GTX INC /DE/
Form S-3
December 26, 2007

Table of Contents

As filed with the Securities and Exchange Commission on December 26, 2007
Registration No. 333-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM S-3
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

GTx, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**62-1715807**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

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

MITCHELL S. STEINER, M.D., F.A.C.S.
CHIEF EXECUTIVE OFFICER
GTx, Inc.
3 N. Dunlap Street
Van Vleet Building
Memphis, TN 38163
(901) 523-9700
(Name, address, including zip code, and telephone number,
including area code, of agent for service)

Copies to:
SUZANNE SAWOCHKA HOOPER, ESQ.
Cooley Godward Kronish LLP
Five Palo Alto Square
3000 El Camino Real
Palo Alto, CA 94306-2155
(650) 843-5000

Approximate date of commencement of proposed sale to the public:
From time to time after the effective date of this registration statement

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. o

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. þ

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

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

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. o

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. o

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered (1)	Proposed Maximum Offering Price Per Share (2)	Proposed Maximum Aggregate Offering Price (2)	Amount of Registration Fee
Common Stock, par value $0.001 per share	1,285,347 shares	$15.335	$19,710,796.25	$606

(1) Pursuant to Rule 416 under the Securities Act, the shares being registered hereunder include such indeterminate number of shares of common stock as may be issuable with respect to the shares being registered hereunder as a result of stock splits, stock dividends or similar transactions.

(2) Estimated solely for the purpose of calculating the amount of the registration fee pursuant to Rule 457 promulgated under the Securities Act. The offering price per share and the aggregate offering price are based upon the average of the high and low prices of the Registrant s common stock as reported on the NASDAQ Global Market on December 24, 2007.

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

Table of Contents

Subject to Completion, Dated December 26, 2007

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

PROSPECTUS

1,285,347 Shares
Common Stock

This prospectus relates to the offer and sale, from time to time, of up to 1,285,347 shares of our common stock by the selling stockholder named in this prospectus. We are not selling any common stock under this prospectus and will not receive any of the proceeds from the sale of shares by the selling stockholder.

The selling stockholder identified in this prospectus, or its permitted transferees or other successors-in-interest, may offer the shares from time to time through public or private transactions at prevailing market prices, at prices related to prevailing market prices, or at privately negotiated prices. We provide more information about how the selling stockholder may sell its shares of common stock in the section entitled Plan of Distribution on beginning on page 19 of this prospectus.

Our common stock is traded on the NASDAQ Global Market under the symbol GTXI. On December 24, 2007, the last reported sale price of our common stock on the NASDAQ Global Market was $15.23.

Investing in our common stock involves a high degree of risk. You should review carefully the risks and uncertainties described under the heading Risk Factors beginning on page 2 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is , 20 .

TABLE OF CONTENTS

ABOUT THIS PROSPECTUS

You should rely only on the information contained or incorporated by reference in this prospectus. We have not, and the selling stockholder has not, authorized anyone to provide you with information different from that contained in this prospectus. The selling stockholder is offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where it is lawful to do so. The information in this prospectus is accurate only as of the date of this prospectus and any information we have incorporated by reference is accurate only as of the date of the document incorporated by reference, regardless of the time of delivery of this prospectus or any sale of our common stock.

This prospectus and the information incorporated herein by reference includes trademarks, service marks and trade names owned by us or other companies. All trademarks, service marks and trade names included or incorporated by reference into this prospectus are the property of their respective owners.

Unless otherwise mentioned or unless the context requires otherwise, all references in this prospectus to GTx, we, our or similar references mean GTx, Inc.

Table of Contents

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere or incorporated by reference into this prospectus. Because it is a summary, it does not contain all of the information that you should consider before investing in our securities. You should read this entire prospectus carefully, including the section entitled Risk Factors and the documents that we incorporate by reference into this prospectus, before making an investment decision.

GTx, Inc.

We are a biopharmaceutical company dedicated to the discovery, development and commercialization of small molecules that selectively target hormone pathways to treat cancer, osteoporosis and bone loss, muscle wasting and other serious medical conditions. We are developing ACAPODENE (toremifene citrate), a selective estrogen receptor modulator, or SERM, in two separate clinical programs in men: first, a pivotal Phase III clinical trial for the treatment of multiple serious side effects of androgen deprivation therapy for advanced prostate cancer, and second, a pivotal Phase III clinical trial for the prevention of prostate cancer in high risk men with precancerous prostate lesions called high grade prostatic intraepithelial neoplasia. We have licensed to Ipsen Limited exclusive rights in the European Union, Switzerland, Norway, Iceland, Lichtenstein and the Commonwealth of Independent States to develop and commercialize ACAPODENE and other products containing toremifene in all indications that we have licensed from Orion Corporation, which include all indications in humans except the treatment and prevention of breast cancer outside of the United States. We are also developing Ostarine, a selective androgen receptor modulator, or SARM, which is currently being evaluated in a Phase II clinical trial for the treatment of muscle loss in patients with cancer. We have entered into an exclusive license and collaboration agreement with Merck & Co., Inc., or Merck, governing our and Merck s joint research, development and global commercialization of SARMs with the potential to treat age-related muscle loss (sarcopenia) as well as other musculoskeletal conditions. We also have an extensive preclinical pipeline generated from our own discovery program. We are evolving into a selective nuclear hormone receptor modulator company that develops small molecules to target hormone pathways to address a myriad of unmet medical needs in men and women.

We plan to build specialized sales and marketing capabilities to promote our product candidates to urologists and medical oncologists in the United States and to seek additional partners to commercialize our product candidates in broader markets in the United States and in the rest of the world. We currently market FARESTON (toremifene citrate 60 mg) tablets, which have been approved by the U.S. Food and Drug Administration, or FDA, for the treatment of metastatic breast cancer in postmenopausal women in the United States. The active pharmaceutical ingredient in FARESTON is the same as in ACAPODENE, but at a different dose.

We have a limited operating history and may not be able to attain profitability. We have financed our operations and internal growth primarily through private placements of preferred stock and our public offerings of common stock. We have incurred losses in each year since our inception in 1997 and we expect to continue to incur net losses over the next several years as we continue our clinical development and research and development activities, apply for regulatory approvals, expand our sales and marketing capabilities and grow our operations.

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

The Offering

Under this prospectus, the selling stockholder may, from time to time, sell up to 1,285,347 shares of our common stock in one or more offerings. We are not selling any shares of common stock under this prospectus and we will not receive any of the proceeds from the sale by the selling stockholder of the shares of common stock covered by this prospectus. See Use of Proceeds and Plan of Distribution below.

Table of Contents

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should consider carefully the risk factors described below, and all other information contained in or incorporated by reference in this prospectus, before deciding whether to buy our common stock. If any of the following risks actually occur, the market price of our common stock could decline, and you could lose all or part of your investment. Additional risks not presently known to us or that we currently believe are immaterial may also significantly impair our business operations and could result in a complete loss of your investment.

Risks Related to Our Financial Results and Need for Additional Financing

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

We have a limited operating history. As of September 30, 2007, we had an accumulated deficit of $257.3 million. We have incurred losses in each year since our inception in 1997. Net losses were $27.6 million for the nine months ended September 30, 2007, $30.8 million in 2006, $36.8 million in 2005 and $22.3 million in 2004. We expect to continue to incur significant and increasing operating losses for the foreseeable future. These losses have had and will continue to have an adverse effect on our stockholders equity and working capital.

