



PROSPECTUS SUPPLEMENT  
(To Prospectus dated August 17, 2005)

3,799,600 Shares

**GTx**

The Men's Health Biotech Company

## Common Stock

GTx, Inc. is offering up to 3,799,600 shares of its common stock by this prospectus supplement and the accompanying prospectus at a price per share of \$16.00.

The common stock is listed on The NASDAQ Global Market under the symbol "GTXL." The last reported sale price of the common stock on December 12, 2006 was \$16.79 per share.

We are offering these shares of common stock on a best efforts basis primarily to institutional investors. We have retained Lazard Capital Markets LLC to act as lead placement agent and Cowen and Company, LLC to act as co-placement agent in connection with this offering.

See "Risk Factors" beginning on page S-8 of this prospectus supplement and on page 2 of the accompanying prospectus to read about factors you should consider before buying shares of the common stock.

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus supplement or the accompanying prospectus. Any representation to the contrary is a criminal offense.**

	<u>Per Share</u>	<u>Maximum Offering Amount</u>
Public Offering Price	\$ 16.00	\$ 60,793,600
Placement Agents' Fee	\$ 0.80	\$ 3,039,680
Proceeds, before expenses, to us	\$ 15.20	\$ 57,753,920

We estimate the total expenses of this offering, excluding the placement agents' fee, will be approximately \$400,000. Because there is no minimum offering amount required as a condition to closing in this offering, the actual offering amount, the placement agents' fee and net proceeds to us, if any, in this offering may be substantially less than the maximum offering amounts set forth above. We are not required to sell any specific number or dollar amount of the shares of common stock offered in this offering, but the placement agents will use their best efforts to arrange for the sale of all of the shares of common stock offered. Pursuant to an escrow agreement among us, the placement agents and an escrow agent, some or all of the funds received in payment for the shares of common stock sold in this offering will be wired to an interest bearing escrow account and held until we and the placement agents notify the escrow agent that this offering has closed, indicating the date on which the shares of common stock are to be delivered to the purchasers and the proceeds are to be delivered to us.

**LAZARD CAPITAL MARKETS****COWEN AND COMPANY**

Prospectus Supplement dated December 13, 2006.

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**ABOUT THIS PROSPECTUS SUPPLEMENT**

This document is in two parts. The first part is this prospectus supplement, which describes the specific terms of the common stock being offered by us. The second part, the accompanying prospectus dated August 17, 2005, gives more general information about our common stock. You should read the entire prospectus supplement and the accompanying prospectus, as well as the information incorporated by reference in this prospectus supplement and the accompanying prospectus, before making an investment decision.

You should rely only on the information contained or incorporated by reference in this prospectus supplement and the accompanying prospectus. If the description of the offering varies between this prospectus supplement and the accompanying prospectus, you should rely on the information in this prospectus supplement. We have not authorized anyone to provide you with information different from that contained or incorporated by reference in this prospectus supplement and the accompanying prospectus. Under no circumstances should the delivery to you of this prospectus supplement and the accompanying prospectus or any sale made pursuant to this prospectus supplement create any implication that the information contained in this prospectus supplement and the accompanying prospectus is correct as of any time after the date of this prospectus supplement.

We are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted. The distribution of this prospectus supplement and the accompanying prospectus and the offering of the common stock in certain jurisdictions may be

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restricted by law. Persons outside the United States who come into possession of this prospectus supplement and/or the accompanying prospectus must inform themselves about, and observe any restrictions relating to, the offering of the common stock and the distribution of this prospectus supplement outside the United States. This prospectus supplement and the accompanying prospectus do not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, any securities offered by this prospectus supplement and the accompanying prospectus by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

Unless we indicate otherwise, references in this prospectus supplement to “GTx,” “we,” “our” and “us” refer to GTx, Inc.

**GTx, INC.**

**Our Business**

We are a biopharmaceutical company dedicated to the discovery, development and commercialization of therapeutics for cancer and serious conditions related to men's health. Our lead drug discovery and development programs are focused on small molecules that selectively modulate the effects of estrogens and androgens, two essential classes of hormones. We are developing ACAPODENE® (toremifene citrate), a selective estrogen receptor modulator, or SERM, in two separate clinical programs in men: first, a pivotal Phase III clinical trial for the treatment of serious side effects of androgen deprivation therapy, or ADT, for advanced prostate cancer, and second, a pivotal Phase III clinical trial for the prevention of prostate cancer in high risk men with precancerous prostate lesions called high grade prostatic intraepithelial neoplasia, or high grade PIN. We have licensed to Ipsen Limited, or Ipsen, exclusive rights in the European Union, Switzerland, Norway, Iceland, Lichtenstein and the Commonwealth of Independent States to develop and commercialize ACAPODENE® and other products containing toremifene for all indications other than the prevention and treatment of breast cancer. We are also developing ostarine, a selective androgen receptor modulator, or SARM, for the treatment of muscle wasting from various types of cancer, which is known as cancer cachexia, and we plan to initiate a Phase IIb clinical trial evaluating ostarine for the treatment of cancer cachexia by the summer of 2007. We believe that ostarine has the potential to treat a variety of other indications, including muscle wasting and bone loss in frail elderly patients, osteoporosis, muscle wasting in end stage renal disease patients, and severe burn wounds and associated muscle wasting.

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

Our most advanced product candidate, ACAPODENE®, is being developed to treat both the multiple side effects of ADT and to prevent prostate cancer in high risk men with high grade PIN. ADT is the standard medical treatment for patients who have advanced, recurrent or metastatic prostate cancer, and we believe that there will be approximately one million prostate cancer survivors who are expected to be treated with ADT by 2008. The low estrogen levels caused by ADT can lead to serious side effects, including: severe bone loss, or osteoporosis, resulting in skeletal fractures; hot flashes; lipid changes and breast pain and enlargement, or gynecomastia. There are currently no drugs approved by the United States Food and Drug Administration, or FDA, for the treatment of multiple side effects of ADT. We commenced a pivotal Phase III clinical trial of ACAPODENE® under a Special Protocol Assessment, or SPA, with the FDA for this indication in November 2003. A SPA is designed to facilitate the FDA's review and approval of drug products by allowing the agency to evaluate the proposed design and size of clinical trials that are intended to form the primary basis for determining a drug product's efficacy. If agreement is reached with the FDA, a SPA documents the terms and conditions under which the design of the subject trial will be adequate for submission of the efficacy and human safety portion of a New Drug Application, or a NDA. We reached our enrollment goal in the fall of 2005 with approximately 1,400 patients randomized for the trial. The primary endpoint is the incidence of vertebral skeletal fractures measured by x-ray, and the secondary endpoints include bone mineral density, or BMD, hot flashes, gynecomastia and lipid changes. In December 2005, we conducted a planned interim analysis of BMD in the first 197 patients to complete a full year of treatment. Patients treated with ACAPODENE® demonstrated statistically significant increases in BMD compared to placebo in all three skeletal sites measured, with lumbar spine showing an improvement of 2.3 percentage points ( $p < 0.001$ ), hip, a 2.0 percentage point improvement ( $p = 0.001$ ), and femoral neck, a 1.5 percentage point improvement ( $p = 0.009$ ). In June 2006, we conducted a lipid interim analysis of the same 197 patients. Patients treated with ACAPODENE® had statistically significant lower levels of total cholesterol, LDL, and

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triglycerides, reduction in the ratio of total cholesterol to HDL, and higher levels of HDL, when compared to patients on placebo. However, data on all patients completing the study will need to be evaluated before any conclusions about clinical significance of the lipid findings can be drawn. In addition, investors should note that interim results of a clinical trial do not necessarily predict final results. We anticipate that we will complete this Phase III clinical trial in the fourth quarter of 2007. If the results are favorable, we expect to file a NDA with the FDA in the first half of 2008. We are conducting a voluntary one-year blinded Phase IIIb extension trial for patients from the Phase III study to gather additional fracture and safety data. This Phase IIIb clinical study is a separate clinical trial and will not affect the anticipated timeline for the completion of the ongoing Phase III clinical trial in the fourth quarter of 2007 and the potential submission of the NDA with the FDA.

