on page F-1. The index to these reports and our financial statements is included in Part IV, Item 15 below.

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

Not applicable.

## ITEM 9A. CONTROLS AND PROCEDURES

### Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, 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, 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, 2009 using the criteria for effective internal control over financial reporting as described in Internal Control Integrated Framework, issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, we concluded that, as of December 31, 2009, our internal control over financial reporting was effective. The effectiveness of our internal control over financial reporting has been audited by Ernst & Young LLP, an independent registered public accounting firm.

### Attestation Report of the Independent Registered Public Accounting Firm

Ernst & Young LLP, an independent registered public accounting firm, has issued an audit report on the effectiveness of our internal control over financial reporting, which report is included elsewhere herein.

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**Changes in Internal Control over Financial Reporting**

There were no changes in our internal control over financial reporting during the fourth quarter of 2009 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**ITEM 9B. OTHER INFORMATION**

Effective October 1, 2009, we terminated our sublease agreement dated April 1, 2005 (the Prior Lease ) with the University of Tennessee Research Foundation ( UTRF ) and entered into a new sublease agreement ( New Lease ) with UTRF for the lease of approximately 53,000 square feet of laboratory and office space located at 3 North Dunlap Street, Memphis, Tennessee (the Premises ). The Prior Lease, which previously governed the lease of the Premises, was set to expire on December 31, 2009. The monthly base rent was $36,000 per month under the Prior Lease. Under the terms of the New Lease, the term of the New Lease expires on December 31, 2012, unless sooner terminated in accordance with the terms of the New Lease. Further, we have an option to extend the New Lease for an additional two years. The monthly base rent for the Premises during the term (and any extended term) under the New Lease is $36,000 per month.

Under the terms of the New Lease, we continue to be responsible for our proportionate share of all operating expenses, including utilities, taxes, and repairs and maintenance. We also continue to be responsible for maintaining certain insurance policies during the term. In the event of a default of certain of our obligations under the New Lease, UTRF would have right to terminate the New Lease. The foregoing is only a brief description of the material terms of the Prior Lease and New Lease does not purport to be a complete statement of the rights and obligations of the parties thereunder, and is qualified in its entirety by reference to the Prior Lease that was filed as Exhibit 10.27 to our Quarterly Report on Form 10-Q, filed with the SEC on July 27, 2005, and the New Lease that is filed as Exhibit 10.55 to this Annual Report on Form 10-K. For a description of our contractual relationship with UTRF, other than with respect to the Prior Lease and the New Lease, please see Item 1, Business Licenses and Collaborative Relationships University of Tennessee Research Foundation.

**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 2010 Annual Meeting of Stockholders with the U.S. Securities and Exchange Commission pursuant to Regulation 14A (the 2010 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 2010 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 and nominees for director, including information with respect to our audit committee and audit committee financial experts, may be found under the section entitled Proposal No. 1 Election of Directors and Additional Information About the Board of Directors and Certain Corporate Governance Matters appearing in the 2010 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 Section 16(a) Beneficial Ownership Reporting Compliance appearing in the 2010 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 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 Governance. We will provide a copy of these documents to any person, without charge, upon request, by writing to us at GTx, Inc., Director, Corporate Communications and Financial Analysis, 175 Toyota Plaza, Suite 700, Memphis, Tennessee 38103. We intend to satisfy the disclosure requirement

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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 location 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 2010 Proxy Statement under the sections entitled Compensation Discussion and Analysis, Executive Compensation 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 2010 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 our Compensation Discussion and Analysis is incorporated herein by reference to the information from the 2010 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 2010 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 2010 Proxy Statement under the section entitled Equity Compensation Plan Information.

**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 2010 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 2010 Proxy Statement under the section entitled Additional Information About the Board of Directors and Certain Corporate Governance Matters 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 2010 Proxy Statement under the section entitled Proposal No. 2 Ratification of Appointment of Independent Registered Public Accounting Firm.

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## PART IV

## ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)(1) Index to Financial Statements



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

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

(b) Exhibits

| Number | Description |
|---|---|
| 3.1 | Restated Certificate of Incorporation of GTx, Inc. (1) |
| 3.2 | Amended and Restated Bylaws of GTx, Inc.(2) |
| 4.1 | Reference is made to Exhibits 3.1 and 3.2 |
| 4.2 | Specimen of Common Stock Certificate(3) |
| 4.3 | Amended and Restated Registration Rights Agreement between Registrant and Oracle Partners, L.P. dated August 7, 2003(3) |
| 4.4* | Amended and Restated Registration Rights Agreement between Registrant and J. R. Hyde, III dated August 7, 2003(3) |
| 4.5 | Consent, Waiver and Amendment between the Registrant and Oracle Partners, L.P., Oracle Investment Management, Inc. and Oracle Institutional Partners, L.P. dated November 29, 2007(4) |
| 4.6* | Consent, Waiver and Amendment between Registrant and J. R. Hyde, III and Pittco Associates, L.P. dated December 3, 2007(4) |
| 4.7 | Registration Rights Agreement between Registrant and Merck & Co., Inc. dated December 18, 2007(5) |
| 10.1*+ | Genotherapeutics, Inc. 1999 Stock Option Plan, as amended through December 10, 2009, and Form of Stock Option Agreement |
| 10.2*+ | |

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|---|---|
| | GTx, Inc. 2000 Stock Option Plan, as amended through December 10, 2009, and Form of Stock Option Agreement |
| 10.3*+ | GTx, Inc. 2001 Stock Option Plan, as amended through November 3, 2009, and Form of Stock Option Agreement |
| 10.4*+ | GTx, Inc. 2002 Stock Option Plan, as amended through November 3, 2009, and Form of Stock Option Agreement |
| 10.5* | GTx, Inc. 2004 Equity Incentive Plan and Form of Stock Option Agreement(3) |
| 10.6* | GTx, Inc. 2004 Equity Incentive Plan, as amended effective April 30, 2008(6) |
| 10.8* | Amended and Restated Employment Agreement dated November 10, 2008, between Registrant and Mitchell S. Steiner, M.D.(7) |
| 10.9* | Amended and Restated Employment Agreement dated November 10, 2008, between Registrant and Marc S. Hanover(7) |
| 10.10* | Amended and Restated Employment Agreement dated November 10, 2008, between Registrant and Mark E. Mosteller(7) |
| 10.11* | Amended and Restated Employment Agreement dated November 10, 2008, between Registrant and Henry P. Doggrell(7) |
| 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) |

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| Number | Description |
|---|---|
| 10.15 | Amended and Restated License and Supply Agreement dated October 22, 2001, between Registrant and Orion Corporation[9] |
| 10.16 | Amendment No. 1 to the License and Supply Agreement dated March 5, 2003, between Registrant and Orion Corporation[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[9] |
| 10.25 | Amended and Restated License and Supply Agreement effective January 1, 2005, between Registrant and Orion Corporation[11] |
| 10.26 | Sublease Agreement dated April 1, 2005, as amended, between Registrant and TriStar Enterprises, Inc.[12] |
| 10.27* | Amended and Restated Employment Agreement dated November 10, 2008 between Registrant and James T. Dalton[7] |
| 10.28*+ | 2010 Compensation Information for Registrant s Executive Officers |
| 10.29* | 2009 Compensation Information for Registrant s Executive Officers[7] |
| 10.30* | GTx, Inc. 2004 Non-Employee Directors Stock Option Plan and Form of Stock Option Agreement[3] |
| 10.31* | Amended and Restated GTx, Inc. 2004 Non-Employee Directors Stock Option Plan, effective April 26, 2006[13] |
| 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[14] |
| 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[15] |
| 10.34* | Form of Stock Option Agreement under the Amended and Restated GTx, Inc. 2004 Non-Employee Directors Stock Option Plan[16] |
| 10.35 | Partial Assignment Agreement among Registrant, Orion Corporation and Ipsen Limited dated September 7, 2006[17] |
| 10.36 | Collaboration and License Agreement between Registrant and Ipsen Limited dated September 7, 2006[18] |
| 10.38* | Amended and Restated Employment Agreement dated November 10, 2008, between Registrant and Ronald A. Morton, Jr., M.D.[7] |