Because of the numerous risks and uncertainties associated with developing small molecule drugs, we are unable to predict the extent of any future losses or when we will become profitable, if at all. We have primarily financed our operations and internal growth through sales of common stock and preferred stock, including $30.0 million in proceeds from the sale of our common stock to Merck & Co., Inc., or Merck, pursuant to a stock purchase agreement we entered into with Merck in November 2007. In addition, we have received up-front license fees and payments pursuant to our collaborative arrangements with third parties. FARESTON is currently our only commercial product and, we expect, will account for all of our product revenue for the foreseeable future. For the nine months ended September 30, 2007, we recognized $820,000 in net revenues from the sale of FARESTON.

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

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

We will need to raise additional capital to:

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

We estimate that our current cash resources, interest on these funds and product revenue from the sale of FARESTON, together with the proceeds from the sale of our common stock to Merck in December 2007 and the upfront licensing fee that Merck agreed to pay to us under our exclusive license and collaboration agreement with Merck, will be sufficient to meet our projected operating requirements through at least the first quarter of 2009. This estimate does not include funding from milestone payments that we may receive under our existing collaborations with Ipsen and Merck, nor does it include any funding that we may receive under potential future collaboration arrangements with other pharmaceutical companies or potential future issuances and sales of our securities. Our future funding requirements will depend on many factors, including:

- the scope, rate of progress and cost of our clinical trials and other research and development activities;
- future clinical trial results;
- the achievement of certain milestone events under, and other matters related to, our collaborative arrangements with Merck and Ipsen;

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

Table of Contents

the cost and timing of regulatory approvals;

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

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

the cost of establishing clinical and commercial supplies of our product candidates and any products that we and/or our 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 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 revenues from the sale of FARESTON.

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

Risks Related to Development of Product Candidates

We will not be able to commercialize our product candidates if our preclinical studies do not produce successful results or 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.

For example, several patients in our Phase III clinical trial of ACAPODENE 80 mg for the multiple side effects of androgen deprivation therapy have withdrawn from the trial, in accordance with the trial protocol, to seek treatment for a significant loss in bone mineral density. Even if these patients are receiving a placebo, their withdrawal from the trial may result in delays or an inability to achieve the proscribed statistical endpoint. Also, in this trial, as well as in our other clinical studies, the efficacy and/or safety results from the trial may be insufficient to support the filing or approval of a new drug application, or NDA, with the FDA.

We or our 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;

we or our 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.

Table of Contents

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

If we or our 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 or our 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 two Phase III clinical trials for ACAPODENE, some patients have experienced venous thromboembolic events, such as deep vein thromboses and pulmonary embolisms, as well as myocardial infarctions, or heart attacks, one of which resulted in a patient s death, which were considered by investigators as possibly related to treatment with ACAPODENE. Because these trials are blinded, we cannot establish whether these patients received placebo or ACAPODENE in the trials. There have been no drug-related serious adverse events related to our other product candidates. In addition, in our Phase II clinical trial for Ostarine, 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 these events increases in number or severity, if a regulatory authority believes that these events constitute an adverse effect caused by the drug, or if other effects are identified during clinical trials that we are currently conducting, during clinical trials that we or our collaborators may conduct in the future or after any of our product candidates are approved and marketed:

- we or our 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.

Table of Contents

Risks Related to Our Dependence on Third Parties

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 and our ability to develop product candidates and commercialize any product candidates on a timely and competitive basis.

We have agreed to purchase from Orion Corporation, or Orion, our worldwide requirements of toremifene, the active pharmaceutical ingredient in ACAPODENE, in a finished tablet form at specified transfer prices under a license and supply agreement. Similarly, Ipsen has agreed to purchase from Orion ACAPODENE tablets for clinical testing and commercial sale in the European Union, Switzerland, Norway, Iceland, Lichtenstein and the Commonwealth of Independent States, which we refer to collectively as the European Territory, under an amended supply agreement with Orion. As such, both we and Ipsen rely on Orion as the single source supplier of ACAPODENE.

In the event that Orion terminates our license and supply agreement due to our uncured material breach or bankruptcy, we would not be able to manufacture ACAPODENE until the expiration of Orion s patents with respect to the composition of matter of toremifene, the active pharmaceutical ingredient in ACAPODENE. Although Orion s composition of matter patents within the European Territory have expired, and as such, would not prevent Ipsen from manufacturing ACAPODENE within the European Territory, there is no obligation on the part of Orion to transfer its manufacturing technology to Ipsen or to assist Ipsen in developing manufacturing capabilities to meet Ipsen s supply needs if Ipsen is in material breach of its supply agreement with Orion. Although we and Ipsen have agreed to collaborate with each other in the event either of our supply rights are terminated by Orion for any reason, a disruption in the supply of ACAPODENE could delay the development of and impair our and Ipsen s ability to commercialize ACAPODENE. In addition, Orion may terminate its obligation to supply us and Ipsen with toremifene if Orion ceases its manufacture of toremifene permanently, or Orion may terminate its obligation to supply us with toremifene if ACAPODENE is not approved for commercial sale in the United States prior to December 31, 2009. If such termination occurs because Orion is no longer manufacturing toremifene, or because such regulatory approval is not obtained prior to the specified date, we and Ipsen will have the right to manufacture ACAPODENE, but any arrangements we make for an alternative supply would still have to be made with a qualified alternative supplier with appropriate FDA approval in order for us to obtain our supply requirements for ACAPODENE. We and Ipsen have mutually agreed to cooperate in the manufacture of ACAPODENE in the event Orion ceases manufacture of toremifene for any of the above-mentioned reasons.

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

We have relied on third party vendors for Ostarine. We recently executed agreements with third party contractors for the manufacture of Ostarine drug substance and the supply of Ostarine drug product for our Phase II clinical trial for the treatment of muscle loss in patients with cancer. However, Merck has assumed primary manufacturing responsibilities for Ostarine and other SARM products developed under our exclusive license and collaboration agreement with Merck. If our current supply of Ostarine becomes unusable or if our Ostarine supply is not sufficient to complete our clinical trials and Merck does not manufacture and supply sufficient quantities of clinical trial materials to support our clinical trials, we could experience a delay in conducting 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 relationships with Orion for ACAPODENE and Merck for Ostarine and other SARM product candidates, or to do so at an acceptable cost, or if these 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. However, we may not be permitted to obtain alternate suppliers for ACAPODENE under our license agreement with Orion if Orion terminates its supply of ACAPODENE due to our uncured material breach or bankruptcy. Any inability to obtain alternate suppliers, including an inability to obtain approval from the FDA of an alternate supplier, would delay or prevent the clinical development and commercialization of these product candidates.

Table of Contents

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:
  - if it permanently ceases manufacture of toremifene or if we do not obtain regulatory approval of ACAPODENE in the United States prior to December 31, 2009; or
  - if Orion terminates due to our uncured material breach or bankruptcy.