In the United States, prostate cancer is one of the most commonly diagnosed cancers and the second leading cause of cancer-related deaths in men. Scientific evidence has established that men who have high grade PIN are at high risk of developing prostate cancer (approximately 50% of the men with high grade PIN found on a prostate biopsy develop prostate cancer within three years). In the United States, there are over 115,000 new cases of high grade PIN diagnosed each year and an estimated 14 million men under the age of 80 unknowingly harbor this condition. Currently, there is no approved treatment to prevent prostate cancer in men with high grade PIN. In January 2005, we initiated a pivotal Phase III clinical trial of orally administered ACAPODENE® for the prevention of prostate cancer in men with high grade PIN, which is being conducted under a SPA with the FDA. We reached our enrollment goal of 1,260 patients in May 2006 and expect to enroll approximately 300 additional patients into the trial by the end of 2006, who will also participate in sub-studies requested by the FDA. We will evaluate efficacy endpoints 36 months after completion of enrollment, with an interim efficacy analysis within 24 months of completion of enrollment, which we currently expect will occur either in the fourth quarter of 2007 or the first quarter of 2008. If the efficacy results at 24 months are favorable, we plan to file a NDA with the FDA during 2008. If we are able to file a NDA based on the results of the 24 month interim analysis, we will need to continue to collect safety data during the review process to satisfy the FDA's safety requirements set forth in the SPA. In 2004, we completed a randomized, double-blind, placebo-controlled, dose-finding Phase IIb clinical trial of ACAPODENE® in men with recently diagnosed high grade PIN to determine the efficacy and safety of a daily dose of ACAPODENE® for 12 months. The trial enrolled 514 men and was conducted at 64 clinical sites across the United States. The primary endpoint of this trial was the incidence of prostate cancer at 12 months. We analyzed the results of this trial on a stratified basis, in which we assessed the effect of individual clinical sites on the overall statistical analysis of the trial result, and on an unstratified basis, in which we did not assess such effect. In a stratified analysis of the per protocol population, which is the intent-to-treat population less two patients in the group that received 20 mg of ACAPODENE® who were deemed to be not compliant with the protocol, the cumulative, or overall, risk of prostate cancer was 24.4% in the group that received 20 mg of ACAPODENE compared with 31.2% in the group that received placebo. The p-value for this result was less than 0.05. Thus, the cumulative risk of prostate cancer based on a stratified analysis of the per protocol population was 22.0% lower in the 20 mg treatment group, which would imply an annualized rate of prevention of cancers of 6.8 per 100 men treated. In a stratified analysis of the subgroup of patients who had no biopsy evidence of prostate cancer at their initial screening biopsy or their six-month biopsy and completed the full course of therapy in the trial, the cumulative risk of prostate cancer was 9.1% in the group that received 20 mg of ACAPODENE® compared with 17.4% in the group that received placebo, a 48.2% reduction. For men who were diagnosed with prostate cancer, those treated with ACAPODENE® had similar tumor grades to those of placebo patients, providing evidence that ACAPODENE® does not adversely affect the severity of the tumor in those patients who develop prostate cancer. ACAPODENE® was well tolerated, as the number of adverse events was similar between those patients receiving ACAPODENE® compared to placebo.

In our third clinical program, ostarine, a SARM, is being developed to treat a variety of medical conditions relating to muscle wasting and/or bone loss in acute and chronic diseases. After approximately age 30, people lose about one-half pound of muscle every year. This muscle loss

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accelerates in people with chronic illness and other conditions that stress the body, and this muscle loss depletes protein reserves and detrimentally impacts recovery. Testosterone and other anabolic steroids have been proven to reverse involuntary muscle wasting caused by aging, burns and trauma, cancer, end-stage renal disease, chronic obstructive pulmonary disease and other diseases. However, testosterone and other anabolic steroids may cause serious unwanted side effects, including stimulating prostate cancer growth in men and masculinization in women. Ostarine is a novel non-steroidal agent designed to have anabolic activity like testosterone without unwanted side effects on the prostate and skin and in a once daily oral dose.

We plan to build specialized sales and marketing capabilities to promote our product candidates to urologists and medical oncologists in the United States and to seek partners to commercialize our product candidates to 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 FDA for the treatment of metastatic breast cancer in post-menopausal women in the United States. The active pharmaceutical ingredient in FARESTON® is the same as in ACAPODENE®, but at a different dose.

### **Recent Developments**

In December 2006, we announced that ostarine met its primary endpoint in a Phase II proof of concept, double-blind, randomized, placebo-controlled clinical trial in 60 elderly men and 60 postmenopausal women. We initiated this proof of concept Phase II clinical trial of ostarine in May 2006 and completed enrollment in July 2006. The trial was designed to evaluate the activity of ostarine on building muscle and promoting bone as well as to assess safety in both elderly men and postmenopausal women. Without a prescribed diet or exercise regimen, all subjects treated with ostarine had a dose dependent increase in total lean body mass (muscle), the trial's primary endpoint, with the 3 mg cohort achieving an increase of 1.3 kg compared to baseline and 1.4 kg compared to placebo ( $p < 0.001$ ) after three months of treatment. Treatment with ostarine also resulted in a dose dependent improvement in functional performance, a secondary endpoint measured by a stair climb test, with the 3 mg cohort achieving a clinically significant improvement in both speed ( $p = 0.006$ ) and power ( $p = 0.005$ ) compared to baseline. Ostarine continued to demonstrate a favorable safety profile, with no serious adverse events reported. Ostarine also exhibited tissue selectivity with beneficial effects on lean body mass and performance and with no apparent change in measurements for serum PSA, sebum production, or serum LH compared to placebo. We recently conducted discussions with various divisions of the FDA to investigate the required regulatory pathways for several indications under consideration for ostarine's ongoing clinical development. With more clarity regarding the required regulatory pathway and with proof of concept Phase II clinical data, we have selected cancer cachexia as the initial acute indication for ostarine development. We plan to initiate a Phase IIb ostarine clinical trial for cancer cachexia by the summer of 2007. Although we had planned to commence a Phase II clinical trial of ostarine in burn patients, we do not currently intend to pursue the development of ostarine for the treatment of severe burn wounds and associated wasting and have terminated that clinical trial.

Also in December 2006, we reacquired our rights to develop and commercialize andarine and all backup compounds previously licensed to Ortho Biotech Products, L.P., a subsidiary of Johnson & Johnson, or Ortho Biotech, pursuant to a joint collaboration and license agreement we had entered into with Ortho Biotech in March 2004, which has been terminated.

On November 28, 2006, we received correspondence from counsel representing the University of Tennessee Research Foundation, or UTRF, demanding \$940,000 in annual license maintenance fees and residual alliance royalties under two exclusive license agreements we entered into with UTRF pursuant to which UTRF granted us worldwide exclusive licenses under its composition of matter and method of use patents relating to SARM compounds, including andarine and ostarine, to market, distribute and sell licensed products. We are disputing, and have not paid to UTRF, the \$940,000 in annual license maintenance fees and residual alliance royalties as demanded by UTRF.

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Under these exclusive license agreements with UTRF, in the event of a default or failure by us to perform any of the terms, covenants or provisions of these agreements, we have 30 days after the giving of written notice of any default to correct the default. If the default is not corrected within this 30-day period, UTRF has the right, at its option, to cancel and terminate these exclusive license agreements. In the event that we do not pay to UTRF the \$940,000 in annual license maintenance fees and residual alliance royalties as demanded by UTRF, or we fail to reach an agreement with UTRF with respect to these payments, UTRF may elect to exercise its option to terminate these exclusive license agreements. If UTRF were to exercise such option, and we did not prevail in our position that we are not in default under these agreements or otherwise establish that UTRF did not have a right to terminate the licenses, then the loss of these licenses would have a material adverse effect on the continued development of our SARM program and our business prospects would suffer. We are currently in discussions with UTRF with respect to UTRF's demand for payment and intend to take appropriate action in order to avoid termination of these license agreements.

### **Company Information**

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



**The Offering**

Common stock we are offering	3,799,600 shares
Common stock to be outstanding after this offering	34,805,317 shares
Risk Factors	See "Risk Factors" beginning on page S-8 for a discussion of factors that you should consider before buying shares of our common stock.
Use of proceeds	To fund clinical development and other research and development activities and for working capital and general corporate purposes. See "Use of Proceeds" on page S-28.
NASDAQ Global Market symbol	GTXI

The number of shares of common stock to be outstanding immediately after this offering as shown above is based on 31,005,717 shares of common stock outstanding as of September 30, 2006. This number excludes, as of September 30, 2006:

- 1,471,334 shares of our common stock issuable upon exercise of outstanding options granted under our stock option plans at a weighted average exercise price of \$8.28 per share; and
- an aggregate of 1,554,672 additional shares of common stock reserved for future issuance under our stock option plans. This number does not include additional shares that will be reserved in connection with automatic annual increases to the number of shares issuable under the terms of such plans.