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|---|---|
| 10.40 | Consolidated, Amended, and Restated License Agreement dated July 24, 2007, between Registrant and University of Tennessee Research Foundation[8] |
| 10.41 | Amended and Restated License Agreement dated September 24, 2007, between Registrant and University of Tennessee Research Foundation[8] |
| 10.42 | Stock Purchase Agreement, dated November 5, 2007, between the Registrant and Merck & Co., Inc.[19] |
| 10.43 | Exclusive License and Collaboration Agreement between the Registrant and Merck & Co., Inc. dated November 5, 2007[20] |
| 10.44* | Amended and Restated Employment Agreement, dated November 10, 2008, between Registrant and Gregory A. Deener[7] |
| 10.46 | Sublease Agreement, dated December 17, 2007 by and between the Registrant and ESS SUSA Holdings, LLC[20] |
| 10.47 | First Amendment, dated December 29, 2008, to the Consolidated, Amended and Restated License Agreement dated July 24, 2007 between the Registrant and University of Tennessee Research Foundation[7] |
| 10.48 | First Amendment, dated December 29, 2008, to the Amended and Restated License Agreement dated September 24, 2007 between the Registrant and University of Tennessee Research Foundation[7] |
| 10.49* | Directors Deferred Compensation Plan, as amended effective November 4, 2008[7] |
| 10.50* | Non-Employee Director Compensation Policy of GTx, Inc., effective January 1, 2009[7] |
| 10.51* | Amended and Restated GTx, Inc. 2004 Non-Employee Directors Stock Option Plan, as amended effective November 4, 2008[7] |
| 10.52* | GTx, Inc. 2004 Equity Incentive Plan, as amended effective November 4, 2008 and Form of Stock Option Agreement[7] |
| 10.53* | Amended and Restated GTx, Inc. Executive Bonus Compensation Plan, effective November 4, 2008[7] |
| 10.54 | First Amendment, dated July 21, 2008, to the Sublease and Parking Sublicense Agreements dated December 17, 2007 by and between the Registrant and ESS SUSA Holdings, LLC[7] |
| 10.55+ | Sublease Agreement dated October 1, 2009 between Registrant and University of Tennessee Research Foundation |
| 12.1+ | Statement of Computation of Deficiency of Earnings Available to Cover Fixed Charges |
| 23.1+ | Consent of Independent Registered Public Accounting Firm |

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| Number | Description |
|---|---|
| 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)[23] |
| 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)[23] |

Confidential treatment has been granted with respect to certain portions of this exhibit. This exhibit omits the information subject to this confidentiality request. Omitted portions have been filed separately with the SEC.

* Indicates a management contract or compensation plan or arrangement.

\+ 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 the like numbered Exhibit to the Registrant s Current Report on Form 8-K (File No. 000-50549), filed with the SEC on July 26, 2007 and incorporated herein by reference.

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

(4) Filed as the like numbered Exhibit to the Registrant s registration statement on Form S-3 (File No. 333-148321), filed with the SEC on December 26, 2007, and incorporated herein by reference.

(5) Filed as the like numbered Exhibit to the Registrant s Current Report on Form 8-K (File No. 000-50549), filed with the

Securities and Exchange Commission on December 18, 2007, and incorporated herein by reference.

(6) Filed as the like numbered Exhibit to the Registrant s Current Report on Form 8-K (File No. 000-50549), filed with the SEC on May 6, 2008, and incorporated herein by reference.

(7) Filed as the like numbered Exhibit to the Registrant s Annual Report on Form 10-K (File No. 000-50549), filed with the SEC on March 3, 2009, and incorporated herein by reference.

(8) Filed as the like numbered Exhibit to the Registrant s Quarterly Report on Form 10-Q (File No. 000-50549), filed with the SEC on November 9, 2007, and incorporated herein by reference.

(9) Filed as the like numbered Exhibit to the Registrant s Annual Report on

Form 10-K (File No. 000-50549), filed with the SEC on March 9, 2007, and incorporated herein by reference.

(10) Filed as Exhibit 10.1 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.

(11) 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.

(12) 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.

(13) Filed as Exhibit 10.1 to the Registrant s Current Report on Form 8-K (File No. 000-50549),

filed with the SEC on April 27, 2006, and incorporated herein by reference.

(14) 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.

(15) Filed as 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.

(16) Filed as Exhibit 10.35 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.

(17) Filed as Exhibit 10.36 to the Registrant s Quarterly Report

on Form 10-Q
(File No.
000-50549), filed
with the

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SEC on November 3, 2006, and incorporated herein by reference.

(18) Filed as 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.

(19) Filed as the like numbered Exhibit to the Registrant s Current Report on Form 8-K (File No. 000-50549), filed with the SEC on November 6, 2007, and incorporated herein by reference.

(20) Filed as the like numbered Exhibit to the Registrant s Annual Report on Form 10-K (File No. 000-50549), filed with the SEC on March 11, 2008,

and incorporated herein by reference.

(21) 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 15, 2010

## 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<br>J. R. Hyde, III | Chairman of the Board of Directors | March 15, 2010 |
| /s/ Mitchell S. Steiner<br>Mitchell S. Steiner, M.D., F.A.C.S. | Chief Executive Officer, Vice Chairman and Director (Principal Executive Officer) | March 15, 2010 |
| /s/ Mark E. Mosteller<br>Mark E. Mosteller, CPA | Vice President, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer) | March 15, 2010 |
| /s/ Marc S. Hanover<br>Marc S. Hanover | Director | March 15, 2010 |
| /s/ Michael G. Carter<br>Michael G. Carter, M. D. | Director | March 15, 2010 |
| /s/ J. Kenneth Glass | Director | March 15, 2010 |

| | | |
|---|---|---|
| J. Kenneth Glass | | |
| /s/ Robert W. Karr | Director | March 15, 2010 |
| Robert W. Karr, M.D. | | |

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| | | Date |
|---|---|---|
| /s/ John H. Pontius | Director | March 15, 2010 |
| John H. Pontius | | |
| /s/ Kenneth S. Robinson | Director | March 15, 2010 |
| Rev. Kenneth S. Robinson, M.D. | | |
| /s/ Timothy R. G. Sear | Director | March 15, 2010 |
| Timothy R. G. Sear | | |

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**GTx, Inc.**
**INDEX TO FINANCIAL STATEMENTS**

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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, 2009 using the criteria for effective internal control over financial reporting as described in Internal Control Integrated Framework, issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, we concluded that, as of December 31, 2009, our internal control over financial reporting was effective. The effectiveness of our internal control over financial reporting has been audited by Ernst & Young LLP, an independent registered public accounting firm.

/s/ Mitchell S. Steiner

**Mitchell S. Steiner, M.D., F.A.C.S.**
Vice Chairman and

Chief Executive Officer
Memphis, Tennessee
March 15, 2010

/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 of GTx, Inc.

