ZONAGEN INC
Form S-1/A
December 17, 2004

As filed with the Securities and Exchange Commission on December 17, 2004

Registration No. 333-119861

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Amendment No. 2
to

Form S-1

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

Zonagen, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**72-0233274**	**2834**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification Number)*	*(Primary Standard Industrial Classification Code Number)*

2408 Timberloch Dr., Suite B-1

The Woodlands, Texas 77380
(281) 719-3400
(Address, including zip code, and telephone number, including area code, of registrant s principal executive offices)

Joseph S. Podolski

President and Chief Executive Officer
2408 Timberloch Dr., Suite B-1
The Woodlands, Texas 77380
(281) 719-3400
(Name, address, including zip code, and telephone number, including area code, of agent for service)

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Approximate date of commencement of proposed sale to the public: As soon as practicable after this Registration Statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act, check the following box. o

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

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

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

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box. o

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

The information in this prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject to completion, dated 1 , 2004.

4,000,000 Shares

Common Stock

We are offering 4,000,000 shares of our common stock. We have granted the underwriters a 30-day option to purchase up to an additional 600,000 shares to cover over-allotments.

Our common stock is quoted on the Nasdaq SmallCap Market and the Pacific Exchange under the symbol ZONA. The last reported sale price of our common stock on the Nasdaq SmallCap Market on November 29, 2004 was $3.83.

Investing in our common stock involves risks. See Risk Factors beginning on page 7.

	Per Share	Total
Public Offering Price	$	$
Underwriting Discount	$	$
Proceeds to Zonagen (before expenses)	$	$

Neither the Securities and Exchange Commission nor any other regulatory body has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares to purchasers on , 2004.

PUNK, ZIEGEL & COMPANY WR HAMBRECHT + CO

The date of this prospectus is , 2004.

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You should rely only on the information contained in this prospectus. We have not, and the underwriters have not, authorized anyone to provide you with information that is different. This prospectus is not an offer to sell, nor is it seeking an offer to buy, these securities in any jurisdiction where the offer or sale of these securities is not permitted. You should assume that the information contained in this prospectus is accurate as of the date on the front of this prospectus only. Our business, financial condition, results of operations and prospects may have changed since that date.

Our estimates of market size in this prospectus are based on, in certain cases, public disclosure, industry and trade publications and reports prepared by third parties.

Progenta™, Androxal™, VASOMAX®, Bimexes™ and ERxin™ are our trademarks. This prospectus also contains trademarks, trade names and service marks of other companies, which are the property of their respective owners.

PROSPECTUS SUMMARY

This summary highlights selected information described more fully elsewhere in this prospectus. This summary does not contain all the information you should consider before investing in our common stock. You should read the entire prospectus, including the financial statements and related notes, before making an investment decision with respect to our common stock. You should pay special attention to the Risk Factors section of this prospectus for a discussion of factors you should consider before investing in our common stock.

References in this prospectus to Zonagen, the company, we, us, our, or similar terms refer to Zonagen, Inc., except as otherwise indicat

Our Business

We are a biopharmaceutical company focused on the development of new drugs to treat hormonal and reproductive system disorders. We operate in a near-virtual manner, outsourcing the majority of tasks associated with our development programs, including all of our preclinical and clinical research and development, using contract research organizations and sponsored research arrangements. Our four employees oversee the work of our suppliers in regards to drug development programs for product candidates for specific indications within our sphere of specialization that appear suitable for commercial development. We design, with the assistance of clinical consultants, a preclinical and clinical program that could potentially lead to the filing of a new drug application, or NDA, for that indication.

Our lead product candidate, Progenta, is based on technology that we licensed from the National Institutes of Health, the Centers for Disease Control and Prevention, and the Food and Drug Administration, or collectively, the NIH, under an exclusive, worldwide license in 1999. Progenta, which is in Phase Ib clinical trials, is an orally available small molecule compound that we are developing for the treatment of uterine fibroids and endometriosis. Uterine fibroids are common non-cancerous tumors that arise from the smooth muscle layer of the uterus. Endometriosis is a condition that occurs when endometrial tissue, which is tissue that normally lines the inside of the uterus, is found outside of the uterus. This misplaced tissue develops into growths or lesions that react to the menstrual cycle in the same way that endometrial tissue does, which results in internal bleeding and inflammation and can cause pain, infertility, scar tissue formation and bowel problems. Our second product candidate is Androxal, an orally available small molecule compound being developed for the treatment of men with testosterone deficiency. Androxal, which recently completed Phase I/II clinical trials, is a patent-pending new chemical entity conceived and assigned to us by our current President and CEO, Joseph Podolski. This proprietary compound is designed to restore normal testosterone production in males with functional testes and diminished pituitary function, a condition commonly referred to in the aging male as andropause.