## RISK FACTORS

*Our business is subject to various risks, including those described below. You should carefully consider the following risks, together with all of the other information included in this prospectus supplement, the accompanying prospectus and the documents incorporated by reference before investing in our common stock. Any of these risks could materially adversely affect our business, operating results and financial condition.*

### **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, 2006, we had an accumulated deficit of \$225.1 million, of which \$96.3 million related to non-cash dividends and adjustments to the preferred stock redemption value. We have incurred losses in each year since our inception in 1997. Net losses were \$30.8 million for the nine months ended September 30, 2006, \$36.8 million in 2005, \$22.3 million in 2004, and \$14.2 million in 2003. We expect to continue to incur significant and increasing operating losses for the foreseeable future. These losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

Because of the numerous risks and uncertainties associated with developing small molecule drugs, we are unable to predict the extent of any future losses or when we will become profitable, if at all. We have financed our operations and internal growth almost exclusively through sales of common stock and preferred stock. In addition, we have received upfront license fees and payments pursuant to our collaboration agreement with Ortho Biotech for andarine and certain other SARMS, which was terminated in December 2006, and our collaboration agreement with Ipsen Limited for European rights to ACAPODENE® and other toremifene-based products. FARESTON® is currently our only commercial product and, we expect, will account for all of our product revenue for the foreseeable future. For the nine months ended September 30, 2006, we recognized \$1.5 million in net revenues from the sale of FARESTON®.

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

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

We will need to raise additional capital to:

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

We believe that the net proceeds from this offering, our current cash resources, interest on these funds and product revenue from the sale of FARESTON® will be sufficient to meet our projected operating requirements through the first quarter of 2009. This estimate does not include any potential product launch costs for ACAPODENE® in the event that it is approved for marketing by the FDA.

Our future funding requirements will depend on many factors, including:

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

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

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

#### **Risks Related to Development of Product Candidates**

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

Preclinical and clinical testing is expensive, can take many years and has an uncertain outcome. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and interim results of a clinical trial do not necessarily predict final results. Typically, the failure rate for development candidates is high. Significant delays in clinical testing could materially impact our product development costs. We do not know whether planned clinical trials will begin on time, will need to be restructured or will be completed on schedule, if at all. Several patients in our Phase III clinical trial of ACAPODENE® for the side effects of androgen deprivation therapy have withdrawn from the trial, in accordance with the trial protocol, to seek treatment for a loss in bone mineral density. Even if these patients are receiving a placebo, their withdrawal from the trial may result in delays or an inability to statistically reach an endpoint. We

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

- regulators or institutional review boards may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- our preclinical or clinical trials may produce negative or inconclusive results, which may require us to conduct additional preclinical or clinical testing or to abandon projects that we expect to be promising;
- registration or enrollment in our clinical trials may be slower than we currently anticipate, resulting in significant delays;
- we might have to suspend or terminate our clinical trials if the participating patients are being exposed to unacceptable health risks;
- regulators or institutional review boards may suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements; and
- our product candidates may not have the desired effects or may include undesirable side effects.

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

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<sup>®</sup> 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<sup>®</sup>. Although this observation suggests that ACAPODENE<sup>®</sup> 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<sup>®</sup> on the reduction in incidence or severity of hot flashes. Similarly, an assessment of the potential to treat gynecomastia with ACAPODENE<sup>®</sup> in this second Phase II clinical trial was inconclusive. We are assessing the effect of ACAPODENE<sup>®</sup> on gynecomastia and hot flashes in our Phase III clinical trial. Our preclinical or clinical trials may produce negative or inconclusive results that would not support our belief regarding the potential effectiveness of our product candidates.

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

To date, in our two Phase III clinical trials for ACAPODENE<sup>®</sup>, some subjects have experienced venous thromboembolic events, such as deep vein thromboses and pulmonary embolisms, and myocardial infarctions, one of which resulted in a patient's death, which were considered by investigators as possibly related to treatment with ACAPODENE<sup>®</sup>. Because these trials are blinded, we cannot establish whether these patients received placebo or ACAPODENE<sup>®</sup> in the trial. There have been no drug-related serious adverse events related to our other product candidates. A drug

safety monitoring board meets every six months to review unblinded data from the ACAPODENE® Phase III clinical trials that we are conducting. In August 2006, the drug safety monitoring board reviewed safety data from in excess of 2,000 patients, including the venous thromboembolic events and myocardial infarctions referred to above, and recommended continuing both clinical trials with no changes to the trial protocols. In addition, in our Phase II clinical trial for ostarine, we observed a dose-related elevation of hepatic enzymes, and in our preclinical studies for ostarine, we observed expected effects on the reproductive organs in the male population, since our drug targets the androgen receptor which is located on these organs.

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

- we may be required to conduct additional pre-clinical or clinical trials, make changes in labeling of any such approved products, reformulate any such products, or implement changes to or obtain new approvals of our or our contractors' manufacturing facilities;
- regulatory authorities may be unwilling to approve our product candidates or may withdraw approval of our products;
- we may experience a significant drop in the sales of the affected products;
- our reputation in the marketplace may suffer; and
- we may become the target of lawsuits, including class action suits.

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

### **Risks Related to Our Dependence on Third Parties**

***If third parties do not manufacture our product candidates in sufficient quantities and at an acceptable cost, clinical development and commercialization of our product candidates would be delayed.***

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

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

In the event that Orion terminates our license and supply agreement due to our uncured material breach or bankruptcy, we would not be able to manufacture ACAPODENE® until Orion's patents with respect to the composition of matter of toremifene, the active pharmaceutical ingredient in ACAPODENE®, expire. Although Orion's composition of matter patents within the European Territory have expired, and as such, would not prevent Ipsen from manufacturing ACAPODENE® within the European Territory, there is no obligation on the part of Orion to transfer its manufacturing technology to Ipsen or to assist Ipsen in developing manufacturing capabilities to meet Ipsen's

supply needs if Ipsen is in material breach of its supply agreement with Orion. Although we and Ipsen have agreed to collaborate with each other in the event either of our supply rights are terminated by Orion for any reason, a disruption in the supply of ACAPODENE® could delay the development of and impair our and Ipsen's ability to commercialize ACAPODENE®. In addition, Orion may terminate its obligation to supply us and Ipsen with toremifene if Orion ceases its manufacture of toremifene permanently, or Orion may terminate its obligation to supply us with toremifene if ACAPODENE® is not approved for commercial sale in the United States by December 31, 2009. If such termination occurs because Orion is no longer manufacturing toremifene, or because such regulatory approval is not obtained prior to the specified date, we and Ipsen will have the right to manufacture ACAPODENE®, but any arrangements we make for an alternative supply would still have to be made with a qualified alternative supplier with appropriate FDA approval in order for us to obtain our supply requirements for ACAPODENE®. We and Ipsen have mutually agreed to cooperate in the manufacture of ACAPODENE® in the event Orion ceases manufacture of toremifene for any of the above-mentioned reasons.

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

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

We may not be able to maintain or renew our existing or any other third-party manufacturing arrangements on acceptable terms, if at all. If we are unable to continue relationships with Orion for ACAPODENE® and EaglePicher for ostarine, or to do so at an acceptable cost, or if these or other suppliers fail to meet our requirements for these product candidates or for andarine for any reason, we would be required to obtain alternate suppliers. However, we may not be permitted to obtain alternate suppliers for ACAPODENE® under our license agreement with Orion if Orion terminates its supply of ACAPODENE® due to our uncured material breach or bankruptcy. Any inability to obtain alternate suppliers, including an inability to obtain approval from the FDA of an alternate supplier, would delay or prevent the clinical development and commercialization of these product candidates.

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

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

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party because of factors beyond our control;
- the possible termination or non-renewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us; and
- the possible exercise by Orion of its right to terminate its obligation to supply us with toremifene:
  - if it permanently ceases manufacture of toremifene or if we do not obtain regulatory approval of ACAPODENE® in the United States prior to December 31, 2009; or
  - if Orion terminates due to our uncured material breach or bankruptcy.