We have audited GTx, Inc. s internal control over financial reporting as of December 31, 2009, 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 included in the accompanying Management s Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on 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, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, 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, GTx, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2009, 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 of GTx, Inc. as of December 31, 2009 and 2008, and the related statements of operations, stockholders (deficit) equity and cash flows for each of the three years in the period ended December 31, 2009 and our report dated March 15, 2010 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Memphis, Tennessee
March 15, 2010

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**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders of GTx, Inc.

We have audited the accompanying balance sheets of GTx, Inc. as of December 31, 2009 and 2008, and the related statements of operations, stockholders (deficit) equity and cash flows for each of the three years in the period ended December 31, 2009. 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, 2009 and 2008, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2009, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of GTx, Inc. s internal control over financial reporting as of December 31, 2009, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 15, 2010 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Memphis, Tennessee
March 15, 2010

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

| | December 31, 2009 | December 31, 2008 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 40,219 | $ 95,510 |
| Short-term investments | 8,825 | 2,157 |
| Accounts receivable, net | 406 | 487 |
| Inventory | 116 | 92 |
| Receivable from collaboration partners | 189 | 777 |
| Prepaid expenses and other current assets | 920 | 1,001 |
| Total current assets | 50,675 | 100,024 |
| Property and equipment, net | 3,291 | 3,988 |
| Intangible and other assets, net | 3,755 | 4,097 |
| Total assets | $ 57,721 | $ 108,109 |
| **LIABILITIES AND STOCKHOLDERS (DEFICIT) EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 1,268 | $ 2,821 |
| Accrued expenses and other current liabilities | 4,730 | 6,666 |
| Deferred revenue current portion | 9,954 | 11,490 |
| Total current liabilities | 15,952 | 20,977 |
| Deferred revenue, less current portion | 49,898 | 54,732 |
| Other long-term liabilities | 621 | 382 |
| Commitments and contingencies | | |
| Stockholders (deficit) equity: | | |
| Common stock, $0.001 par value: 60,000,000 shares authorized; 36,420,901 shares issued and outstanding at December 31, 2009 and 36,392,443 shares issued and outstanding at December 31, 2008 | 36 | 36 |
| Additional paid-in capital | 359,388 | 353,900 |
| Accumulated deficit | (368,174) | (321,918) |
| Total stockholders (deficit) equity | (8,750) | 32,018 |
| Total liabilities and stockholders (deficit) equity | $ 57,721 | $ 108,109 |

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, | | |
|---|---|---|---|
| | **2009** | **2008** | **2007** |
| Revenues: | | | |
| Product sales, net | $ 3,289 | $ 1,088 | $ 1,076 |
| Collaboration revenue | 11,441 | 12,440 | 6,050 |
| Total revenues | 14,730 | 13,528 | 7,126 |
| Costs and expenses: | | | |
| Cost of product sales | 1,290 | 649 | 621 |
| Research and development expenses | 32,344 | 44,259 | 38,508 |
| General and administrative expenses | 27,749 | 23,105 | 13,501 |
| Total costs and expenses | 61,383 | 68,013 | 52,630 |
| Loss from operations | (46,653) | (54,485) | (45,504) |
| Interest income | 159 | 2,705 | 5,145 |
| Loss before income taxes | (46,494) | (51,780) | (40,359) |
| Income tax benefit | 238 | | |
| Net loss | $ (46,256) | $ (51,780) | $ (40,359) |
| Net loss per share: | | | |
| Basic and diluted | $ (1.27) | $ (1.43) | $ (1.16) |
| Weighted average shares used in computing net loss per share: | | | |
| Basic and diluted | 36,415,379 | 36,301,558 | 34,940,151 |

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

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**GTx, Inc.**
**STATEMENTS OF STOCKHOLDERS (DEFICIT) EQUITY**
**For the Years Ended December 31, 2009, 2008 and 2007**
**(in thousands, except share and per share data)**

| | Stockholders (Deficit) Equity | | | | |
|---|---|---|---|---|---|
| | Common Stock | | Additional Paid-in | | Total Stockholders (Deficit) |
| | Shares | Amount | Capital | Accumulated Deficit | Equity |
| Balances at January 1, 2007 | 34,822,362 | $ 35 | $ 326,793 | $ (229,779) | $ 97,049 |
| Issuance of common stock | 1,285,347 | 1 | 19,176 | | 19,177 |
| Exercise of employee stock options | 108,554 | | 826 | | 826 |
| Directors deferred compensation | | | 183 | | 183 |
| Share-based compensation | | | 2,041 | | 2,041 |
| Net loss and comprehensive loss | | | | (40,359) | (40,359) |
| Balances at December 31, 2007 | 36,216,263 | 36 | 349,019 | (270,138) | 78,917 |
| Exercise of employee stock options | 176,180 | | 1,167 | | 1,167 |
| Directors deferred compensation | | | 178 | | 178 |
| Share-based compensation | | | 3,536 | | 3,536 |
| Net loss and comprehensive loss | | | | (51,780) | (51,780) |
| Balances at December 31, 2008 | 36,392,443 | 36 | 353,900 | (321,918) | 32,018 |
| Exercise of employee stock options | 18,434 | | 136 | | 136 |
| Directors deferred compensation | | | 178 | | 178 |
| Issuance of common stock under deferred compensation arrangements | 10,024 | | | | |
| Share-based compensation | | | 5,174 | | 5,174 |
| Net loss and comprehensive loss | | | | (46,256) | (46,256) |
| Balances at December 31, 2009 | 36,420,901 | $ 36 | $ 359,388 | $ (368,174) | $ (8,750) |

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, | | |
|---|---|---|---|
| | **2009** | **2008** | **2007** |
| **Cash flows from operating activities:** | | | |
| Net loss | $ (46,256) | $ (51,780) | $ (40,359) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Depreciation and amortization | 1,785 | 1,562 | 1,150 |
| Share-based compensation | 5,174 | 3,536 | 2,041 |
| Directors deferred compensation | 178 | 178 | 183 |
| Deferred revenue amortization | (11,441) | (10,957) | (6,050) |
| Write off of property and equipment | 114 | | |
| Foreign currency transaction loss (gain) | | 34 | (140) |
| Loss on retirement of property and equipment | | | 9 |
| Changes in assets and liabilities: | | | |
| Short-term investments, trading | 2,157 | 7,653 | (9,810) |
| Accounts receivable, net | 81 | (370) | (56) |
| Inventory | (24) | (14) | 129 |
| Receivable from collaboration partners | 588 | 40,610 | (39,372) |
| Prepaid expenses and other assets | 85 | 383 | (21) |
| Accounts payable | (1,553) | 1,207 | 278 |
| Accrued expenses and other long-term liabilities | (1,956) | 33 | 3,561 |
| Deferred revenue | 5,071 | 5,000 | 50,823 |
| Net cash used in operating activities | (45,997) | (2,925) | (37,634) |
| **Cash flows from investing activities:** | | | |
| Purchase of property and equipment | (600) | (2,905) | (1,223) |
| Purchase of short-term investments, held to maturity | (11,275) | | |
| Proceeds from maturities of short-term investments, held to maturity | 2,450 | | |
| Purchase of intangible assets | | | (513) |
| Net cash used in investing activities | (9,425) | (2,905) | (1,736) |
| **Cash flows from financing activities:** | | | |
| Proceeds from issuance of common stock | | | 19,177 |
| Proceeds from exercise of employee stock options | 136 | 1,167 | 826 |
| Payments on capital lease obligation | (5) | (5) | (5) |
| Net cash provided by financing activities | 131 | 1,162 | 19,998 |
| Net decrease in cash and cash equivalents | (55,291) | (4,668) | (19,372) |
| Cash and cash equivalents, beginning of year | 95,510 | 100,178 | 119,550 |
| Cash and cash equivalents, end of year | $ 40,219 | $ 95,510 | $ 100,178 |

| | | | |
|---|---|---|---|
| **Supplemental schedule of non-cash investing and financing activities:** | | | |
| Equipment purchased under debt or capital lease | $ 268 | $ | $ |

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

### *Business*

GTx, Inc. ( GTx or the Company ), 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 prevent and treat cancer, fractures and bone loss, muscle loss and other serious medical conditions. GTx operates in one business segment.