If we are not able to obtain adequate supplies of our product candidates, it will be more difficult for us to develop our product candidates and compete effectively. Our product candidates and any products that we and/or our collaborators may develop may compete with other product candidates and products for access to manufacturing facilities. For example, the active pharmaceutical ingredient in ACAPODENE is also the active pharmaceutical ingredient in FARESTON. Further, Orion has agreed to supply ACAPODENE tablets to Ipsen for clinical trials and commercial supply in the European Territory. Orion also manufactures toremifene for third parties for sale outside the United States for the treatment of advanced breast cancer in postmenopausal women.

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

We are dependent on our collaborative arrangement with Ipsen to develop and commercialize ACAPODENE in the European Territory and are dependent on our collaborative arrangement with Merck for the joint research, development and commercialization of SARM compounds and products. 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 or Merck as a collaborator in the development or commercialization of ACAPODENE or SARM compounds and related SARM products, respectively, any dispute over the terms of our collaborations with Ipsen or Merck, or any other adverse developments in our relationships with Ipsen or Merck could materially harm our business and might accelerate our need for additional capital. For example, Ipsen is obligated to initiate and conduct appropriate clinical studies as required by the appropriate regulatory authorities in order to obtain marketing approvals of ACAPODENE within the European Territory. Any failure on the part of Ipsen to initiate these studies could delay the commercialization of ACAPODENE within the European Territory. Likewise, with the exception of our Phase II clinical trial evaluating Ostarine for the treatment of muscle loss in patients with cancer, Merck is responsible for conducting all clinical trials for SARM product candidates developed under the collaboration, and the failure of Merck to initiate these clinical trials would adversely affect the development of our SARM product candidates.

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

Dependence on collaborative arrangements, including our arrangements with Ipsen and Merck for the development and commercialization of ACAPODENE and SARM compounds and products, respectively, subjects us to a number of risks, including:

- we are not able to control either the amount and timing of resources that Ipsen devotes to ACAPODENE or the amount of timing and resources that Merck devotes to SARM compounds and products developed under our collaboration with Merck;

Table of Contents

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

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

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

under certain circumstances, Ipsen may not be required to commercialize ACAPODENE 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 ACAPODENE in some or all of the countries within the European Territory;

should a collaborator fail to develop or commercialize one of our compounds or product candidates, we may not receive any future milestone payments and will not receive any royalties for 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, 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 arrangements with Ipsen and Merck.

We may not receive any future milestone payments provided for under our collaborative arrangements with Ipsen and Merck if our agreements with them are terminated, if certain clinical development and regulatory milestones under our agreements with them are not achieved, with respect to our agreement with Ipsen, if Ipsen fails to develop and commercialize ACAPODENE in the European Territory, or, with respect to our agreement with Merck, if we and Merck fail to develop and commercialize any of the SARMs included in or arising from our collaboration. In addition, even if required regulatory approvals are obtained, it is possible that neither Ipsen nor Merck will successfully market and sell ACAPODENE or any SARM products, respectively, 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 each of Ipsen and Merck may be entitled to offset a portion of any royalties due to us if Ipsen or Merck licenses patent rights from a third party that would otherwise be infringed by Ipsen s or Merck s use, manufacture, sale or import of toremifene or SARM compounds, respectively.

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 ACAPODENE within the European Territory. We and Ipsen have also agreed to grant to the other a right of first negotiation with respect to the development, marketing, sale and distribution of any new SERM-based products for the field of the prevention and treatment of prostate cancer or related side effects, or any other indication the parties agree on. However, we cannot assure you that we will be able to reach an agreement with Ipsen on reasonable terms, or at all, for any new SERM-based products.

Under our agreement with Merck, we and Merck have agreed that neither party will engage in the development and commercialization of SARMs with any third party for an agreed upon period of time. However, we cannot assure you that we and Merck will be able to successfully develop new SARM products or identify new indications for existing and/or future SARM products under our collaboration with Merck. Additionally, Merck has the right to terminate our

agreement with Merck for any reason after a specified period of time with prior written notice, and Ipsen has the right to terminate our agreement with Ipsen 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. Both Ipsen and Merck may terminate their agreements with us following our uncured material breach or bankruptcy. If our agreements with Ipsen and Merck are terminated, the anticipated future benefits to us from these agreements would be eliminated, the development and commercialization of ACAPODENE in the European Territory and the development and commercialization of our SARM product candidates could be delayed, and our costs of development would increase. For example, Merck s obligation to pay us $15.0 million in guaranteed cost reimbursements for research funding over a three year period is subject to our exclusive license and collaboration agreement with Merck not being terminated for cause and there not occurring certain change of control events involving

Table of Contents

us during such three-year period. In any such or similar events, we may not realize the anticipated benefits from our collaborative arrangements with Ipsen and Merck.

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

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

Risks Related to Our Intellectual Property

Our license agreement with Orion excludes the use of toremifene in humans to treat breast cancer outside the United States and may limit our ability to market ACAPODENE for human uses of toremifene outside the United States.

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

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

Furthermore, we and our affiliates are prohibited from marketing or selling products containing toremifene or related SERM compounds for human use in the United States and other major countries located outside the European Union during the term of Orion s patents covering toremifene in such countries, which in the United States expire in September 2009. The binding effect of this noncompetition provision on us and our affiliates may make it more difficult for us to be acquired by some potential buyers during the relevant time periods even if we determine that a sale of the company would be in the best interests of our stockholders.

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

Our commercial success will depend in part on obtaining and maintaining patent and trade secret protection for our product candidates, the methods for treating patients in the product indications using these product candidates and the methods used to synthesize these product candidates. We will be able to protect our product candidates and the methods for treating patients in the product indications using these product candidates from unauthorized use by third parties only to the extent that we or our exclusive licensors own or control such valid and enforceable patents or trade secrets. Additionally, Ipsen s ability to successfully market ACAPODENE within a substantial portion of the European Territory may depend on 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 the University of Tennessee Research Foundation, or 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, which UTRF is required to do at

our request. In addition, under the terms of our agreements with the diagnostic companies to which we provide clinical samples from our Phase IIb and Phase III clinical trials of

Table of Contents

ACAPODENE, we will not obtain any intellectual property rights in any of their developments, including any test developed to detect high grade PIN or prostate cancer.

Even if our product candidates and the methods for treating patients for prescribed indications using these product candidates are covered by valid and enforceable patents and have claims with sufficient scope and support in the specification, the patents will provide protection only for a limited amount of time. For example, the patent that we have licensed from Orion covering the composition of matter of toremifene expires in the United States in September 2009. Foreign counterparts of this patent have either already expired or will expire in Australia, Italy, Sweden and Switzerland in 2008, that is, before we or Ipsen will receive regulatory approval to commercialize ACAPODENE. As a result, outside the United States and in the United States after 2009, we will need to rely primarily on the protection afforded by method of use patents relating to the use of ACAPODENE for the relevant product indications that have been issued or may be issued from our owned or licensed patent applications. Also, within the European Union, Ipsen may need to rely primarily on the protection afforded by marketing and data exclusivity for the ACAPODENE products to be sold within the countries comprising the European Union. To date, most of our applications for method of use patents filed for ACAPODENE outside of the United States are still pending and have not yielded issued patents. Although we intend to apply, if appropriate, for extensions of patent terms under applicable United States laws pertaining to our method of use patents, we may not be able to secure any such regulatory exclusivity or extension of patent term. Loss of marketing and data exclusivity for the ACAPODENE products to be commercialized within the European Union could adversely affect its ability to successfully commercialize these products, and our failure to obtain any extension of patent terms for our method of use patents could adversely affect our prospects for protecting our ACAPODENE products from competitive pressures in the United States for the time periods we currently expect. We are not eligible for any such exclusivity or further extension of the composition of matter patent of toremifene licensed to us by Orion in the United States.