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

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

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

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

***We are dependent on our collaborative arrangement with Ipsen to develop and commercialize ACAPODENE® in the European Territory. We may also be dependent upon additional collaborative arrangements to complete the development and commercialization of some of our other product candidates. These collaborative arrangements may place the development***

***and commercialization of our product candidates outside our control, may require us to relinquish important rights or may otherwise be on terms unfavorable to us.***

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

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

Dependence on collaborative arrangements, including our arrangement with Ipsen for the development and commercialization of ACAPODENE<sup>®</sup>, subjects us to a number of risks, including:

- we are not able to control the amount and timing of resources that Ipsen devotes to ACAPODENE<sup>®</sup>;
- 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<sup>®</sup> in certain countries of the European Territory if it is determined that it is not commercially reasonable for it to do so;
- pricing reimbursement constraints within the European Territory may diminish the prospects of our receiving royalty payments from Ipsen on aggregate net sales of ACAPODENE<sup>®</sup> in some or all of the countries within the European Territory;
- should a collaborator fail to develop or commercialize one of our compounds or product candidates, we may not receive any future milestone payments and will not receive any royalties for this compound or product candidate;
- business combinations or significant changes in a collaborator's business strategy may also adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement;
- a collaborator could move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors; 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.

Additionally, we and Ipsen have agreed that neither party will seek to commercialize, promote, market or sell certain products within the European Territory for an agreed period of time subsequent to the time of the first commercial launch of ACAPODENE<sup>®</sup> within the European Territory. We and Ipsen have also agreed to grant to the other a right of first negotiation with respect to the development, marketing, sale and distribution of any new SERM-based products for the field of the prevention and treatment of prostate cancer or related side effects, or any other indication the parties agree on. Furthermore, our royalty rates under our collaboration agreement with Ipsen are subject to a possible reduction if a generic version of toremifene achieves specified sales levels in a major country within the European Territory or if Ipsen licenses patent rights from a third party that would



otherwise be infringed by Ipsen's use, manufacture, sale or import of toremifene. Ipsen has the right to terminate the collaboration agreement with 12 months prior written notice for any reason and with 30 days prior written notice as a result of legitimate and documented safety concerns. If the royalty rates under our collaboration agreement are reduced or if Ipsen terminates the collaboration agreement, the anticipated benefits to us from this agreement would be significantly reduced or eliminated. In addition, if Ipsen terminates the collaboration agreement, the development of ACAPODENE® in the European Territory could be delayed and our costs of development would increase.

#### **Risks Related to Our Intellectual Property**

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

Our exclusive license 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 the granting of marketing and data exclusivity from the appropriate regulatory authorities.

Our rights to specified patent applications relating to SARM compounds that we have licensed from UTRF are subject to the terms of UTRF's license with The Ohio State University Research Foundation, or OSURF, and our rights to future related improvements are subject to UTRF's exercise

of an exclusive option under its agreement with OSURF for such improvements, which UTRF can exercise at no additional cost to it. In addition, under the terms of our agreements with the diagnostic companies to which we provide clinical samples from our Phase IIb and Phase III clinical trial of ACAPODENE®, we will not obtain any intellectual property rights in any of their developments, including any test developed to detect high grade PIN or prostate cancer.

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

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

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

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

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

We have licensed intellectual property rights and technology from Orion and UTRF under our license agreements with each of Orion and UTRF. Each of these 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 would lose our rights to utilize the technology and intellectual property covered by that agreement to market, distribute and sell our licensed products, which may prevent us from continuing our business. For example, on November 28, 2006, we received correspondence from counsel representing UTRF demanding \$940,000 in annual license maintenance fees and residual alliance royalties under two exclusive license agreements we entered into with UTRF pursuant to which UTRF granted us worldwide exclusive licenses under its composition of matter and method of use patents relating to SARM compounds, including andarine and ostarine, to market, distribute and sell licensed products. We are disputing, and have not paid to UTRF, the \$940,000 in annual license maintenance fees and residual alliance royalties as demanded by UTRF. Under these exclusive license agreements with UTRF, in the event of a default or failure by us to perform any of the terms, covenants or provisions of these agreements, we have 30 days after the giving of written notice of any default to correct the default. If the default is not corrected within this 30-day period, UTRF has the right, at its option, to cancel and terminate these exclusive license agreements. In the event that we do not pay to UTRF the \$940,000 in annual license maintenance fees and residual alliance royalties as demanded by UTRF, or we fail to reach an agreement with UTRF with respect to these payments, UTRF may elect to exercise its option to terminate these exclusive license agreements. If UTRF were to exercise such option, and we did not prevail in our position that we are not in default under these agreements or otherwise establish that UTRF did not have a right to terminate the licenses, then the loss of these licenses would have a material adverse effect on the continued development of our SARM program and our business prospects would suffer. We are currently in discussions with UTRF with respect to UTRF's demand for payment and intend to take appropriate action in order to avoid termination of these license agreements.

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

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

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

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

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

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

#### **Risk Related to Regulatory Approval of Our Product Candidates**

***If we or our collaborators are not able to obtain required regulatory approvals, we or our collaborators will not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired.***

Our product candidates and the activities associated with their development and commercialization are subject to comprehensive regulation by the FDA, and other regulatory agencies in the United States and by comparable authorities in other countries. Failure to obtain regulatory approval for a product candidate will prevent us from commercializing our product candidate and will prevent our collaborators from commercializing the product candidate in the licensed territories. We have not received regulatory approval to market any of our product candidates in any jurisdiction and have only limited experience in preparing and filing the applications necessary to gain regulatory approvals. In addition, we will not receive a substantial majority of the milestone payments provided under our collaboration and license agreement with Ipsen or any royalty payments if Ipsen is unable to obtain the necessary regulatory approvals to commercialize ACAPODENE® within the European Territory. The process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon the type, complexity and novelty of the product candidates involved.

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

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

The FDA has substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. For example, we are conducting our Phase III clinical trials of ACAPODENE® to treat the side effects of androgen deprivation therapy and for the reduction in the incidence of prostate cancer in men with high grade PIN under Special Protocol Assessments from the FDA. A SPA is designed to facilitate the FDA's review and approval of drug products by allowing the agency to evaluate the proposed design and size of clinical trials that are intended to form the primary basis for determining a drug product's efficacy. If agreement is reached with the FDA, a SPA documents the terms and conditions under which the design of the subject trial will be adequate for submission of the efficacy and human safety portion of a NDA. However, there are circumstances under which we may not receive the benefits of a SPA, notably including if the FDA subsequently identifies a substantial scientific issue essential to determining the product's safety or efficacy. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate. Furthermore, even if we file an application with the FDA for marketing approval of a product candidate, it may not result in marketing approval from the FDA.

We do not expect to receive regulatory approval for the commercial sale of any of our product candidates that are in development for the next few years. Similarly, it is not anticipated that Ipsen will receive the appropriate regulatory approvals to market ACAPODENE® within the European Territory until at least the same time period, if not later, than we expect to receive regulatory approval within the United States. 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, 2005 filed with the Securities and Exchange Commission for additional information regarding risks associated with approval, as well as risks related to post-approval requirements.

#### **Risks Related to Commercialization**

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

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

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

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

FARESTON® is currently our only marketed product. Sales of FARESTON® in the United States have been declining and we anticipate that they will continue to do so. Continued sales of FARESTON® could be impacted by many factors. The occurrence of one or more of the following risks may cause sales of FARESTON® to decline more than we currently anticipate:

- the loss of the availability of Orion's website to market FARESTON®, which is an important source of advertising;
- the loss of one or more of our three largest wholesale drug distributors, which accounted for approximately 94% of our revenue generated from the sale of FARESTON® for the nine months ended September 30, 2006;
- the continued success of competing products, including aromatase inhibitors;
- the loss of coverage or reimbursement for FARESTON® from Medicare and Medicaid, private health insurers or other third-party payors;
- exposure to product liability claims related to the commercial sale of FARESTON®, which may exceed our product liability insurance;

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- 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.