Progenta

We are developing Progenta to alleviate adverse symptoms associated with both uterine fibroids and endometriosis by selectively blocking the progesterone receptor in women. The National Uterine Fibroid Foundation estimates that possibly as many as 80% of all women in the United States have uterine fibroids, and one in four of these women have symptoms severe enough to require treatment. According to The Endometriosis Association, endometriosis affects 5.5 million women in the United States and Canada and millions more worldwide. The current standards of care for uterine fibroids and endometriosis include surgery and treatment with drugs. The most effective drugs on the market are gonadotropin releasing hormone agonists, or GnRH agonists, such as Lupron® (leuprolide acetate). GnRH are hormones that play an important role in the human reproductive function, and GnRH agonists block the production of these hormones. Lupron is marketed by TAP Pharmaceuticals, a joint venture between Abbott Laboratories and Takeda Chemical Industries, Ltd. Abbott reported total Lupron sales of $787.8 million in 2003 in the United States and Canada for all indications.

We believe Progenta may have advantages over treatment with GnRH agonists. Unlike Progenta, GnRH agonists induce a low estrogen, menopausal-like state in women, and estrogen is necessary for the

maintenance of bone mineral density. Therefore, GnRH agonists tend to promote bone loss and cannot be used for more than six months at a time. When women cease treatment with GnRH agonists, fibroids rapidly regenerate and symptoms associated with endometriosis quickly reappear. We believe Progenta may have advantages over treatment with GnRH agonists because, in our animal research to date, Progenta does not appear to induce a low estrogen state and therefore should not promote bone loss, which could make Progenta a better treatment option for patients prior to surgery. In addition, we believe Progenta may provide an attractive alternative to surgery because of its potential to treat these conditions in a long-term, or chronic, fashion, resolving the symptoms that most commonly lead to surgical treatment.

We currently are conducting a Phase Ib clinical trial on Progenta in Poland for the treatment of uterine fibroids, which is scheduled to be completed by the end of 2004 and is of a small sample size of 28 people. All clinical trial results are subject to review by the U.S. Food and Drug Administration, or FDA, and the FDA may disagree with our conclusions about safety or efficacy. Preliminary observations from our Phase Ib clinical trial for Progenta for the treatment of uterine fibroids have shown some reduction in fibroid size numerically equivalent to or superior to GnRH agonists, as measured by ultrasound. Because the effects of a GnRH agonist are best evaluated after at least three months of dosing, these preliminary results may be reversed by the final results of this clinical trial or from later stage clinical trials with significantly larger and more diverse patient populations treated for longer periods of time. We intend to begin a Phase II clinical trial for Progenta in the United States for the treatment of uterine fibroids during 2005, subject to the review of our Phase Ib data by the FDA. We have not yet filed an investigational new drug application, or IND, for Progenta with the FDA. If the FDA approves our IND, only then would we be permitted to conduct a clinical trial in the United States for Progenta.

Based upon the final results of our current clinical trial for Progenta for uterine fibroids, we plan to conduct a Phase II clinical trial in Poland on Progenta for endometriosis. We believe Progenta may have advantages over current therapies because it is non-invasive, has, to date, shown a positive side effect profile compared to GnRH agonists, and has the potential for chronic use. However, we have not yet conducted any clinical trials for Progenta for the treatment of endometriosis, and any clinical trials we may conduct may not produce positive results.

Androxal

Testosterone deficiency in men is linked to several negative physical and mental conditions, including loss of muscle tone, reduced sexual desire, and deterioration of memory and certain other cognitive functions. Testosterone production normally decreases as men age, sometimes leading to testosterone deficiency in a condition commonly referred to as andropause. According to the Urology Channel, recent estimates show that approximately 13 million men in the United States experience testosterone deficiency. Current therapies focus on testosterone replacement by delivering testosterone to the blood stream either through the skin or via injection. The current gold standard in the industry is Androgel®, a topical gel marketed by Solvay Pharmaceuticals, which reported Androgel sales of approximately $283 million in 2003 in North America.

We believe Androxal may have advantages over current therapies because it is being designed as an oral therapy that acts centrally to restore normal testosterone function in the body, rather than simply replacing diminished testosterone. The administration of replacement testosterone has been linked to numerous potential adverse effects, including shrinkage of the testes. In addition, a safe and effective oral treatment for testosterone deficiency has to date been unavailable.