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

Even if patents are issued to us or our licensors regarding our product candidates or methods of using them, those patents can be challenged by our competitors who can argue such patents are invalid or unenforceable or that the claims of the issued patents should be limited or narrowly construed. Patents also will not protect our product candidates if competitors devise ways of making or using these product candidates without legally infringing our patents. The Federal Food, Drug, and Cosmetic Act and FDA regulations and policies create a regulatory environment that encourages companies to challenge branded drug patents or to create noninfringing versions of a patented product in order to facilitate the approval of abbreviated new drug applications for generic substitutes. These same types of incentives encourage competitors to submit new drug applications that rely on literature and clinical data not prepared for or by the drug sponsor, providing another less burdensome pathway to approval.

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

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

We have licensed intellectual property rights and technology from Orion and UTRF under our license agreements with each of them. Each of these license agreements may be terminated by the other party if we are in breach of our obligations under, or fail to perform any terms of, the agreement and fail to cure that breach. If any of these agreements were terminated, then we may lose our rights to utilize the technology and intellectual property covered by that agreement to market, distribute and sell our licensed products, which may prevent us from continuing our business. Additionally, the termination of our UTRF license related to SARM technology

Table of Contents

could lead to a termination of our exclusive license and collaboration agreement with Merck, which would terminate our rights to any potential milestone or royalty payments from Merck.

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

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

Even in the event that patents are issued from our pending method of use patent applications, after the expiration of the patent covering the composition of matter of toremifene in a particular country, competitors could market and sell toremifene products for uses for which FARESTON has already been approved. Thus, physicians in such countries would be permitted to prescribe these other toremifene products for indications that are protected by our method of use patents or patents issuing from pending patent applications, even though these other toremifene products would not have been approved for those uses, and in most cases, the physician would not be liable for contributing to the infringement of our patents. Moreover, because Orion has licensed and could further license other parties to market, sell and distribute toremifene for breast cancer outside the United States, physicians in such countries could prescribe these products sold pursuant to another Orion license off-label. This further increases the risk of off-label competition developing for ACAPODENE for the indications for which we and Ipsen are developing this product candidate. In addition, if no patents are issued with respect to our pending method of use patent applications related to the use of ACAPODENE in the countries outside of the United States where these applications are currently pending, after the expiration of the patent covering the composition of matter of toremifene in a particular country, we would have no patent to prevent competitors from marketing and selling generic versions of toremifene at doses and in formulations equivalent to ACAPODENE for the indications covered by our pending method of use patent applications. Also, regulatory authorities may not recognize marketing and data exclusivity for ACAPODENE in the European Union for the treatment of prostate cancer and the multiple side effects resulting from androgen deprivation therapy. If generic versions of toremifene are able to be sold in countries within the European Territory for the indications for which Ipsen anticipates marketing ACAPODENE, the royalties to be paid to us by Ipsen will be reduced if the total generic sales exceed a certain threshold for a certain period of time. Similarly, the royalties we will be paying to Orion for its licensing and supply of toremifene will be reduced if generic sales thresholds are reached.

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

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

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

be prohibited from selling or licensing any product that we and/or collaborators may develop unless the patent holder licenses the patent to us, which the patent holder is not required to do;

Table of Contents

be required to pay substantial royalties or grant a cross license to our patents to another patent holder; or

be required to redesign the formulation of a product candidate so it does not infringe, which may not be possible or could require substantial funds and time.

In addition, under our collaboration and license agreement with Ipsen and our exclusive license and collaboration agreement with Merck, Ipsen and Merck 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 or Merck 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 or our collaborators are not able to obtain required regulatory approvals, we or our collaborators will not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired.

Our product candidates and the activities associated with their development and commercialization are subject to comprehensive regulation by the FDA, 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 our collaborators from commercializing the product candidate. We have not received regulatory approval to market any of our product candidates in any jurisdiction and have only limited experience in preparing and filing the applications necessary to gain regulatory approvals. In addition, we will not receive a substantial majority of the milestone payments provided under our collaboration and license agreement with Ipsen or any royalty payments if Ipsen is unable to obtain the necessary regulatory approvals to commercialize ACAPODENE within the European Territory. Likewise, we may not receive a majority of the milestone payments or any royalty payments provided for under our exclusive license and collaboration agreement with Merck if Merck is not able to obtain the necessary regulatory approvals to commercialize any SARM products, including Ostarine, developed under the collaboration. 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 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 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 require the adoption of risk management plans, referred to in the FDA Amendments Act as risk evaluation and mitigation strategies, or REMS. The REMS may include requirements for special labeling or medication guides for patients, special communication plans to healthcare professionals, and restrictions on distribution and use. The FDA also may impose various civil or criminal sanctions for failure to comply with regulatory requirements, including withdrawal of product approval.

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

The FDA has substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. For example, we are conducting our Phase III clinical trials of ACAPODENE to treat the side effects of androgen deprivation therapy and for the prevention of prostate cancer in high risk men with high grade prostatic intraepithelial neoplasia, or high grade PIN, under Special Protocol Assessments, or SPAs, from the FDA. An 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, an 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 an NDA. However, there are circumstances under which we may not receive the benefits of an SPA, notably if the FDA subsequently identifies a substantial scientific issue essential to determining the

Table of Contents

product s safety or efficacy. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate. Furthermore, even if we file an application with the FDA for marketing approval of a product candidate, it may not result in marketing approval from the FDA.

We may not receive regulatory approval for the commercial sale of any of our product candidates that are in development for at least another year, if ever. Similarly, it is not anticipated that Ipsen will receive the appropriate regulatory approvals to market ACAPODENE within the European Territory any sooner than we will achieve regulatory approval in the United States, and it may be thereafter. The inability to obtain FDA approval or approval from comparable authorities in other countries for our product candidates would prevent us or our collaborators from commercializing these product candidates in the United States or other countries. See the section entitled Business Government Regulation under Part I, Item 1 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2006 filed with the Securities and Exchange Commission 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 and/or our collaborators may develop will depend upon the degree of market acceptance among physicians, patients, healthcare payors and the medical community.

Any products that we and/or our 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:

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.

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

FARESTON is currently our only marketed product. Sales of FARESTON in the United States have been declining and we anticipate that they will continue to do so. Sales of pharmaceuticals for breast cancer in the SERM class have declined in recent years as aromatase inhibitors have gained market share. We believe that aromatase inhibitors will continue to capture breast cancer market share from SERMs, including from FARESTON, resulting in a continued decline in FARESTON sales. 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 accounted for approximately 93% of our revenue generated from the sale of FARESTON for the nine months ended September 30, 2007;

the continued success of competing products, including aromatase inhibitors;

the loss of coverage or reimbursement for FARESTON from Medicare and Medicaid, private health insurers or other third-party payors;

exposure to product liability claims related to the commercial sale of FARESTON, which may exceed our product liability insurance;

Table of Contents

the failure of Orion to maintain regulatory filings or comply with applicable FDA requirements with respect to FARESTON;

the ability of third parties to market and sell generic toremifene products that will compete with FARESTON for the treatment of breast cancer after the composition of matter patents that we license from Orion expire in the United States in September 2009;

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

our inability to manufacture FARESTON until Orion s patents with respect to the composition of matter of toremifene expire if Orion terminates our license and supply agreement due to our uncured material breach or bankruptcy.