GTx is developing toremifene citrate, a selective estrogen receptor modulator ( SERM ). GTx has completed a pivotal Phase III clinical trial evaluating toremifene 80 mg to reduce fractures and treat other estrogen deficiency side effects of androgen deprivation therapy ( ADT ) in men with prostate cancer. In December 2008, the Company submitted a New Drug Application ( NDA ) for toremifene 80 mg to reduce fractures in men with prostate cancer on ADT to the U.S. Food and Drug Administration ( FDA ). In October 2009, the Company received a Complete Response Letter from the FDA regarding its NDA for toremifene 80 mg notifying the Company that the FDA would not approve the Company s NDA in its present form. The FDA identified two deficiencies in the Complete Response Letter and recommended that the following information be provided to the FDA to address these clinical deficiencies: (i) results of a second adequate and well-controlled Phase III clinical trial demonstrating the safety and efficacy of toremifene 80 mg to reduce fractures in men with prostate cancer on ADT and (ii) results from an adequate and well-controlled clinical trial demonstrating that toremifene 80 mg treatment to reduce fractures in men with prostate cancer on ADT does not have a detrimental effect on either time-to-disease progression or overall survival. The Company met with the FDA in December 2009 to better understand the Company s options for addressing the deficiencies identified by the FDA in the Complete Response Letter. In 2010, the Company plans to submit to and discuss with the FDA a proposed protocol for a second pivotal Phase III clinical trial evaluating toremifene 80 mg to reduce fractures in men with prostate cancer on ADT to address in a single clinical trial the deficiencies identified by the FDA in the Complete Response Letter. GTx is also developing toremifene 20 mg in an ongoing pivotal Phase III clinical trial for the prevention of prostate cancer in high risk men with high grade prostatic intraepithelial neoplasia ( high grade PIN ). GTx licensed to Ipsen Biopharm Limited, formerly known as Ipsen Developments Limited, ( 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 toremifene for all indications which the Company has licensed from Orion Corporation ( Orion ). The Company is developing selective androgen receptor modulators ( SARMs ), a new class of drugs with the potential to treat cancer cachexia (cancer induced muscle loss) and chronic sarcopenia, which is the loss of skeletal muscle mass resulting in reduced physical strength and ability to perform activities of daily living, as well as other musculoskeletal wasting or muscle loss conditions. In March 2010, the Company reacquired full rights to its SARM program, including Ostarine™ (previously designated by Merck & Co., Inc., or Merck , as MK-2866), following the termination by the Company and Merck of the exclusive license and collaboration agreement for SARM compounds and related SARM products. See Note 14, *Subsequent Events,* for further discussion. GTx is also developing GTx-758, an oral luteinizing hormone inhibitor for the first line treatment of advanced prostate cancer. In February 2010, the Company initiated a Phase II clinical trial evaluating the ability of GTx-758 to reduce testosterone to castrate levels.

The Company markets FARESTON® (toremifene citrate) 60 mg tablets, approved for the treatment of metastatic breast cancer in postmenopausal women in the United States.

## 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.

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

***Cash and Cash Equivalents***

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

***Short-term Investments***

At December 31, 2009, short-term investments consisted of certificates of deposit with original maturities of greater than three months and less than one year. As the Company has the positive intent and ability to hold the certificates of deposit until maturity, these investments have been classified as held to maturity investments and are stated at cost, which approximates fair value.

At December 31, 2008, short-term investments consisted of an investment in Bank of America Corporation s Columbia Strategic Cash Portfolio (the Fund ). The Company s investment in the Fund was liquidated in its entirety during September 2009. For the years ended December 31, 2009 and 2008, the Company recognized a gain on its investment in the Fund of approximately $98 and a loss of approximately $597, respectively.

The fair values of these investments were determined based on quoted market prices in active markets and other observable market data, or Level 1 and Level 2 inputs. Where quoted market prices in active markets were not available, inputs other than quoted prices that are observable, either directly or indirectly, were used to determine the fair values of these investments.

***Accounts Receivable***

Accounts receivable are recorded net of allowances for cash discounts for prompt payment. The Company makes judgments as to its ability to collect outstanding receivables and will provide allowances for the portion of receivables if and when collection becomes doubtful. The Company has not recorded reserves related to the collectability of its accounts receivable for the years ended December 31, 2009 and 2008.

***Inventory***

Inventory consists of FARESTON® tablets that are manufactured by Orion and delivered to the Company as finished goods. Inventory is stated at the lower of cost (first-in, first-out method) or market. The Company analyzes its current inventory levels and will write down inventory if it has become un-saleable or has a cost basis in excess of its expected net realizable value. To date, there have been no inventory write-downs.

***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:

| | |
|---|---|
| Laboratory and office equipment | 3 to 5 years |
| Leasehold improvements | 3 to 7 years |
| Furniture and fixtures | 5 years |
| Computer equipment and software | 3 years |

***Intangible Assets***

The Company amortizes its purchased intangible assets with finite lives over their estimated economic lives. The Company s intangible assets consist of license fees and represent the value of each license acquired by the

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

Company pursuant to the agreements described in Note 6. The license fees are being amortized on a straight-line basis over the respective terms of the agreements.

***Impairment of Long-Lived Assets***

The Company reviews long-lived assets for impairment whenever 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. An impairment loss would be recognized when estimated future cash flows are less than the carrying amount. The cash flow estimates would be based on management s best estimates, using appropriate and customary assumptions and projections at the time.

***Fair Value of Financial Instruments***

The carrying amounts of the Company s financial instruments, which include cash, cash equivalents, short-term investments, accounts receivable and accounts payable approximate their fair values. The method of determining the fair value for the Company s short-term investments is discussed under *Short-term Investments* in this Note 2.

***Concentration of Risk***

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents, short-term investments and accounts receivable. The Company has established guidelines relating to diversification and maturities of its cash equivalents and short-term investments which are designed to manage risk. The Company s cash equivalents consist of bank deposits, certificates of deposit, and money market mutual funds. Bank deposits may at times be in excess of FDIC insurance limits. The Company s short-term investments consist of investments in certificates of deposit with original maturities of greater than 3 months and less than 1 year as discussed under *Short-term Investments* in this Note 2.

Three wholesale drug distributors individually comprised 48%, 33% and 16%, respectively, of the Company s accounts receivable as of December 31, 2009. These same three distributors represented 39%, 37% and 19%, respectively, of the Company s product sales for the year ended December 31, 2009.

***Revenue Recognition***

The Company recognizes revenue from net product sales of FARESTON® less deductions for estimated sales discounts and sales returns. Revenue from product sales is recognized when persuasive evidence of an arrangement exists, title passes, the price is fixed or determinable, and collectability is reasonably assured. 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, 2009 and 2008, the Company s accrual for product returns was $494 and $815, respectively.