We recently completed a Phase I/II clinical trial for Androxal in the United States for the treatment of men with testosterone deficiency and submitted final data to the FDA. All clinical trial results are subject to review by the FDA, and the FDA may disagree with our conclusions about safety and efficacy; however, we believe these clinical trial results indicate that the safety and efficacy of Androxal compare favorably to the current market leader, Androgel. We caution that these results may be reversed by the results of later stage clinical trials with significantly larger and more diverse patient populations treated for longer periods of time. We met with FDA staff members on November 10, 2004 to review our clinical plan for the approval of Androxal. We are awaiting the written record of this meeting, but based on our discussions, we believe that

the FDA will require an additional endpoint, for example, improved libido or increased muscle mass, associated with the primary endpoint of increased testosterone levels. The FDA has agreed to review our protocols for our trials in a timely fashion under a special protocol assessment, or SPA. The FDA deems Androxal to be a new chemical entity, and additional lengthy animal studies will be required before long term human studies may be initiated and before an NDA may be filed.

Risks Affecting Us

Our business is subject to numerous risks, as discussed more fully in the section entitled Risk Factors immediately following this prospectus summary.

We have suffered substantial operating losses to date and expect our operating losses to increase over at least the next few years while we expend capital on our development programs for Progenta and Androxal.

We may not succeed in the clinical development of Progenta or Androxal.

Our inability to fulfill our obligations under our license with the NIH for Progenta may result in forfeiture of our rights to Progenta.

There is a patent holder that claims priority over our patent for Androxal.

We cannot assure that we will not have to defend our patents from other infringement claims nor that third parties will not infringe our patents.

We will need substantial additional capital to commercialize Progenta and Androxal and such capital may not be available to us when we need it on acceptable terms or at all.

We are conducting our clinical trial for Progenta in Poland, and we cannot assure that the FDA will readily accept data from foreign investigators.

We may have difficulty in obtaining the compound needed for the manufacture of Progenta in amounts sufficient to continue our clinical trials on a timely basis and at a reasonable cost.

Other companies may produce drugs which are superior to ours or may reach the market before our drugs.

We cannot assure that future governmental regulations will not substantially impair our ability to continue without substantial additional costs.

Our Corporate Information

We were formed as a Delaware corporation in 1987 and completed our initial public offering in 1993. Until 2000, we focused our development activities on our phentolamine-based product candidates for the treatment of sexual dysfunction, including VASOMAX. We partnered with Schering-Plough Ltd. and its affiliate to commercialize VASOMAX following completion of our Phase III clinical trials for VASOMAX for the treatment of male erectile dysfunction. After encountering difficulties in obtaining regulatory approval for VASOMAX, we and Schering-Plough terminated our partnership and we attempted to redeploy our assets through a strategic combination from 2000 to 2003. We acquired rights to Progenta under an exclusive, worldwide license from the NIH in 1999 and developed Androxal internally in 2001 but spent limited amounts of cash on preclinical studies for their development during the period when we were considering redeploying our assets. After a Dutch auction self tender offer was completed in January 2004 in which we repurchased 57% of our then-outstanding common stock, we increased our development activities for Progenta and Androxal by commencing a Phase Ib clinical trial for Progenta in Poland for the treatment of uterine fibroids and completing our Phase I/ II clinical trial for Androxal in the United States for the treatment of men with testosterone deficiency. To date, we have not successfully commercialized a product candidate in the United States.

Our principal executive offices are located at 2408 Timberloch Dr., Suite B-1, The Woodlands, Texas 77380, and our telephone number is (281) 719-3400. Our website address is *http://www.zonagen.com.* We do not incorporate the information on, or accessible through, our website into this prospectus, and you should not consider it part of this prospectus.

The Offering

Common stock offered by us	4,000,000 shares
Common stock to be outstanding immediately after this offering	8,992,901 shares
Use of proceeds	We estimate that our net proceeds from this offering will be approximately $13.5 million. We plan to use the proceeds to continue clinical development of our Progenta and Androxal product candidates. In addition, we may use a portion of the net proceeds for working capital and general corporate purposes. Pending these uses, the net proceeds will be invested in investment-grade, interest-bearing securities.
Nasdaq SmallCap and Pacific Exchange ticker symbol	ZONA

The number of shares of common stock outstanding immediately after this offering is based on 4,992,901 shares outstanding as of November 30, 2004 and excludes:

- 1,786,846 shares of our common stock issuable upon exercise of options previously granted to employees and non-employee directors;
- 381,933 additional shares of our common stock that are available for grant and reserved for issuance under our 2004 stock option plan and our 2000 director plan; and
- 127,366 shares reserved for issuance under our 2000 employee stock purchase plan.