If we are unable to expand our sales and marketing capabilities or 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. For example, building a sales force is expensive and time-consuming and could delay any launch of a product candidate. We are relying on Ipsen to market and distribute our ACAPODENE product candidates through Ipsen s established sales and marketing network within the European Territory. If our collaboration and license agreement with Ipsen is terminated for any reason, our ability to sell our ACAPODENE product candidates in the European Territory would be adversely affected, and we may be unable to develop or engage an effective sales force to successfully market and sell our ACAPODENE product candidates in the European Territory. 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. Similarly, we are relying on Merck for the commercialization of any SARM products developed under our collaboration with Merck and if our exclusive license and collaboration agreement with Merck is terminated for any reason, our ability to successfully market and sell any of our SARM product candidates would be adversely affected, and we may be unable to develop or engage an effective sales force to successfully market and sell any SARM products that we may develop, including Ostarine. 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 or our 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 and/or our 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 and/or our 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 or our collaborators are able to charge for products we and/or our 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 and/or our 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 12 months or longer after the receipt of regulatory marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we or our collaborators may be required to conduct a clinical trial that compares the cost effectiveness of our product candidates or products to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in our 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 and/or our collaborators may develop or sell. Cost-control initiatives could decrease

Table of Contents

the price we might establish for products that we or our 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 or our collaborators receive for any products that we and/or our collaborators may develop, negatively affecting our revenues and prospects for profitability.

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 $25.0 million annual aggregate limit. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost and we may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise.

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

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

Various products are currently marketed or used off-label for some of the diseases and conditions that we are targeting, and a number of companies are or may be developing new treatments. These product uses, as well as promotional efforts by competitors and/or clinical trial results of competitive products, could significantly diminish our or our collaborators ability to market and sell any products that we and/or our collaborators may develop. For example, although there are no products that have been approved by the FDA to treat multiple side effects of androgen deprivation therapy, we are aware of a number of drugs marketed by Eli Lilly (Evista®), Merck (Fosamax®), Sanofi-Aventis and Procter & Gamble (Actonel®), Wyeth Pharmaceuticals (Effexor®), Boehringer Ingelheim (Catapres®), Novartis (Zometa®) and Bristol Myers Squibb (Megace®) that are prescribed to treat single side effects

of androgen deprivation therapy; that external beam radiation and tamoxifen are used to treat breast pain and enlargement; and that Amgen is developing a product candidate for the treatment of osteoporosis in prostate cancer patients. While we have the only pharmaceutical product in clinical development to prevent prostate cancer in high risk men with high grade PIN, GlaxoSmithKline is conducting a Phase III study for Avodart® on prostate cancer prevention in men with elevated prostate specific antigen. In addition,

Table of Contents

there are nutritional supplement studies (for example, selenium) investigating prostate cancer prevention in men with high grade PIN. Similarly, while there are no drugs that have been approved by the FDA for the treatment of muscle wasting from cancer, there are drugs marketed by Steris Laboratories and Savient Pharmaceuticals that are being prescribed off-label for the treatment of some types of muscle wasting from cancer. Testosterone and other anabolic agents are used to treat involuntary weight loss in patients who have acute muscle wasting. Also, Ligand Pharmaceuticals has announced that it is conducting preclinical studies in order to initiate clinical trials for a SARM product candidate in 2008. In addition, there are other SARM product candidates at an earlier stage of development that may compete with our product candidates. Wyeth and Amgen have myostatin inhibitors in development which may compete for similar patients as Ostarine. This could result in reduced sales and pricing pressure on our product candidates, if approved, which in turn would reduce our ability to generate revenue and have a negative impact on our results of operations.

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

Risks Related to Employees and Growth

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

Our success depends on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel and on our ability to develop and maintain important relationships with leading academic institutions, clinicians and scientists. If we are not able to attract and keep senior management and key scientific personnel, particularly Dr. Mitchell S. Steiner, we may not be able to successfully develop or commercialize our product candidates. All of our employees are at-will employees and can terminate their employment at any time. We do not carry key person insurance covering members of senior management, other than $25 million of insurance covering Dr. Steiner.

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

In order to continue our clinical trials and commercialize our product candidates, we will need to expand the number of our managerial, operational, financial and other employees. We currently anticipate that we will need between 150 and 250 additional employees by the time that ACAPODENE is initially commercialized, including 50 to 100 sales representatives. The competition for qualified personnel in the biotechnology field is intense.

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

Risks Related to Our Common Stock

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

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

- adverse results or delays in our clinical trials;
- the timing of achievement of our and our 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;

Table of Contents

actions taken by regulatory agencies with respect to our product candidates or products, our clinical trials or our sales and marketing activities;

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

developments with respect to our collaborations with Ipsen and Merck;

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

regulatory developments in the United States and foreign countries;

changes in the structure of health care payment systems;

any intellectual property infringement lawsuit involving us;

announcements of technological innovations or new products by us or our competitors;

market conditions for the biotechnology or pharmaceutical industries in general;

actual or anticipated fluctuations in our results of operations;

changes in financial estimates or recommendations by securities analysts;

sales of large blocks of our common stock;

sales of our common stock by our executive officers, directors and significant stockholders;

changes in accounting principles; and

the loss of any of our key scientific or management personnel.

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

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

As of September 30, 2007, our officers, directors and holders of 5% or more of our outstanding common stock (based upon public filings) beneficially owned approximately 82.1% of our outstanding common stock and our officers and directors alone owned approximately 49.6% of our outstanding common stock. As a result, these stockholders, acting together, will be able to control all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with our interests or the interests of other stockholders.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

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

a classified Board of Directors;

a prohibition on actions by our stockholders by written consent;

Table of Contents

the ability of our Board of Directors to issue preferred stock without stockholder approval, which could be used to institute a poison pill that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our Board of Directors; and

limitations on the removal of directors.

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

A significant portion of our total outstanding shares are restricted from immediate resale but may be sold into the market in the near future. This could cause the market price of our common stock to drop significantly, even if our business is doing well.

For the 12-month period ended September 30, 2007, the average daily trading volume of our common stock on the NASDAQ Global Market was approximately 145,811 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 18, 2007, we had 36,216,263 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 10.9 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. In addition, we filed a registration statement of which this prospectus is a part covering the 1,285,347 shares of common stock that we issued to Merck in December 2007. Finally, all shares of common stock that we may issue under our employee benefit plans can be freely sold in the public market upon issuance.