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

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

We have limited experience as a company in the sales, marketing and distribution of pharmaceutical products. There are risks involved with building our own sales and marketing capabilities, as well as entering into arrangements with third parties to perform these services. For example, building a sales force is expensive and time-consuming and could delay any launch of a product candidate. Similarly, we are relying on Ipsen to market and distribute our ACAPODENE® product candidates through Ipsen's established sales and marketing network within the European Territory. If our collaboration and license agreement with Ipsen is terminated for any reason, our ability to sell our ACAPODENE® product candidates in the European Territory would be adversely affected, and we may be unable to develop or engage an effective sales force to successfully market and sell our ACAPODENE® product candidates in the European Territory. In addition, to the extent that we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenues are likely to be lower than if we market and sell any products that we develop ourselves.

***If we are unable to obtain adequate coverage and reimbursement from third-party payors for products we sell at acceptable prices, our revenues and prospects for profitability will suffer.***

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

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

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

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

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

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

- decreased demand for any product candidates or products;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue; and
- the inability to commercialize any products for which we obtain or hold approvals.

We have product liability insurance that covers our clinical trials and commercial products up to a \$20.0 million annual aggregate limit. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost and we may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise.

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

We face competition from established pharmaceutical and biotechnology companies, as well as from academic institutions, government agencies and private and public research institutions. Our commercial opportunities will be reduced or eliminated if our competitors develop and commercialize



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products that are safer, more effective, have fewer side effects or are less expensive than any products that we may develop. In addition, significant delays in the development of our product candidates could allow our competitors to bring products to market before us and impair our ability to commercialize our product candidates.

Various products are currently marketed or sold and used off-label for some of the diseases and conditions that we are targeting, and a number of companies are or may be developing new treatments. The occurrence of such off-label uses could significantly reduce our ability to market and sell any products that we may develop. For example, although there are no products that have been approved by the FDA to treat multiple side effects of androgen deprivation therapy, we are aware of a number of drugs marketed by Eli Lilly (Evista), Merck (Fosamax), Sanofi-Aventis and Procter & Gamble (Actonel), Wyeth Pharmaceuticals (Effexor), Boehringer Ingelheim (Catapres), Novartis (Zometa) and Bristol Myers Squibb (Megace) that are prescribed off-label to treat single side effects of this therapy; that external beam radiation is used to treat breast pain and enlargement; and that Amgen is developing a product candidate for the treatment of osteoporosis in prostate cancer patients. While we have the only pharmaceutical product in clinical development to prevent prostate cancer in men with high grade PIN, GlaxoSmithKline is conducting a Phase III study for Avodart on prostate cancer prevention which purposely excludes the high risk patient group of men with high grade PIN. In addition, there are nutritional supplement studies (for example, selenium) investigating prostate cancer prevention in men with high grade PIN. Similarly, while there are no drugs that have been approved by the FDA for the treatment of muscle wasting from cancer, there are drugs marketed by Steris Laboratories and Savient Pharmaceuticals that are being prescribed off-label for the treatment of some types of muscle wasting from cancer. Testosterone and other anabolic agents are used to treat involuntary weight loss in patients who have acute muscle wasting. Also, TAP Pharmaceuticals and Ligand Pharmaceuticals have entered into a collaboration agreement to develop a SARM and may be initiating Phase II studies in 2006. In addition, there are other SARM product candidates at an earlier stage of development that may compete with our product candidates. Wyeth and Amgen have myostatin inhibitors in development which may compete for similar patients as ostarine. This could result in reduced sales and pricing pressure on our product candidates, if approved, which in turn would reduce our ability to generate revenue and have a negative impact on our results of operations.

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

### **Risks Related to Employees and Growth**

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

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

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

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

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

#### **Risks Related to this Offering and Our Common Stock**

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

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

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

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

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

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

As of September 30, 2006, our officers, directors and holders of 5% or more of our outstanding common stock beneficially owned approximately 78.9% of our outstanding common stock. Our officers and directors owned approximately 58.4% of our outstanding common stock as of September 30, 2006. As a result, these stockholders, acting together, will be able to control all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with our interests or the interests of other stockholders.

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

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

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

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

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

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

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

For the 12 month period ended September 30, 2006, the average daily trading volume of our common stock on the NASDAQ Global Market was approximately 85,000 shares. As a result, future sales of a substantial number of shares of our common stock in the public market, or the perception that such sales may occur, could adversely affect the then-prevailing market price of our common stock. As of September 30, 2006, we had 31,005,717 shares of common stock outstanding.

We, along with our executive officers and directors, have agreed to specified lock-up provisions with regard to future sales of our common stock for a period of 90 days after the offering as set forth in the placement agent agreement, subject to certain exceptions. The market price for shares of our common stock may drop significantly if stockholders subject to these lock-up provisions sell a substantial number of shares when the restrictions on resale lapse, or such shares are sold pursuant to specified exceptions, or if the placement agents waive these lock-up provisions and allow the stockholders to sell some or all of their shares. Based on information currently available to us, all of the shares to be outstanding after this offering will be eligible for sale in the public market following expiration of these lock-up provisions, subject in some cases to volume and other limitations under federal securities laws.

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

## DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus supplement, the accompanying prospectus and the documents incorporated by reference include and incorporate 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 which may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. Forward-looking statements include statements about:

- the anticipated progress of our research, development and clinical programs;
- potential future licensing fees, milestone payments and royalty payments including any milestone payments or royalty payments that we may receive under our collaboration and license agreement with Ipsen Limited;
- our and our collaborator's ability to market, commercialize and achieve market acceptance for our product candidates or products that we may develop;
- our ability to generate additional product candidates for clinical testing;
- our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others; and
- our estimates regarding the sufficiency of our cash resources.

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

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

## USE OF PROCEEDS

We estimate that the net proceeds from the sale of 3,799,600 shares of common stock that we are offering will be approximately \$57.4 million, based on an offering price of \$16.00 per share, after deducting placement agents' fees and estimated offering expenses payable by us.

We expect to use the net proceeds from this offering to fund clinical development and other research and development activities and for working capital and general corporate purposes. In addition, we may use a portion of the net proceeds from this offering to acquire equipment, products, technologies or businesses, although we currently have no commitments or agreements relating to any of these types of transactions.

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

## DILUTION

If you invest in our common stock in this offering, your ownership interest will be diluted to the extent of the difference between the offering price per share and the net tangible book value per share after this offering. Our net tangible book value as of September 30, 2006 was approximately \$39.1 million, or approximately \$1.26 per share of common stock. Net tangible book value per share represents total tangible assets less total liabilities, divided by the number of shares of common stock outstanding. Dilution in net tangible book value per share represents the difference between the amount per share paid by purchasers of shares of common stock in this offering and the net tangible book value per share of common stock immediately after the closing of this offering.

After giving effect to the sale of the shares of common stock at an offering price of \$16.00 per share, after deducting placement agents' fees and estimated offering expenses payable by us, our net tangible book value as of September 30, 2006 would have been approximately \$96.5 million, or \$2.77 per share of common stock. This represents an immediate increase in net tangible book value of \$1.51 per share to existing stockholders and an immediate dilution of \$13.23 per share to new investors purchasing shares of common stock in this offering at the offering price.

The following table illustrates this dilution on a per share basis:

Offering price per share		\$ 16.00
Net tangible book value per share as of September 30, 2006	\$ 1.26	
Increase per share attributable to this offering	<u>1.51</u>	
As adjusted net tangible book value per share after this offering		<u>2.77</u>
Dilution per share to new investors		<u>\$ 13.23</u>

The calculations above are based on 31,005,717 shares of common stock outstanding as of September 30, 2006. This number excludes, as of September 30, 2006:

- 1,471,334 shares of our common stock issuable upon exercise of outstanding options granted under our stock option plans at a weighted average exercise price of \$8.28 per share; and
- an aggregate of 1,554,672 additional shares of common stock reserved for future issuance under our stock option plans. This number does not include additional shares that will be reserved in connection with automatic annual increases to the number of shares issuable under the terms of such plans.

## PLAN OF DISTRIBUTION

We are offering the shares of our common stock through placement agents. Subject to the terms and conditions contained in the placement agent agreement dated December 13, 2006, Lazard Capital Markets LLC has agreed to act as lead placement agent and Cowen and Company, LLC has agreed to act as co-placement agent for the sale of up to 3,799,600 shares of our common stock. The placement agents are not purchasing or selling any shares by this prospectus supplement, nor are they required to arrange for the purchase or sale of any specific number or dollar amount of shares, but have agreed to use best efforts to arrange for the sale of all 3,799,600 shares.