Collaboration revenue consists of non-refundable upfront payments, license fees, reimbursements for research and development activities, and milestone payments associated with the Company s collaboration and license agreements discussed in Note 8. Revenues from licensing agreements are recognized based on the performance requirements of the specific agreements. The Company has analyzed agreements with multiple element arrangements to determine whether the deliverables under the agreement, including license and performance obligations such as joint steering committee participation and research and development activities, can be separated or whether all of the deliverables must be accounted for as a single unit of accounting. For these arrangements, the Company was not able to identify evidence of fair value for the undelivered elements and therefore recognizes any consideration for a single unit of accounting in the same manner as revenue is recognized for the final deliverable, which is ratable over the performance period. The performance period was estimated at the inception of each agreement and is reevaluated at each reporting period. Revenues from milestone payments for which the Company has no continuing performance obligations are recognized upon achievement of the performance milestone, as

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defined in the related agreement, provided the milestone is substantive and a culmination of the earnings process has occurred. Performance obligations typically consist of significant milestones in the development life cycle of the related product candidates and technology, such as initiation of clinical trials, achievement of specified clinical trial endpoints, filing for approval with regulatory agencies and approvals by regulatory agencies.

***Research and Development Expenses***

Research and development expenses include, but are not limited to, the Company s expenses for personnel, supplies, and facilities associated with research activities, screening and identification of product candidates, formulation and synthesis activities, manufacturing, preclinical studies, toxicology studies, clinical trials, regulatory and medical affairs, quality assurance activities and license and royalty fees. The Company expenses these costs in the period in which they are incurred. The Company estimates its liabilities for research and development expenses in order to match the recognition of expenses to the period in which the actual services are received. As such, accrued liabilities related to third party research and development activities are recognized based upon the Company s estimate of services received and degree of completion of the services in accordance with the specific third party contract.

The Company purchased approximately $941 of toremifene 80 mg tablets in the fourth quarter of 2009. The cost of this inventory was included in research and development expense for the year ended December 31, 2009 due to the delay in regulatory approval of toremifene 80 mg to reduce fractures in men with prostate cancer on ADT. See Note 1 for further discussion.

***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, 2009 and 2008, net of the valuation allowance, the net deferred tax assets were reduced to zero. See Note 9 for further discussion.

***Stock Options***

The Company has stock option and equity incentive plans that provide for the purchase or acquisition of the Company s common stock by certain of the Company s employees and directors. The Company recognizes compensation expense for its share-based payments based on the fair value of the awards over the period during which an employee or director is required to provide service in exchange for the award. See Note 3 for further discussion.

***Basic and Diluted Net Loss Per Share***

Basic net loss per share is calculated based on the weighted average number of common shares outstanding during the period. Diluted net loss per share gives effect to the dilutive potential of common stock consisting of stock options.

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The following table sets forth the computation of the Company s basic and diluted net loss per share for the years ended December 31, 2009, 2008 and 2007:

| | Years Ended December 31, | | |
|---|---|---|---|
| | **2009** | **2008** | **2007** |
| **Basic and diluted net loss per share** | | | |
| Numerator: | | | |
| Net loss | $ (46,256) | $ (51,780) | $ (40,359) |
| Denominator: | | | |
| Common stock outstanding at beginning of period | 36,392,443 | 36,216,263 | 34,822,362 |
| Issuance of common stock on a weighted average basis | | | 49,301 |
| Issuance of common stock under deferred compensation arrangements on a weighted average basis | 9,200 | | |
| Exercise of employee stock options on a weighted average basis | 13,736 | 85,295 | 68,488 |
| Weighted average shares used in computing basic and diluted net loss per share | 36,415,379 | 36,301,558 | 34,940,151(1) |
| Basic and diluted net loss per share | $ (1.27) | $ (1.43) | $ (1.16) |

(1) The weighted average shares used in computing basic and diluted net loss per share for the year ended December 31, 2007 included 49,301 shares, which represents the weighted average effect during the period of the Company s issuance of 1,285,347 shares of common stock to Merck on

December 18, 2007.

Weighted average options outstanding to purchase shares of common stock of 3,597,716, 2,638,760, and 1,835,743 were excluded from the calculation of diluted net loss per share for the years ended December 31, 2009, 2008 and 2007, respectively, as inclusion of the options would have had an anti-dilutive effect on the net loss per share for the periods. At December 31, 2009, the Company had outstanding 36,420,901 shares of common stock.

***Comprehensive Loss***

For all periods presented, there were no differences between net loss and comprehensive loss.

***Recent Accounting Pronouncements***

In October 2009, the Financial Accounting Standards Board ( FASB ) issued Accounting Standards Update No. 2009-13, *Revenue Recognition (Topic 605): Multiple-Deliverable Revenue Arrangements (a consensus of the FASB Emerging Issues Task Force)* ( ASU No. 2009-13 ). ASU No. 2009-13 amends revenue recognition guidance related to multiple deliverable arrangements to provide new guidance concerning the determination of whether an arrangement involving multiple deliverables contains more than one unit of accounting and the manner in which arrangement consideration should be allocated to such deliverables. The amended guidance is effective for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010 and may be applied prospectively or retroactively. The Company does not expect the adoption of ASU No. 2009-13 to have a material impact on its financial position or results of operations.

**3. Share-Based Compensation**

Share-based payments include stock option grants under the Company s stock option and equity incentive plans and deferred compensation arrangements for the Company s non-employee directors.

The Company grants to employees and non-employee directors options to purchase common stock under various plans at prices equal to the fair market value of the stock on the dates the options are granted as determined in accordance with the terms of the applicable plan. 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

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employee options. Employees generally have three months after the employment relationship ends to exercise all vested options except in the case of voluntary retirement, disability or death, where exercise periods are generally longer. The Company issues new shares of common stock upon the exercise of options. 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 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 amount of share-based compensation expense recognized is reduced ratably over the vesting period by an estimate of the percentage of options granted that are expected to be forfeited or canceled before becoming fully vested.

Total share-based compensation expense for the year ended December 31, 2009 was $5,352, of which $2,143 and $3,209 were recorded in the statement of operations as research and development expenses and general and administrative expenses, respectively. Total share-based compensation expense for the year ended December 31, 2008 was $3,714, of which $1,682 and $2,032 were recorded in the statement of operations as research and development expenses and general and administrative expenses, respectively. Total share-based compensation expense for the year ended December 31, 2007 was $2,224, of which $1,047 and $1,177 were recorded in the statement of operations as research and development expenses and general and administrative expenses, respectively. Share-based compensation expense for the years ended December 31, 2009, 2008 and 2007 included share-based compensation expense related to deferred compensation arrangements for the Company s non-employee directors of $178, $178 and $183, respectively. See Note 10 for further discussion of deferred compensation arrangements for the Company s non-employee directors.

For the years ended December 31, 2009, 2008 and 2007, the weighted average grant date fair value per share of options granted was $8.45, $8.54 and $10.41, respectively. The weighted average for key assumptions used in determining the grant date fair value of options granted in 2009, 2008 and 2007, and a summary of the methodology applied to develop each assumption were as follows:

| | Years Ended December 31, | | |
|---|---|---|---|
| | **2009** | **2008** | **2007** |
| Expected price volatility | 55.0% | 51.6% | 50.6% |
| Risk-free interest rate | 2.04% | 3.5% | 4.6% |
| Weighted average expected life in years | 6.9 years | 6.9 years | 6.9 years |
| Dividend yield | 0% | 0% | 0% |

*Expected Price Volatility* This is a measure of the amount by which a price has fluctuated or is expected to fluctuate. The Company based its determination of expected volatility on its historical stock price volatility. An increase in the expected price volatility will increase compensation expense.

*Risk-Free Interest Rate* This is determined using U.S. Treasury rates where the term is consistent with the expected life of the stock options. 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 determined by calculating the average of the vesting term and the contractual term of the options. The Company has utilized this method due to the lack of historical option exercise information related to the Company s stock option and equity incentive plans. Options granted have a maximum term of ten years. An increase in the expected life will increase compensation expense.