FORWARD-LOOKING STATEMENTS

This prospectus, including the information that we incorporate by reference, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements involve known and unknown risks, uncertainties and other important 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 and our collaborators research, development and clinical programs, including whether future clinical trials will achieve similar results to clinical trials that we have successfully concluded;

potential future licensing fees, milestone payments and royalty payments, including any milestone payments or royalty payments that we may receive under our collaborative arrangements with Ipsen Limited and Merck & Co., Inc.;

our and our collaborators ability to market, commercialize and achieve market acceptance for our product candidates or products that we and/or our collaborators may develop;

our and our collaborators 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 expressi identify forward-looking statements. Forward-looking statements reflect our current views with respect to future events, are based on assumptions and are subject to risks, uncertainties and other important factors. We discuss many of these risks, uncertainties and other important factors in greater detail under the heading Risk Factors contained in this prospectus, and in our most recent annual report on Form 10-K and in our most recent quarterly report on Form 10-Q, as well as any amendments thereto reflected in subsequent

Table of Contents

filings with the SEC. Given these risks, uncertainties and other important factors, you should not place undue reliance on these forward-looking statements. Also, these forward-looking statements represent our estimates and assumptions only as of the date such forward-looking statements are made. You should carefully read this prospectus together with the information incorporated herein by reference as described under the heading Where You Can Find Additional Information, 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 why actual results could differ materially from those anticipated in any forward-looking statements, even if new information becomes available in the future.

USE OF PROCEEDS

We will not receive any of the proceeds from the sale of shares of our common stock by the selling stockholder pursuant to this prospectus. The selling stockholder will receive all of the proceeds from the sale of the shares of common stock covered by this prospectus. For information about the selling stockholder, see Selling Stockholder.

SELLING STOCKHOLDER

The shares of common stock covered by this prospectus consist of 1,285,347 shares of common stock that we issued and sold to the selling stockholder in a private placement on December 18, 2007. In connection with the issuance and sale of these shares to the selling stockholder, we entered into a registration rights agreement with the selling stockholder. The registration statement of which this prospectus is a part has been filed pursuant to the registration rights agreement. We are registering the shares of common stock issued to the selling stockholder to permit the resale of these shares by the selling stockholder from time to time after the date of this prospectus.

The following table presents information regarding Merck & Co., Inc., or Merck, as the selling stockholder, and the shares that it may offer and sell from time to time under this prospectus. This table is prepared based on information supplied to us by Merck and reflects holdings as of December 18, 2007. As used in this prospectus, the term selling stockholder includes Merck and any donees, pledgees, transferees or other successors-in-interest selling shares received after the date of this prospectus from the selling stockholder as a gift, pledge or other non-sale related transfer. The number of shares in the column titled Number of Shares of Common Stock Being Offered represents all of the shares that the selling stockholder may offer under this prospectus. The selling stockholder may sell some, all or none of its shares. We do not know how long the selling stockholder will hold the shares before selling them, and we currently have no agreements, arrangements or understandings with the selling stockholder regarding the sale of any of the shares.

Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to the shares indicated in the table below. The information regarding shares to be beneficially owned after the offering assumes the sale of all shares offered by the selling stockholder. The percentage ownership data is based on 36,216,263 shares of our common stock actually outstanding as of December 18, 2007, which includes the 1,285,347 shares of our common stock covered by this prospectus.

	Shares of Common Stock Beneficially Owned Prior to Offering		Number of Shares of Common Stock Being Offered	Shares of Common Stock to be Beneficially Owned After Offering	
Name of Selling Stockholder	**Number**	**Percent**		**Number**	**Percent**
Merck & Co., Inc.	1,285,347	3.5%	1,285,347		%

Relationship with the Selling Stockholder

On November 5, 2007, we entered into an exclusive license and collaboration agreement with Merck governing our and Merck s joint research, development and commercialization of selective androgen receptor modulator, or SARM, compounds and related SARM products, including SARMs currently being developed by us and Merck and those yet to be discovered, for all potential indications of interest. Pursuant to the agreement, we granted Merck an exclusive worldwide license under our SARM-related patents and know-how. Under the agreement, we will conduct preclinical

research of SARM compounds and products, and Merck will be responsible for conducting and funding development and commercialization of products developed under the agreement. Merck agreed to pay us an upfront licensing fee of $40.0 million and Merck also agreed to pay us $15.0 million in guaranteed three-year cost

Table of Contents

reimbursements for research funding (provided that with respect to Merck s obligations for such cost reimbursements, the agreement is not terminated for cause and there does not occur certain change of control events involving us during such three-year period). We are eligible to receive under the agreement up to $422.0 million in future milestone payments associated with the development and regulatory approval of a lead product candidate as defined in the agreement (including Ostarine), if multiple indications are developed and receive required regulatory approvals, as well as additional milestone payments for the development and regulatory approval of other product candidates developed under the agreement, in all cases assuming the achievement of such development and regulatory approval milestones and assuming the continued effectiveness of the agreement. Merck also has agreed to pay us tiered royalties on net sales of products that may be developed under the agreement.

With the exception of the foregoing, the selling stockholder has not had any position, office or other material relationship with us or our affiliates.

PLAN OF DISTRIBUTION

We are registering the shares of common stock issued to the selling stockholder to permit the resale of these shares by the selling stockholder from time to time after the date of this prospectus. The term selling stockholder includes donees, pledgees, transferees or other successors-in-interest selling shares received after the date of this prospectus from the selling stockholder as a gift, pledge or other non-sale related transfer. The selling stockholder will act independently of us in making decisions with respect to the timing, manner and size of each sale. Such sales may be made on one or more exchanges or in the over-the-counter market or otherwise, at prices and under terms then prevailing or at prices related to the then current market price or in negotiated transactions. The selling stockholder may sell its shares by one or more of, or a combination of, the following methods:

- purchases by a broker-dealer as principal and resale by such broker-dealer for its own account pursuant to this prospectus;
- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer so engaged will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- an over-the-counter distribution;
- in privately negotiated transactions;
- through the settlement of short sales;
- through the writing or settlement of options or other hedging transactions, whether such options are listed on an options exchange or otherwise;
- a combination of any such methods of sale; and
- any other method permitted pursuant to applicable law.

In addition, the selling stockholder also may resell all or a portion of the shares in open market transactions in reliance upon Rule 144 under the Securities Act, as permitted by that rule, or Section 4(1) under the Securities Act, if available, rather than under this prospectus, provided that the selling stockholder meets the criteria and conforms to the requirements of those provisions.

Broker-dealers engaged by the selling stockholder may arrange for other broker-dealers to participate in sales. If the selling stockholder effects such transactions by selling shares of common stock to or through underwriters, broker-dealers or agents, such underwriters, broker-dealers or agents may receive commissions in the form of discounts, concessions or commissions from the selling stockholder or commissions from purchasers of the shares of common stock for whom they may act as agent or to whom they may sell as principal. Such commissions will be in

amounts to be negotiated, but, except as set forth in a supplement to this prospectus, in the case of an agency transaction, will not be in excess of a customary brokerage commission in compliance with FINRA Rule 2440; and in the case of a principal transaction a markup or markdown in compliance with FINRA IM-2440-1.