The placement agent agreement provides that the obligations of the placement agents and the investors are subject to certain conditions precedent, including the absence of any material adverse change in our business and the receipt of customary legal opinions, letters and certificates.

Confirmations and definitive prospectuses will be distributed to all investors who agree to purchase the common stock, informing investors of the closing date as to such shares. We currently anticipate that closing of the sale of 3,799,600 shares of common stock will take place on or about December 18, 2006. Investors will also be informed of the date and manner in which they must transmit the purchase price for their shares.

On the scheduled closing date, the following will occur:

- we will receive funds in the amount of the aggregate purchase price; and
- Lazard Capital Markets LLC will receive the placement agents' fee on behalf of the placement agents in accordance with the terms of the placement agent agreement.

We will pay the placement agents an aggregate commission equal to 5% of the gross proceeds of the sale of shares of common stock in the offering. We may also reimburse the placement agents for certain legal expenses incurred by them. In no event will the total amount of compensation paid to the placement agents and other securities brokers and dealers upon completion of this offering exceed 8% of the gross proceeds of the offering. The estimated offering expenses payable by us, in addition to the placement agents' fee of \$3,039,680, are approximately \$400,000 which includes legal, accounting and printing costs and various other fees associated with registering and listing the common stock. After deducting estimated fees due to the placement agents and our estimated offering expenses, we expect the net proceeds from this offering to be approximately \$57.4 million.

Lazard Frères & Co. LLC referred this transaction to Lazard Capital Markets LLC and will receive a referral fee from Lazard Capital Markets LLC in connection therewith.

We have agreed to indemnify the placement agents and Lazard Frères & Co. LLC against certain liabilities, including liabilities under the Securities Act of 1933, as amended. We have also agreed to contribute to payments the placement agents and Lazard Frères & Co. LLC may be required to make in respect of such liabilities.

We, along with our executive officers and directors, have agreed to specified lock-up provisions with regard to future sales of our common stock for a period of 90 days after the offering as set forth in the placement agent agreement, subject to certain exceptions.

The placement agent agreement is included as an exhibit to our Current Report on Form 8-K that we will file with the SEC in connection with the consummation of this offering.

The transfer agent for our common stock to be issued in this offering is Computershare located at 150 Royall Street, Canton, MA 02021.

Our common stock is listed on The NASDAQ Global Market under the symbol "GTXI."



## LEGAL MATTERS

The validity of the common stock offered by this prospectus supplement and the accompanying prospectus will be passed upon for us by Cooley Godward Kronish LLP, Palo Alto, California. Certain legal matters will also be passed upon for us by Bass, Berry & Sims PLC, Memphis, Tennessee. Thelen Reid Brown Raysman & Steiner LLP in New York, New York, and Wilmer Cutler Pickering Hale and Dorr LLP in Boston, Massachusetts, are acting as counsel for the placement agents in connection with various matters related to the common stock offered by this prospectus supplement and the accompanying prospectus.

## EXPERTS

Ernst & Young LLP, an 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, 2005, and management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2005, as set forth in their reports, which are incorporated by reference in this prospectus supplement and accompanying prospectus and elsewhere in the registration statement of which the accompanying prospectus is a part. 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 MORE INFORMATION

We are a reporting company and file annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission. You may read and copy our reports, proxy statements and other information at the Securities and Exchange Commission's public reference room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You can request copies of these documents by writing to the Securities and Exchange Commission and paying a fee for the copying cost. Please call the Securities and Exchange Commission at 1-800-SEC-0330 for more information about the operation of the public reference room. Our Securities and Exchange Commission filings are also available at the Securities and Exchange Commission's website at <http://www.sec.gov>.

The Securities and Exchange Commission allows us to "incorporate by reference" information that we file with it, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is an important part of this prospectus supplement. Information in this prospectus supplement supersedes information incorporated by reference that we filed with the Securities and Exchange Commission prior to the date of this prospectus supplement, while information that we file later with the Securities and Exchange Commission will automatically update and supersede this information. We incorporate by reference into this prospectus supplement the documents listed below and any future filings we will make with the Securities and Exchange Commission under Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended, after the date of this prospectus supplement but prior to the termination of the offering of the securities covered by this prospectus supplement, except in each case for information contained in any such filing where we indicate that such information is being furnished and is not to be considered "filed" under the Securities Exchange Act of 1934, as amended.

The following documents filed with the Securities and Exchange Commission are incorporated by reference in this prospectus supplement:

- our annual report on Form 10-K for the year ended December 31, 2005 filed with the SEC on March 2, 2006 (the "2005 10-K");

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- the information specifically incorporated by reference into our 2005 Form 10-K from our definitive proxy statement on Schedule 14A filed with the SEC on March 8, 2006;
- our current report on Form 8-K filed with the SEC on April 24, 2006;
- our current report on Form 8-K filed with the SEC on April 27, 2006 under Items 1.01 and 9.01;
- our quarterly report on Form 10-Q for the quarterly period ended March 31, 2006 filed with the SEC on May 5, 2006;
- our current report on Form 8-K filed with the SEC on May 10, 2006;
- our current reports on Form 8-K filed with the SEC on May 16, 2006;
- our current report on Form 8-K filed with the SEC on June 6, 2006;
- our current report on Form 8-K filed with the SEC on June 22, 2006;
- our current report on Form 8-K filed with the SEC on July 20, 2006;
- our quarterly report on Form 10-Q for the quarterly period ended June 30, 2006 filed with the SEC on August 9, 2006;
- our current report on Form 8-K filed with the SEC on August 9, 2006;
- our current report on Form 8-K filed with the SEC on September 7, 2006 under Items 8.01 and 9.01;
- our current report on Form 8-K filed with the SEC on September 12, 2006;
- our quarterly report on Form 10-Q for the quarterly period ended September 30, 2006 filed with the SEC on November 3, 2006;
- our current report on Form 8-K filed with the SEC on November 3, 2006;
- our current report on Form 8-K filed with the SEC on December 8, 2006; and
- the description of our common stock contained in our registration statement on Form 8-A filed with the Securities and Exchange Commission on January 13, 2004, including all amendments and reports filed for the purpose of updating such information.

We will furnish without charge to you, upon written or oral request, a copy of any or all of the documents incorporated by reference, including exhibits to these documents. You should direct any requests for documents to GTX, Inc., Attention: Corporate Secretary, 3 N. Dunlap Street, Van Vleet Building, Memphis, TN 38163. Our phone number is (901) 523-9700.

PROSPECTUS



GTx, INC.  
\$100,000,000  
Common Stock

From time to time, we may sell common stock in one or more offerings for an aggregate initial offering price of up to \$100,000,000.

We will provide the specific terms of any offering in one or more supplements to this prospectus. You should read this prospectus and any prospectus supplement, as well as any documents incorporated by reference in this prospectus and any prospectus supplement, carefully before you invest.

Our common stock is quoted on the Nasdaq National Market under the trading symbol "GTXI." On August 3, 2005, the last reported sale price of our common stock on the Nasdaq National Market was \$11.50 per share.

THIS PROSPECTUS MAY NOT BE USED TO OFFER OR SELL ANY SECURITIES UNLESS ACCOMPANIED BY A PROSPECTUS SUPPLEMENT.

If any underwriters are involved in the sale of any securities with respect to which this prospectus is being delivered, the names of such underwriters and any applicable commissions or discounts will be set forth in a prospectus supplement. The net proceeds we expect to receive from such sale will also be set forth in a prospectus supplement.

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.

INVESTING IN OUR SECURITIES INVOLVES A HIGH DEGREE OF RISK. SEE THE SECTION ENTITLED "RISK FACTORS" ON PAGE 2 OF THIS PROSPECTUS.

The date of this prospectus is August 17, 2005

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## **GTX, INC.**

GTX, Inc. is a biopharmaceutical company dedicated to the discovery, development and commercialization of therapeutics for serious men's health conditions. Our drug discovery and development programs are focused on small molecules that selectively modulate the effects of estrogens and androgens.