*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.

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The following is a summary of stock option transactions for all of the Company s stock option and equity incentive plans for the three year period ended December 31, 2009:

| | Number of Shares | Weighted Average Exercise Price Per Share |
|---|---|---|
| Options outstanding at January 1, 2007 | 1,458,289 | $ 8.33 |
| Options granted | 566,417 | 18.23 |
| Options forfeited | (36,500) | 12.70 |
| Options exercised | (108,554) | 7.61 |
| Options outstanding at December 31, 2007 | 1,879,652 | 11.27 |
| Options granted | 1,013,000 | 15.19 |
| Options forfeited or expired | (42,496) | 14.07 |
| Options exercised | (176,180) | 6.62 |
| Options outstanding at December 31, 2008 | 2,673,976 | 13.01 |
| Options granted | 1,118,150 | 15.07 |
| Options forfeited or expired | (408,821) | 14.52 |
| Options exercised | (18,434) | 7.37 |
| Options outstanding at December 31, 2009 | 3,364,871 | 13.55 |

The following table summarizes information about stock options outstanding at December 31, 2009:

| 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 | $12.15 | 1,123,129 | 5.07 | $ 8.17 | 811,315 | $ 7.76 |
| $12.30 | $16.84 | 1,533,575 | 8.14 | 15.40 | 136,335 | 13.21 |
| $17.05 | $20.40 | 708,167 | 7.54 | 18.07 | 51,118 | 18.87 |
| | | 3,364,871 | 6.99 | 13.55 | 998,768 | 9.07 |

At December 31, 2009, the aggregate intrinsic value of all outstanding options was $9 with a weighted average remaining contractual term of 7.0 years, of which 998,768 of the outstanding options are currently exercisable with an aggregate intrinsic value of $8, a weighted average exercise price of $9.07 and a weighted average remaining contractual term of 4.22 years. Options to purchase 18,434 shares were exercised during the year ended December 31, 2009. The total intrinsic value of options exercised during the years ended December 31, 2009, 2008, and 2007 was

$99, $1,626, and $1,191, respectively. At December 31, 2009, the total compensation cost related to non-vested options not yet recognized was $12,451, with a weighted average expense recognition period of 2.23 years. Options available for future issuance under the Company s stock option and equity incentive plans were 3,027,159 at December 31, 2009. On January 1, 2010, options available for future issuance under the Company s stock option and equity incentive plans increased to 4,918,204 in accordance with the provisions of such plans.

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**4. Property and Equipment, Net**

Property and equipment consisted of the following:

| | December 31, | |
|---|---|---|
| | **2009** | **2008** |
| Laboratory and office equipment | $ 4,328 | $ 4,174 |
| Computer equipment and software | 3,076 | 2,465 |
| Furniture and fixtures | 1,355 | 1,355 |
| Leasehold improvements | 1,024 | 1,024 |
| In process equipment and software | | 36 |
| | 9,783 | 9,054 |
| Less: accumulated depreciation | (6,492) | (5,066) |
| | $ 3,291 | $ 3,988 |

Depreciation and amortization expense for the years ended December 31, 2009, 2008 and 2007 was $1,447, $1,225 and $841, respectively. Of these amounts, $619, $528 and $388, respectively, were included in research and development expenses in the statements of operations.

**5. Accrued Expenses and Other Current Liabilities**

Accrued expenses and other current liabilities consisted of the following:

| | December 31, | |
|---|---|---|
| | **2009** | **2008** |
| Research and development | $ 1,749 | $ 1,687 |
| General and administrative | 1,029 | 609 |
| Sales and marketing | 819 | 1,355 |
| Employee compensation | 605 | 2,131 |
| Clinical trials | 446 | 884 |
| Current portion of capital lease and financed equipment liabilities | 82 | |
| | $ 4,730 | $ 6,666 |

**6. Intangible Assets**

Intangible assets consisted of the following:

| | December 31, | |
|---|---|---|
| | **2009** | **2008** |
| License fees | $ 5,339 | $ 5,339 |
| Less: accumulated amortization | (1,584) | (1,246) |
| | $ 3,755 | $ 4,093 |

In accordance with the terms of the Amended and Restated License and Supply Agreement that the Company entered into with Orion in December 2004 ( Orion License and Supply Agreement ), the Company paid a license fee of $4,826. This license fee is being amortized on a straight-line basis over the term of the Orion License and Supply

Agreement which the Company estimates to be 16 years. In accordance with the terms of the Consolidated, Amended, and Restated License Agreement ( SARM License Agreement ) and the Amended and Restated License Agreement ( SERM License Agreement ) that the Company entered into with the University of Tennessee Research Foundation ( UTRF ) in July 2007 and September 2007, respectively, the Company paid a one-time up-front fee of $290 per license. The license fees under the SARM License Agreement and the SERM License Agreement are being amortized on a straight-line basis over the respective terms of the agreements, which the Company estimates to be approximately 14 years and 11.5 years, respectively. Amortization expense for the years ended December 31,

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2009, 2008 and 2007 was $338, $337 and $309, respectively. See Note 8 for additional information on intangible assets.

Estimated future amortization expense for purchased intangible assets at December 31, 2009 is as follows:

| **Years Ending December 31,** | |
|---|---|
| 2010 | $ 338 |
| 2011 | 338 |
| 2012 | 338 |
| 2013 | 338 |
| 2014 | 338 |
| Thereafter | 2,065 |
| Total | $ 3,755 |

**7. Common and Preferred Stock**

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

On December 18, 2007, the Company completed a private placement of 1,285,347 shares of common stock to Merck at a per share price of $23.34 (see Note 8).

**8. Collaboration and License Agreements**

***Orion Corporation License and Supply Agreement***

In December 2004, the Company entered into the Orion License and Supply Agreement pursuant to which the Company obtained an exclusive license from Orion to develop and commercialize toremifene-based products for all human indications worldwide, except the treatment and prevention of breast cancer outside of the United States. Additionally, the Orion License and Supply Agreement requires that Orion will manufacture and supply all of the Company s and the Company s sublicensees needs for clinical trial and commercial grade material for toremifene-based products developed and marketed in the United States and abroad, including toremifene globally and FARESTON® in the United States. Orion may terminate its supply obligations at its election at any time as a result of the Company s failure to obtain regulatory approval of one of its toremifene product candidates in the United States prior to December 31, 2009, in which event the Company will have the right to enter into a contract manufacturing agreement with another supplier for toremifene-based products. The Orion 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 Orion License ). Under the Orion License and Supply Agreement, the Company was required to pay a license fee of $4,826. The term of the Orion License and Supply Agreement lasts, on a country-by-country basis, until the later of expiration of the Company s patents claiming processes or methods of use of toremifene for prostate cancer or the end of all marketing or regulatory exclusivity which the Company may obtain for toremifene-based products. The term of the Company s method of use patents extend from 2019 to 2023. Orion may terminate the Orion License and Supply Agreement as a result of the Company s uncured material breach or bankruptcy.

Under the Original Orion 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 Orion 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 royalty payments for toremifene-based products to treat high grade PIN and prevent prostate cancer and reduce fractures in men with prostate cancer on ADT.

The Company has agreed to achieve specified minimum sales requirements of toremifene in the United States after commercialization of a 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

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use of toremifene to treat high grade PIN and prevent prostate cancer and reduce fractures in men with prostate cancer on ADT.