In connection with distributions of the shares of common stock or otherwise, the selling stockholder may enter into hedging transactions with broker-dealers or other financial institutions. In connection with such transactions, broker-dealers or other financial institutions may engage in short sales of the common stock in the course of hedging the positions they assume with the selling stockholder. The selling stockholder may also sell the common stock short and if such short sale shall take place after the date that the registration statement of which this prospectus is a part is declared effective by the SEC, the selling stockholder may deliver shares of

Table of Contents

common stock covered by this prospectus to close out short positions and to return borrowed shares in connection with such short sales. The selling stockholder may also enter into option or other transactions with broker-dealers or other financial institutions which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction). The selling stockholder may also pledge shares to a broker-dealer or other financial institution, and, upon a default, such broker-dealer or other financial institution may effect sales of the pledged shares pursuant to this prospectus (as supplemented or amended to reflect such transaction).

In offering the shares of common stock covered by this prospectus, the selling stockholder and any broker-dealers or agents participating in the distribution of the shares may be deemed to be underwriters within the meaning of the Securities Act in connection with such sales. In such event, any commissions paid, or any discounts or concessions allowed to, any such broker-dealer or agent and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. To the extent that the selling stockholder may be deemed to be an underwriter, the selling stockholder will be subject to the prospectus delivery requirements of the Securities Act and may be subject to certain statutory liabilities of, including but not limited to, Sections 11, 12 and 17 of the Securities Act and Rule 10b-5 under the Securities Exchange Act of 1934, as amended, or the Exchange Act.

The selling stockholder has informed us that it is not a registered broker-dealer and does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the common stock. Upon us being notified in writing by the selling stockholder that any material arrangement has been entered into with a broker-dealer for the sale of common stock through a block trade, special offering, exchange distribution or secondary distribution or a purchase by a broker or dealer, a supplement to this prospectus will be filed, if required, pursuant to Rule 424(b) under the Securities Act, disclosing:

the name of the participating broker-dealer(s);

the number of shares involved;

the price at which such shares of common stock were sold;

the commissions paid or discounts or concessions allowed to such broker-dealer(s), where applicable;

that such broker-dealer(s) did not conduct any investigation to verify the information set out or incorporated by reference in this prospectus; and

other facts material to the transaction.

In no event shall any broker-dealer receive fees, commissions and markups, which, in the aggregate, would exceed eight percent.

In order to comply with the securities laws of some states, if applicable, the shares must be sold in those states only through registered or licensed brokers or dealers. In addition, some states may restrict the selling stockholder from selling its shares unless the shares have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

We have advised the selling stockholder that the anti-manipulation rules of Regulation M under the Exchange Act may apply to sales of shares in the market and to the activities of the selling stockholder and its affiliates, which may limit the timing of purchases and sales of any of the shares of common stock by the selling stockholder and any other participating person. Regulation M may also restrict the ability of any person engaged in the distribution of the shares of common stock to engage in market-making activities with respect to the shares of common stock. All of the foregoing may affect the marketability of the shares of common stock and the ability of any person or entity to engage in market-making activities with respect to the shares of common stock.

We will make copies of this prospectus available to the selling stockholder for the purpose of satisfying the prospectus delivery requirements of the Securities Act. We will pay all expenses of the registration of the shares of common stock pursuant to the registration rights agreement we entered into with the selling stockholder, including, without limitation, SEC filing fees and expenses of compliance with state securities or blue sky laws; *provided, however*, that the selling stockholder will pay all underwriting discounts and selling commissions, if any, and any legal expenses incurred by it. We will indemnify the selling stockholder against certain liabilities, including some liabilities under the Securities Act, in accordance with the registration rights agreement, or the selling stockholder will be entitled to contribution. We may be indemnified by the selling stockholder against certain liabilities, including some liabilities under the Securities Act, that may arise from any written information furnished to us by or behalf of the

Table of Contents

selling stockholder expressly for use in this prospectus, in accordance with the registration rights agreement, or we may be entitled to contribution.

We have agreed with the selling stockholder to cause the registration statement of which this prospectus is a part to remain effective until such time as all of the shares covered by this prospectus (a) are eligible to be sold pursuant to Rule 144 under the Securities Act during any ninety 90-day period, (b) have been sold pursuant to an effective registration statement or pursuant to Rule 144 under the Securities Act or (c) have been sold, transferred or otherwise disposed of to any person not entitled to the registration rights under the registration rights agreement, but in any event for no longer than the period ending on the later of December 18, 2009 or the end of the first 90-day period following December 18, 2007 during which all shares covered by this prospectus may be sold pursuant to Rule 144 under the Securities Act. Our obligation to cause the registration statement of which this prospectus is a part to remain effective may terminate earlier in the event of certain change in control events involving us, subject to certain conditions.

LEGAL MATTERS

The validity of the shares being offered by this prospectus will be passed upon by Cooley Godward Kronish LLP, Palo Alto, California.

EXPERTS

Ernst & Young LLP, independent registered public accounting firm, has audited our financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2006, and management s assessment of the effectiveness of our internal control over financial reporting as of December 31, 2006, as set forth in their reports, which are incorporated by reference in this prospectus and elsewhere in the registration statement. Our financial statements and management s assessment are incorporated by reference in reliance on Ernst & Young LLP s reports, given on their authority as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We file annual, quarterly and special reports, proxy statements and other information with the SEC. You may read and copy any document we file at the SEC s Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the public reference room. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC, including GTx, Inc. The SEC s Internet site can be found at www.sec.gov.

The SEC allows us to incorporate by reference the information we file with it, which means that we can disclose important information to you by referring you to another document that we have filed separately with the SEC. You should read the information incorporated by reference because it is an important part of this prospectus. We incorporate by reference the following information or documents that we have filed with the SEC (Commission File No. 0-50549):

- our current report on Form 8-K filed with the SEC on February 26, 2007;
- our annual report on Form 10-K for the year ended December 31, 2006 filed with the SEC on March 9, 2007 (the 2006 10-K);
- the information specifically incorporated by reference into our 2006 Form 10-K from our definitive proxy statement on Schedule 14A filed with the SEC on March 14, 2007;
- our current report on Form 8-K filed with the SEC on April 17, 2007;
- our quarterly report on Form 10-Q for the quarter ended March 31, 2007 filed with the SEC on May 7, 2007;
- our current report on Form 8-K filed with the SEC on July 3, 2007;
- our current report on Form 8-K filed with the SEC on July 12, 2007;

our current report on Form 8-K filed with the SEC on July 26, 2007;

our current report on Form 10-Q for the quarter ended June 30, 2007 filed with the SEC on August 1, 2007;

Table of Contents

our current reports on Form 8-K filed with the SEC on November 6, 2007 (except for the information furnished under Item 2.02 or any related exhibit);

our current report on Form 10-Q for the quarter ended September 30, 2007 filed with the SEC on November 9, 2007;

our current report on Form 8-K filed with the SEC on December 13, 2007;

our current report on Form 8-K filed with the SEC on December 18, 2007; and

the description of our common stock, which is registered under Section 12 of the Exchange Act, in our registration statement on Form 8-A, filed with the SEC on January 13, 2004, including any amendments or reports filed for the purpose of updating such description.

Any information in any of the foregoing documents will automatically be deemed to be modified or superseded to the extent that information in this prospectus or in a later filed document that is incorporated or deemed to be incorporated herein by reference modifies or replaces such information.

We also incorporate by reference any future filings (other than current reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed on such form that are related to such items) made with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act, until we file a post-effective amendment that indicates the termination of the offering of the securities made by this prospectus. Information in such future filings updates and supplements the information provided in this prospectus. Any statements in any such future filings will automatically be deemed to modify and supersede any information in any document we previously filed with the SEC that is incorporated or deemed to be incorporated herein by reference to the extent that statements in the later filed document modify or replace such earlier statements.