We have four clinical programs. We are developing Acapodene (toremifene citrate) in two clinical programs in men: (1) a pivotal Phase III clinical trial for the prevention of prostate cancer in high risk men and (2) a pivotal Phase III clinical trial for the treatment of serious side effects of androgen deprivation therapy for advanced prostate cancer. In our third clinical program, we and our partner, Ortho Biotech Products, L.P., a subsidiary of Johnson & Johnson, are developing andarine, a selective androgen receptor modulator, or SARM, for cancer cachexia. We are working with Ortho Biotech to progress andarine into a Phase II clinical trial. In our fourth clinical program, we are developing our second SARM, ostarine, for andropause and other chronic wasting conditions related to aging, including frailty and sarcopenia. We also have the exclusive right to market FARESTON (toremifene citrate 60 mg) tablets, which have been approved by the U.S. Food and Drug Administration for the treatment of metastatic breast cancer, in the United States. The active pharmaceutical ingredient in FARESTON is the same as in Acapodene, but at a different dose.

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](http://www.gtxinc.com). The information contained in our website is no a part of this prospectus or any prospectus supplement.

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

## **ABOUT THIS PROSPECTUS**

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission using a "shelf" registration process. Under this shelf registration process, we may sell common stock in one or more offerings, up to a total dollar amount of \$100,000,000. This prospectus provides you with a general description of the securities we may offer. Each time we sell common stock, we will provide a prospectus supplement that will contain more specific information about the terms of that offering. We may also add, update or change in the prospectus supplement any of the information contained in this prospectus. However, no prospectus supplement will fundamentally change the terms that are set forth in this prospectus or offer a security that is not registered and described in this prospectus at the time of its effectiveness. This prospectus, together with applicable prospectus supplements, includes all material information relating to this offering. If there is any inconsistency between the information in this prospectus and the information in the accompanying prospectus supplement, you should rely on the information in the prospectus supplement. Please carefully read both this prospectus and any prospectus supplement together with the additional information described below under "Where You Can Find More Information."

You should rely only on the information we have provided or incorporated by reference in this prospectus or any prospectus supplement. We have not authorized anyone to provide you with different information. No dealer, salesperson or other person is authorized to give any information or to represent anything not contained in this prospectus or any prospectus supplement. You must not rely on any unauthorized information or representation. This prospectus is an offer to sell only the securities offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. You should assume that the information in this prospectus or any prospectus supplement is accurate only as of the date on the front of the document and that 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 a security.

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

## **RISK FACTORS**

Investment in our securities involves a high degree of risk. You should consider carefully the risk factors in any prospectus supplement and in our filings with the Securities and Exchange Commission, as well as other information in this prospectus and any prospectus supplement and the documents incorporated by reference herein or therein, before purchasing any of our securities. Each of the risk factors could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our securities.

## **FORWARD-LOOKING INFORMATION**

This prospectus, any prospectus supplement and the documents that we incorporate by reference contain statements indicating expectations about future performance and other forward-looking statements that involve risks and uncertainties. We usually use words such as "may," "will," "should," "expect," "plan," "anticipate," "believe," "estimate," "predict," "future," "intend," "potential" or "continue" or the negative of these terms or similar expressions to identify forward-looking statements. These statements appear throughout this prospectus, any prospectus supplement and the documents that we incorporate by reference and are statements regarding our current intent, belief or expectation, primarily with respect to our operations and related industry developments. Examples of these statements include, but are not limited to, statements regarding the following: our current and anticipated clinical trials; the progress of our research and development programs; our corporate collaborations, including potential future licensing fees and milestone and royalty payments; our research and development expenses; protection of our intellectual property; sufficiency of our cash resources; and our operations and legal risks. You should not place undue reliance on these forward-looking statements. Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons. Important factors that could cause or contribute to such differences include, but are not limited to, those discussed in any prospectus supplement or in the documents we incorporate by reference in this prospectus, particularly in the section entitled "Additional Factors That Might Affect Future Results" contained in our filings made with the Securities and Exchange Commission from time to time. Any forward-looking statement speaks only as of the date on which it is made, and we undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

## **USE OF PROCEEDS**

Except as described in any prospectus supplement, we intend to use the net proceeds from the sale of our common stock for research and development and general corporate purposes. We may also use a portion of the net proceeds to acquire or invest in businesses, products and technologies that are complementary to our own. Pending these uses, the net proceeds will be invested in investment-grade, interest-bearing securities.

## **DESCRIPTION OF CAPITAL STOCK**

Our authorized capital stock consists of 60,000,000 shares of common stock, \$0.001 par value per share, and 5,000,000 shares of preferred stock, \$0.001 par value per share. As of July 25, 2005, there were 24,664,716 shares of our common stock outstanding and no shares of preferred stock outstanding.

## **Common Stock**

The holders of common stock are entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders and do not have cumulative voting rights. The affirmative vote of the holders of a majority of the shares of common stock entitled to vote on a matter is required to approve the matter (except when a different vote is required by law, Nasdaq rules, our certificate of incorporation or our bylaws), and directors are elected by plurality vote. Subject to preferences that may be applicable to any outstanding shares of preferred stock, the holders of common stock are entitled to receive ratably such dividends as may be declared by the board of directors out of legally available funds. Upon our liquidation, dissolution or winding up, holders of our common stock are entitled to share ratably in all assets remaining after payment of liabilities and the liquidation preferences of any outstanding shares of preferred stock. Holders of common stock have no preemptive rights and no right to convert their common stock into any other securities. There are no redemption or sinking fund provisions applicable to our common stock. All outstanding shares of our common stock are, and all shares of common stock that may be issued under this prospectus will be, fully paid and non-assessable.

The foregoing summary description of our common stock is based on the provisions of our certificate of incorporation and bylaws and the applicable provisions of the Delaware General Corporation Law. This information may not be complete in all respects and is qualified entirely by reference to the provisions of our certificate of incorporation, bylaws and the Delaware General Corporation Law. For information on how to obtain copies of our certificate of incorporation and bylaws, see "Where You Can Find More Information."

The rights of the holders of our common stock are subject to, and may be adversely affected by, the rights of holders of shares of any preferred stock that we may designate and issue in the future.

## **Preferred Stock**

Pursuant to our certificate of incorporation, our board of directors has the authority, without further action by the stockholders (unless such stockholder action is required by applicable law or Nasdaq rules), to issue up to 5,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon, and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding. Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of us and may adversely affect the market price of the common stock and the voting and other rights of the holders of common stock. We have no present plans to issue preferred stock.

## **Registration Rights**

As of the date of this prospectus, holders of approximately 11,141,057 shares of our common stock are entitled to rights with respect to the registration of those shares of common stock under the Securities Act of 1933. If we propose to register any of our securities under the Securities Act, either for our own account or for the account of others, the holders of these shares are entitled to notice of the registration and are entitled to include, at our expense, their shares of common stock in the registration and any related underwriting, provided, among other conditions, that the underwriters may limit the number of shares to be included in the registration. In addition, the holders of certain of these shares may require us, at our expense and subject to certain limitations, to file a registration statement under the Securities Act with respect to their shares of our common stock. These holders

have waived these registration rights in connection with the offerings that might be made under this registration statement.

### **Anti-Takeover Effects of Provisions of Delaware Law and Our Charter Documents**

*Delaware Takeover Statute.* We are subject to the provisions of Section 203 of the Delaware General Corporation Law. In general, the statute prohibits a publicly-held Delaware corporation such as us from engaging in a business combination with an interested stockholder for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. For purposes of Section 203, a business combination includes a merger, asset or stock sale or other transaction resulting in a financial benefit to the interested stockholder, and an interested stockholder is a person who, together with affiliates and associates, owns, or within three years prior, did own, 15% or more of our voting stock. Section 203 of the Delaware General Corporation Law will generally have an anti-takeover effect for transactions not approved in advance by our board of directors, including discouraging attempts that might result in a premium over the market price for the shares of common stock held by our stockholders.

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

- provide that any action required or permitted to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and may not be effected by any consent in writing;
- establish advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon at a stockholder meeting;
- provide that the authorized number of directors may be changed only by resolution of the board of directors; and
- provide that special meetings of our stockholders may be called only by the chairman of our board of directors, our chief executive officer or our board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors.

The Delaware corporate law statute provides generally that the affirmative vote of a majority of the shares entitled to vote is required to amend a corporation's bylaws, unless a corporation's certificate of incorporation requires a greater percentage or also confers the power upon the corporation's directors. Our bylaws may be amended or repealed by:

- the affirmative vote of a majority of our directors then in office; or
- the affirmative vote of the holders of at least 66 $\frac{2}{3}$ % of the voting power of all then-outstanding shares of our capital stock entitled to vote generally in the election of directors.