***University of Tennessee Research Foundation License Agreements***

In July 2007, the Company and UTRF entered into the SARM License Agreement to consolidate and replace the Company s two previously existing SARM license agreements with UTRF and to modify and expand certain rights and obligations of each of the parties under both license agreements. Pursuant to the SARM License Agreement, the Company was granted exclusive worldwide rights in all existing SARM technologies owned or controlled by UTRF, including all improvements thereto, and exclusive rights to future SARM technology that may be developed by certain scientists at the University of Tennessee or subsequently licensed to UTRF under certain existing inter-institutional agreements with The Ohio State University.

In September 2007, the Company and UTRF entered into the SERM License Agreement to replace its previously existing exclusive worldwide license agreement for toremifene. Pursuant to the SERM License Agreement, the Company was granted exclusive worldwide rights to UTRF s method of use patents relating to SERMs, including toremifene for chemoprevention of prostate cancer as well as future related SERM technologies that may be developed by certain scientists at the University of Tennessee.

Under the SARM License Agreement and the SERM License Agreement (together, the UTRF License Agreements ), the Company paid UTRF a one-time, upfront fee of $290 per UTRF License Agreement as consideration for entering into the UTRF License Agreements. The Company is also obligated to pay UTRF annual license maintenance fees and royalties on sublicense revenues and net sales of products.

In December 2008, the Company and UTRF amended the UTRF License Agreements (together, the License Amendments ). In consideration for the execution of the License Amendments, the Company paid UTRF an aggregate of $540, which was included in research and development expense in the Company s statement of operations for the year ended December 31, 2008.

***Ipsen Collaboration and License Agreement***

In September 2006, the Company entered into a collaboration and license agreement with Ipsen (the Ipsen Collaboration Agreement ) pursuant to which the Company granted Ipsen exclusive rights in the European Territory to develop and commercialize toremifene in all indications which the Company has licensed from 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 Ipsen Collaboration Agreement, Ipsen paid the Company 23,000 as a license fee and expense reimbursement, of which 1,500 was 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. In September 2009, 2008, and 2007, the Company received 500 (approximately $726, $711, and $688, respectively) from Ipsen for the three annual installment payments. Pursuant to the Ipsen Collaboration Agreement, the Company 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 toremifene in certain countries of the European Territory for the high grade PIN indication, subject to certain conditions, and the ADT indication. In February 2008, the Company earned a milestone of 1,000 (approximately $1,482) with the achievement of the primary endpoint in the toremifene 80 mg ADT Phase III clinical trial. This amount was recognized as collaboration revenue in the first quarter of 2008. Ipsen has agreed to be responsible for and to pay all clinical development, regulatory and launch activities to commercialize toremifene 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 which rates will be dependent on whether such sales are for the high grade PIN indication or the ADT indication. The Company will remain responsible for paying upstream royalties on toremifene to both Orion and 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.

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The Company recorded deferred revenue of $29,330 related to the Ipsen upfront license fee and expense reimbursements which is being amortized into revenue on a straight-line basis over an estimated six year development period for toremifene in the European Territory. The estimated development period was increased in the fourth quarter of 2009 from five years to six years based upon revised development plans for the toremifene product candidates. The Company recognized as collaboration revenue $5,777 for the year ended December 31, 2009, and $5,852 for the years ended December 31, 2008 and 2007, respectively, from the amortization of the Ipsen deferred revenue.

***Merck & Co., Inc. Collaboration and License Agreement***

In December 2007, GTx and Merck entered into a global exclusive license and collaboration agreement (the Merck Collaboration Agreement ) governing the Company s and Merck s joint research, development and commercialization of SARM compounds and related SARM products, including SARMs currently being developed by the Company and Merck and those yet to be discovered, for all potential indications of interest. In March 2010, the Company reacquired full rights to its SARM program, including Ostarine™, following the termination by the Company and Merck of the Merck Collaboration Agreement. See Note 14, *Subsequent Events,* for further discussion.

Under the Merck Collaboration Agreement, the Company granted Merck an exclusive worldwide license under its SARM-related patents and know-how. The Company conducted preclinical research of SARM compounds and products, and Merck was primarily responsible under the terms of the agreement for conducting and funding development and commercialization of products developed under the Merck Collaboration Agreement. Merck paid the Company an upfront licensing fee of $40,000. In addition, Merck has agreed to pay the Company $15,000 in guaranteed cost reimbursements for research and development activities in equal annual installments over a three year period beginning on the first anniversary of the effective date of the Merck Collaboration Agreement. The Company received $5,000 from Merck in both December 2008 and December 2009 as the first and second annual payments of cost reimbursements for research and development activities.

The Company and Merck also entered into a Stock Purchase Agreement pursuant to which the Company sold to Merck on December 18, 2007, 1,285,347 newly-issued shares of the Company s common stock for an aggregate purchase price of approximately $30,000, or $23.34 per share.

The Company deferred the recognition of the upfront licensing fee of $40,000 and the $10,800 in equity premium received that represents the difference between the purchase price and the closing price of the Company s common stock on the date the stock was purchased by Merck. These payments were being recognized as revenue over the period of the Company s performance obligation, which the Company estimated to be ten years. The $5,000 of cost reimbursements received in both December 2008 and December 2009 were being recognized as collaboration revenue over the remaining period of the Company s performance obligation. The Company recognized as collaboration revenue $5,664, $5,106, and $198 for the years ended December 31, 2009, 2008, and 2007, respectively, from the amortization of the Merck deferred revenue.

**9. Income Taxes**

The Company has incurred net losses since inception and, consequently, has 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.

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The principal components of the Company s net deferred income tax assets consisted of the following:

| | December 31, 2009 | 2008 |
|---|---|---|
| Deferred income tax assets: | | |
| Net federal and state operating loss carryforwards | $ 75,280 | $ 57,719 |
| Research and development credits | 8,893 | 7,908 |
| Deferred revenue | 22,984 | 25,904 |
| Share-based compensation | 5,188 | 3,251 |
| Other | 901 | 633 |
| Depreciation and amortization | 121 | |
| Total deferred tax assets | 113,367 | 95,415 |
| Deferred income tax liabilities: | | |
| Depreciation and amortization | | 27 |
| Total deferred tax liabilities | | 27 |
| Net deferred income tax assets | 113,367 | 95,388 |
| Valuation allowance | (113,367) | (95,388) |
| | $ | $ |

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 $17,979, $22,765 and $17,027 in 2009, 2008 and 2007, respectively.

At December 31, 2009, the Company had net federal operating loss carryforwards of approximately $197,000, which expire from 2018 to 2029 if not utilized. The Company had state operating loss carryforwards of approximately $166,000, which expire from 2013 to 2024 if not utilized. The Company also had research and development credits of approximately $8,900, which expire from 2020 to 2029 if not utilized.

Both of the net federal and state operating loss carryforwards include approximately $1,900 of deductions related to the exercise of stock options. This amount represents an excess tax benefit and has not been included in the gross deferred tax asset reflected for net federal and state operating loss carryforwards. If utilized, the benefits from these deductions will be recorded as an adjustment to additional paid in capital.

The Company will recognize the impact of a tax position in the financial statements if that position is more likely than not of being sustained on audit based on the technical merits of the position. As of December 31, 2009, the Company had no unrecognized tax benefits. Utilization of the Company s net operating loss 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. The Company has not yet performed a Section 382 change in control study in order to determine if there is a limitation of its net operating loss carryforwards. Until this study is performed, the Company cannot be certain of the use of these loss carryforwards. Additionally, the Company has not yet conducted an in depth study of its research and development credits. This study may result in an increase or decrease to the Company s research and development credits. Until studies are conducted of the Company s net operating loss carryforwards and research and development credits, no amounts are being presented as an uncertain tax position

under FIN 48. The Company s net deferred tax assets have been fully offset by a valuation allowance. Therefore, future changes to the Company s unrecognized tax benefits would be offset by an adjustment to the valuation allowance and there would be no impact on the Company s balance sheet, statement of operations, or cash flows. The Company does not expect its unrecognized tax benefits to change significantly over the next 12 months.