We will provide to each person, including any beneficial owner, to whom a prospectus is delivered, without charge upon written or oral request, a copy of any or all of the documents that are incorporated by reference into this prospectus but not delivered with the prospectus, including exhibits which are specifically incorporated by reference into such documents. Requests should be directed to: GTx, Inc., Attention: Corporate Secretary, 3 N. Dunlap Street, Van Vleet Building, Memphis, TN 38163, telephone (901) 523-9700.

Table of Contents

PART II
INFORMATION NOT REQUIRED IN THE PROSPECTUS

Item 14. Other Expenses of Issuance and Distribution.

The following table sets forth the estimated costs and expenses payable by the registrant in connection with the common stock being registered. The selling stockholder will not bear any portion of such expenses. All the amounts shown are estimates, except for the SEC registration fee.

SEC registration fee	$ 606
Accounting fees and expenses	15,000
Legal fees and expenses	25,000
Printing and miscellaneous expenses	10,000
Total	$ 50,606

Item 15. Indemnification of Directors and Officers.

The registrant s certificate of incorporation contains provisions permitted under Delaware law relating to the liability of directors. These provisions eliminate a director s personal liability for monetary damages resulting from a breach of fiduciary duty, except in circumstances involving wrongful acts, such as:

any breach of the director s duty of loyalty to the registrant or its stockholders;

any act or omission not in good faith or that involves intentional misconduct or a knowing violation of the law;

any act related to unlawful stock repurchases, redemptions or other distribution or payments of dividends; or

any transaction from which the director derived an improper personal benefit.

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

As permitted by Section 145 of the Delaware General Corporation Law, the registrant s bylaws require the registrant to indemnify its directors and executive officers to the fullest extent not prohibited by the Delaware law. The registrant may expand the extent of such indemnification by individual contracts with the registrant s directors and executive officers. Further, the registrant may decline to indemnify any director or executive officer in connection with any proceeding initiated by such person or any proceeding by such person against the registrant or its directors, officers, employees or other agents, unless such indemnification is expressly required to be made by law or the proceeding was authorized by the registrant s board of directors.

The registrant has entered into indemnity agreements with each of its current directors and its executive officers to give such directors and officers additional contractual assurances regarding the scope of the indemnification set forth in the registrant s certificate of incorporation and bylaws and to provide additional procedural protections. At present, there is no pending litigation or proceeding involving any of the registrant s directors, officers or employees for which indemnification is sought, nor is the registrant aware of any threatened litigation that may result in claims for indemnification.

The registrant has the power to indemnify its other officers, employees and other agents, as permitted by Delaware law, but the registrant is not required to do so.

The registrant has a directors and officers insurance and registrant reimbursement policy. The policy insures the registrant s directors and officers against unindemnified losses arising from certain wrongful acts in their capacities as directors and officers and reimburses the registrant for those losses for which the registrant has lawfully indemnified the directors and officers. The policy contains various exclusions, none of which apply to any offerings pursuant to this registration statement.

The registration rights agreement between the registrant and the selling stockholder provides for cross-indemnification in connection with registration of the registrant s common stock on behalf of the selling stockholder.

Table of Contents

Item 16. Exhibits.

Exhibit Number	Description of the Document
3.1	Restated Certificate of Incorporation (1)
3.2	Amended and Restated Bylaws (2)
4.1	Reference is made to Exhibits 3.1 and 3.2
4.2	Specimen 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)
5.1	Opinion of Cooley Godward Kronish LLP
23.1	Consent of Independent Registered Public Accounting Firm
23.2	Consent of Cooley Godward Kronish LLP (included in Exhibit 5.1)
24.1	Power of Attorney (included on signature page)

(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 Securities and Exchange Commission 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 or amendments thereto (File No. 333-109700), originally filed with the Securities and Exchange Commission 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.

Item 17. Undertakings.

The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in the volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus

Table of Contents

filed with the Securities and Exchange Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

provided, however, that paragraphs (1)(i), (1)(ii) and (1)(iii) above do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to Section 13 and Section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:

(i) If the registrant is relying on Rule 430B:

(A) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(B) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by Section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof. *Provided, however*, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date; or

(ii) If the registrant is subject to Rule 430C, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. *Provided, however*, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

(5) That, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant s annual report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (and, where applicable,

each filing of an employee benefit plan s annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by

Table of Contents

reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of the securities at that time shall be deemed to be the initial *bona fide* offering thereof.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act of 1933 and is, therefore unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Exchange Act and will be governed by the final adjudication of such issue.

Table of Contents

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Memphis, State of Tennessee, on December 21, 2007.

GTx, Inc.

By: /s/ Mitchell S. Steiner
Mitchell S. Steiner, M.D., F.A.C.S.
Chief Executive Officer

Table of Contents

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Mitchell S. Steiner, Marc S. Hanover, Henry P. Doggrell and Mark E. Mosteller, and each or any one of them, his or her true and lawful attorney-in-fact and agent, 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 (including post-effective amendments) to this Registration Statement and to sign any and all additional registration statements relating to the Registration Statement and filed pursuant to Rule 462(b) of the Securities Act of 1933, as amended, 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, 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 substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

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

Signature	Title	Date
/s/ Mitchell S. Steiner Mitchell S. Steiner, M.D., F.A.C.S.	Chief Executive Officer, Vice-Chairman and Director (*Principal Executive Officer*)	December 21, 2007
/s/ Mark E. Mosteller Mark E. Mosteller	Chief Financial Officer (*Principal Accounting and Financial Officer*)	December 21, 2007
/s/ J.R. Hyde, III J.R. Hyde, III	Chairman of the Board of Directors	December 21, 2007
/s/ Marc S. Hanover Marc S. Hanover	Director	December 21, 2007
/s/ Michael G. Carter, M.D. Michael G. Carter, M.D.	Director	December 21, 2007
/s/ Andrew M. Clarkson Andrew M. Clarkson	Director	December 21, 2007
/s/ J. Kenneth Glass J. Kenneth Glass	Director	December 21, 2007
/s/ Robert W. Karr	Director	December 21, 2007

Robert W. Karr, M.D.		
/s/ Rosemary Mazanet	Director	December 21, 2007
Rosemary Mazanet, M.D., Ph.D.		
/s/ John H. Pontius	Director	December 21, 2007
John H. Pontius		
/s/ Timothy R. G. Sear	Director	December 21, 2007
Timothy R. G. Sear		

Table of Contents

EXHIBIT INDEX

Exhibit Number	Description of the Document
3.1	Restated Certificate of Incorporation (1)
3.2	Amended and Restated Bylaws (2)
4.1	Reference is made to Exhibits 3.1 and 3.2
4.2	Specimen 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)
5.1	Opinion of Cooley Godward Kronish LLP
23.1	Consent of Independent Registered Public Accounting Firm
23.2	Consent of Cooley Godward Kronish LLP (included in Exhibit 5.1)
24.1	Power of Attorney (included on signature page)

(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 Securities and Exchange Commission 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 or amendments thereto (File No. 333-109700), originally filed with the Securities and Exchange Commission 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.	