The provisions described in the preceding paragraph that are included in our certificate of incorporation may only be amended or repealed by the affirmative vote of a majority of our directors and the affirmative vote of the holders of at least 66 $\frac{2}{3}$ % of the voting power of all then-outstanding shares of our capital stock entitled to vote generally in the election of directors.

These and other provisions contained in our certificate of incorporation and bylaws could delay or discourage some types of transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a



premium for their shares over then current prices, and may limit the ability of stockholders to remove current management or approve transactions that stockholders may deem to be in their best interests and, therefore, could adversely affect the price of our common stock.

#### **Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is Computershare. Its address is 150 Royall Street, Canton, MA 02021.

#### **PLAN OF DISTRIBUTION**

We may sell the common stock through underwriters or dealers, through agents, or directly to one or more purchasers. One or more prospectus supplements will describe the terms of the offering of the common stock, including:

- the name or names of any agents or underwriters;
- the purchase price of the common stock and the proceeds we will receive from the sale;
- any over-allotment options under which underwriters may purchase additional shares of common stock from us;
- any agency fees or underwriting discounts and other items constituting agents' or underwriters' compensation;
- any discounts or concessions allowed or reallocated or paid to dealers; and
- any securities exchange or market on which the common stock may be listed.

Only underwriters named in the prospectus supplement are underwriters of the common stock offered by the prospectus supplement.

If underwriters are used in the sale, they will acquire the common stock for their own account and may resell the common stock from time to time in one or more transactions, including negotiated transactions, at a fixed public offering price or at varying prices determined at the time of sale. The obligations of the underwriters to purchase the common stock will be subject to the conditions set forth in the applicable underwriting agreement. We may offer the common stock to the public through underwriting syndicates represented by managing underwriters or by underwriters without a syndicate. Subject to certain conditions, the underwriters will be obligated to purchase all the common stock offered by the prospectus supplement if they are to purchase any of such offered shares. Any public offering price and any discounts or concessions allowed or reallocated or paid to dealers may change from time to time. We may use underwriters with whom we have a material relationship. We will describe in the prospectus supplement naming the underwriter, the nature of any such relationship.

We may sell the common stock directly or through agents we designate from time to time. We will name any agent involved in the offering and sale of the common stock and we will describe any commissions we will pay the agent in the prospectus supplement. Unless the prospectus supplement states otherwise, our agent will act on a best-efforts basis for the period of its appointment.

We may authorize agents or underwriters to solicit offers by certain types of institutional investors to purchase the common stock from us at the public offering price set forth in the prospectus supplement pursuant to delayed delivery contracts providing for payment and delivery on a specified date in the future. We will describe the conditions to these contracts and the commissions we must pay for solicitation of these contracts in the prospectus supplement.

We may provide agents and underwriters with indemnification against certain civil liabilities, including liabilities under the Securities Act, or contribution with respect to payments that the agents

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or underwriters may make with respect to such liabilities. Agents and underwriters may engage in transactions with, or perform services for, us in the ordinary course of business.

Any underwriter may engage in overallotment, stabilizing transactions, short covering transactions and penalty bids in accordance with Regulation M under the Securities Exchange Act of 1934. Overallotment involves sales in excess of the offering size, which create a short position. Stabilizing transactions permit bids to purchase the underlying shares of common stock so long as the stabilizing bids do not exceed a specified maximum price. Short covering transactions involve exercise by underwriters of an over-allotment option or purchases of the common stock in the open market after the distribution is completed to cover short positions. Penalty bids permit the underwriters to reclaim a selling concession from a dealer when the shares of common stock originally sold by the dealer are purchased in a short covering transaction. Those activities may cause the price of the common stock to be higher than it would otherwise be. If commenced, the underwriters may discontinue any of the activities at any time.

Our common stock is quoted on the Nasdaq National Market. One or more underwriters may make a market in our common stock, but the underwriters will not be obligated to do so and may discontinue market making at any time without notice. We cannot give any assurance as to liquidity of the trading market for our common stock.

Any underwriters who are qualified market makers on the Nasdaq National Market may engage in passive market making transactions in the securities on the Nasdaq National Market in accordance with Rule 103 of Regulation M under the Securities Exchange Act of 1934, during the five business days prior to the pricing of the offering, before the commencement of offers or sales of the securities. Passive market makers must comply with applicable volume and price limitations and must be identified as passive market makers. In general, a passive market maker must display its bid at a price not in excess of the highest independent bid for such security; if all independent bids are lowered below the passive market maker's bid, however, the passive market maker's bid must then be lowered when certain purchase limits are exceeded.

In compliance with guidelines of the National Association of Securities Dealers, or NASD, the maximum consideration or discount to be received by any NASD member or independent broker dealer may not exceed 8% of the aggregate amount of the securities offered pursuant to this prospectus and any applicable prospectus supplement.

### **LEGAL MATTERS**

The validity of the securities being offered hereby will be passed upon by Cooley Godward 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, 2004, as set forth in their report, which is incorporated by reference in this prospectus and elsewhere in the registration statement. Our financial statements are incorporated by reference in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

### **WHERE YOU CAN FIND MORE INFORMATION**

We are a reporting company and file annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission. We have filed with the Securities and Exchange Commission a registration statement on Form S-3 under the Securities Act with respect to the common stock we are offering under this prospectus. This prospectus does not contain all of the information set forth in the registration statement and the exhibits to the registration

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statement. For further information with respect to us and the common stock we are offering under this prospectus, we refer you to the registration statement and the exhibits filed as a part of the registration statement. You may read and copy the registration statement, as well as our reports, proxy statements and other information, at the Securities and Exchange Commission's public reference room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You can request copies of these documents by writing to the Securities and Exchange Commission and paying a fee for the copying cost. Please call the Securities and Exchange Commission at 1-800-SEC-0330 for more information about the operation of the public reference room. Our Securities and Exchange Commission filings are also available at the Securities and Exchange Commission's website at <http://www.sec.gov>.

The Securities and Exchange Commission allows us to "incorporate by reference" information that we file with it, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is an important part of this prospectus. Information in this prospectus supersedes information incorporated by reference that we filed with the Securities and Exchange Commission prior to the date of this prospectus, while information that we file later with the Securities and Exchange Commission will automatically update and supersede this information. We incorporate by reference into this registration statement and prospectus the documents listed below and any future filings we will make with the Securities and Exchange Commission under Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended, after the date of this prospectus but prior to the termination of the offering of the securities covered by this prospectus, except in each case for information contained in any such filing where we indicate that such information is being furnished and is not to be considered "filed" under the Securities Exchange Act of 1934, as amended.

The following documents filed with the Securities and Exchange Commission are incorporated by reference in this prospectus:

- our Annual Report on Form 10-K, as amended, for the year ended December 31, 2004, filed with the Securities and Exchange Commission on March 24, 2005;
- our Quarterly Report on Form 10-Q, as amended, for the quarter ended March 31, 2005, filed with the Securities and Exchange Commission on April 29, 2005;
- our Current Report on Form 8-K filed with the Securities and Exchange Commission on February 1, 2005;
- our Current Report on Form 8-K filed with the Securities and Exchange Commission on February 2, 2005;
- our Current Report on Form 8-K/ A filed with the Securities and Exchange Commission on March 7, 2005;
- our Current Report on Form 8-K filed with the Securities and Exchange Commission on June 2, 2005;
- our Quarterly Report on Form 10-Q for the quarter ended June 30, 2005, filed with the Securities and Exchange Commission on July 27, 2005;
- our Current Report on Form 8-K filed with the Securities and Exchange Commission on August 12, 2005; and
- the description of our common stock contained in our registration statement on Form 8-A filed with the Securities and Exchange Commission on January 13, 2004, including all amendments and reports filed for the purpose of updating such information.

We will furnish without charge to you, upon written or oral request, a copy of any or all of the documents incorporated by reference, including exhibits to these documents. You should direct any requests for documents to GTX, Inc., Attention: Corporate Secretary, 3 N. Dunlap Street, Van Vleet Building, Memphis, TN 38163. Our phone number is (901) 523-9700.

3,799,600

Shares of Common Stock



The Men's Health Biotech Company

PROSPECTUS SUPPLEMENT

**LAZARD CAPITAL MARKETS**

**COWEN AND COMPANY**

December 13, 2006

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