The Company is currently open to audit under the statute of limitations by the Internal Revenue Service and the appropriate state income taxing authorities for all years due to the net loss carryforwards from those years. The Company is currently not under examination by the Internal Revenue Service or any other taxing authorities. The Company has not recorded any interest and penalties on any unrecognized tax benefits since its inception.

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For the year ended December 31, 2009, the Company recognized a federal income tax benefit of $238,000 due to the adoption of a provision in the Housing and Economic Recovery Act of 2008 that allowed the Company to claim refunds for portions of its pre-2006 research and development tax credits.

**10. Directors Deferred Compensation Plan**

Non-employee directors may defer all or a portion of their fees under the Company s Directors Deferred Compensation Plan until termination of their status as directors. Deferrals can be made into a cash account, a stock account, or a combination of both. Stock accounts will be paid out in the form of Company common 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. Cash accounts and stock accounts under the Directors Deferred Compensation Plan are credited with interest or the value of any cash and stock dividends, respectively. Non-employee directors are fully vested in any amounts that they elect to defer under the Directors Deferred Compensation Plan.

For the years ended December 31, 2009, 2008 and 2007, the Company incurred non-employee director fee expense of $298, $241 and $207, respectively, of which $178, $178 and $183 was deferred into stock accounts and will be paid in common stock following separation from service as a director. At December 31, 2009, 72,689 shares of the Company s common stock had been credited to individual director stock accounts under the Directors Deferred Compensation Plan, and no amounts had been credited to individual director cash accounts under the Directors Deferred Compensation Plan.

**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 $16.5 for employees under age 50 and $22 for employees 50 and older in calendar year 2009. 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. The Company elected to match a portion of employee s contributions to the plan in the amount of $551, $395, and $210 in 2009, 2008 and 2007, respectively.

**12. Commitments and Contingencies**

***Operating Lease Commitments***

The Company leases laboratory facilities and office space pursuant to a sublease, which is accounted for as an operating lease. The sublease expires on December 31, 2012, with an option to extend the sublease for an additional two years. The Company subleases additional office space under two subleases that are accounted for as operating leases and have terms that expire on April 30, 2015. These subleases have escalating rent payments and the Company has options to cancel these subleases beginning December 31, 2010 and December 31, 2012, respectively. Total rent expense under these real estate leases was approximately $1,458, $1,302 and $765 for the years ended December 31, 2009, 2008 and 2007, respectively.

As of December 31, 2009, annual minimum payments under operating lease arrangements were as follows:

| | |
|---|---|
| 2010 | $ 1,653 |
| 2011 | 1,145 |
| 2012 | 1,255 |
| Total | $ 4,053 |

***Equipment Financing and Capital Lease Obligations***

The Company has approximately $268 of property and equipment that was financed or acquired through a capital lease at December 31, 2009. The accumulated amortization related to these assets was $24 at December 31, 2009.

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As of December 31, 2009, the annual minimum payments under these financing and capital lease arrangements were as follows:

| | |
|---|---|
| 2010 | $ 92 |
| 2011 | 92 |
| 2012 | 92 |
| 2013 | 7 |
| 2014 | 2 |
| Total | $ 285 |

***Purchase Commitments***

The Company had outstanding contractual purchase obligations of $40 and $23 at December 31, 2009 and 2008, 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, 2009 and 2008, respectively.

**13. Reduction in Force**

In December 2009, the Company implemented a reduction in its workforce in connection with the receipt of the Complete Response Letter from the FDA regarding the Company s NDA for toremifene 80 mg and the associated delay in the potential regulatory approval of toremifene 80 mg to reduce fractures in men with prostate cancer on ADT. The reduction in force was effective immediately and represented approximately 26% of the Company s total workforce. As a result of the workforce reductions, the Company incurred expenses of approximately $944, consisting primarily of severance costs and legal fees, of which $288 was included in research and development expenses and $656 was included in general and administrative expenses. As of December 31, 2009, the Company had $328 of these expenses recorded in accrued expenses and other current liabilities as these amounts are expected to be paid during the first quarter of 2010.

**14. Subsequent Events**

The Company has evaluated all events or transactions that occurred after December 31, 2009 up through the date the financial statements were issued.

*Merck Collaboration and License Agreement*

In March 2010, the Company reacquired full rights to the Company s SARM program following the termination by the Company and Merck of the Merck Collaboration Agreement. Merck remains obligated to pay the Company the final $5,000 payment for research and development activities cost reimbursement in 2010. In the first quarter of 2010, the Company expects to recognize as collaboration revenue all of the remaining $49,856 unamortized revenue that was deferred as of December 31, 2009, as well as the final $5,000 cost reimbursement, as a result of the termination of the Merck Collaboration Agreement.

There were no other material recognizable or nonrecognizable subsequent events during the period evaluated.

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**15. Quarterly Financial Data (Unaudited)**

The following is a summary of the quarterly results of operations for the years ended December 31, 2009 and 2008:

| | 2009 Quarters Ended | | | |
|---|---|---|---|---|
| | March 31 | June 30 | September 30 | December 31 |
| Revenues: | | | | |
| Product sales, net | $ 759 | $ 949 | $ 719 | $ 862 |
| Collaboration revenue | 2,872 | 2,873 | 2,881 | 2,815 |
| Total revenues | 3,631 | 3,822 | 3,600 | 3,677 |
| Costs and expenses: | | | | |
| Cost of product sales | 348 | 431 | 344 | 167 |
| Research and development expenses | 8,312 | 7,746 | 8,123 | 8,163 |
| General and administrative expenses | 6,542 | 6,940 | 7,982 | 6,285 |
| Total costs and expenses | 15,202 | 15,117 | 16,449 | 14,615 |
| Loss from operations | (11,571) | (11,295) | (12,849) | (10,938) |
| Interest income | 76 | 35 | 29 | 19 |
| Loss before income taxes | (11,495) | (11,260) | (12,820) | (10,919) |
| Income tax benefit | 194 | | | 44 |
| Net loss | $ (11,301) | $ (11,260) | $ (12,820) | $ (10,875) |
| Net loss per share: | | | | |
| Basic and diluted | $ (0.31) | $ (0.31) | $ (0.35) | $ (0.30) |

| | 2008 Quarters Ended | | | |
|---|---|---|---|---|
| | March 31 | June 30 | September 30 | December 31 |
| Revenues: | | | | |
| Product sales, net | $ 257 | $ 274 | $ 315 | $ 242 |
| Collaboration revenue | 4,216 | 2,734 | 2,734 | 2,756 |
| Total revenues | 4,473 | 3,008 | 3,049 | 2,998 |
| Costs and expenses: | | | | |
| Cost of product sales | 135 | 155 | 192 | 167 |
| Research and development expenses | 13,999 | 10,370 | 9,244 | 10,646 |
| General and administrative expenses | 4,250 | 6,424 | 6,107 | 6,324 |
| Total costs and expenses | 18,384 | 16,949 | 15,543 | 17,137 |

| | | | | |
|---|---|---|---|---|
| Loss from operations | (13,911) | (13,941) | (12,494) | (14,139) |
| Interest income | 1,168 | 698 | 568 | 271 |
| Net loss | $ (12,743) | $ (13,243) | $ (11,926) | $ (13,868) |
| Net loss per share: | | | | |
| Basic and diluted | $ (0.35) | $ (0.37) | $ (0.33) | $ (0.38) |