Unless otherwise indicated, the information in this prospectus assumes that the underwriters will not exercise the over-allotment option.

Summary Consolidated Financial Information

The summary consolidated financial information for the years ended December 31, 2001, 2002 and 2003 were derived from, and are qualified by reference to, our consolidated financial statements, including the notes thereto, contained elsewhere in this prospectus. The unaudited consolidated summary financial information for the nine months ended September 30, 2003 and September 30, 2004 and the unaudited consolidated balance sheet data at September 30, 2004 were derived from, and are qualified by reference to, our unaudited consolidated financial statements included elsewhere in this prospectus. The following data should be read in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations contained herein.

	Year Ended December 31,			Nine Months Ended September 30,	
	2001	2002	2003	2003	2004
					(Unaudited)
	(In thousands except per share amounts)				
Statement of operations data:					
Revenues and other income					
Licensing fees	$ 2,162	$ 4,228			
Products royalties	58				
Research and development grants	115	315	$ 595	$ 459	$ 118
Interest income	1,526	711	318	254	75
Gain on disposal of fixed assets			102	102	
Other income					35
Total revenues and other income	3,861	5,254	1,015	815	228
Expenses					
Research and development	3,028	6,420	2,161	1,583	1,914
General and administrative	1,672	2,716	2,183	1,707	1,268
Interest expense and amortization of intangibles					
Total expenses	4,700	9,136	4,344	3,290	3,182
Loss from continuing operations	(839)	(3,882)	(3,329)	(2,475)	(2,954)
Loss from discontinued operations					
Gain on disposal					
Net loss before cumulative effect of change in accounting principle	(839)	(3,882)	(3,329)	(2,475)	(2,954)
Cumulative effect of change in accounting principle					
Net loss	$ (839)	$ (3,882)	$ (3,329)	$ (2,475)	$ (2,954)
Loss per share basic and diluted	$ (0.07)	$ (0.34)	$ (0.29)	$ (0.22)	$ (0.57)
Shares used in loss per share calculation:					
Basic	11,333	11,412	11,487	11,489	5,159
Diluted	11,333	11,412	11,487	11,489	5,159

	As of September 30, 2004	
	Actual	As Adjusted (1)
	(Unaudited) (In thousands)	
Balance sheet data:		
Cash and cash equivalents	$2,556	$16,082
Marketable securities	4,000	4,000
Total assets	7,046	20,572
Total current liabilities	415	415
Total stockholders equity	6,631	20,157

(1) The as adjusted balance sheet data as of September 30, 2004 gives effect to the receipt of net proceeds of approximately $13.5 million from the sale of 4,000,000 shares of common stock offered by this prospectus based on the last reported sale price of our common stock on November 29, 2004, after deducting the underwriting discount and estimated offering expenses payable by us.

RISK FACTORS

In considering whether to invest in our common stock, you should carefully read and consider the risks described below, together with all of the information we have included in this prospectus.

Risks Relating to Our Business

Our product candidates are at an early stage of development, and if we are not able to successfully develop and commercialize them, we may not generate sufficient revenues to continue our business operations.

We currently have only two product candidates, and both are in early stages of development. We recently completed a Phase I/ II clinical trial for Androxal in the United States for the treatment of men with testosterone deficiency, and Progenta is currently undergoing a Phase Ib clinical trial in Poland for the treatment of uterine fibroids. We have expended significant time, money and effort in the development of Progenta and Androxal and we will have to spend considerable additional time, money and effort before seeking regulatory approval to market these product candidates. For example, we will be required to complete additional animal studies before we can begin pivotal clinical trials for Androxal in humans.

Our business depends primarily on our ability to successfully complete clinical trials, obtain required regulatory approvals and successfully commercialize Progenta and Androxal. If we fail to commercialize Progenta and Androxal, we may be unable to generate sufficient revenues to attain profitability or continue our business operations and our reputation in the industry and in the investment community could likely be significantly damaged, each of which would cause our stock price to decline.

Because the data from preclinical studies and early clinical trials for Progenta and Androxal are not necessarily predictive of future results, we can provide no assurances that these product candidates will have favorable results in clinical trials or receive regulatory approval.

Before we can obtain regulatory approval for the commercial sale of any product candidate that we wish to develop, we are required to complete preclinical development and extensive clinical trials in humans to demonstrate its safety and efficacy. Positive data from preclinical studies or early clinical trials should not be relied upon as evidence that those studies or trials will produce positive results, or that later or larger-scale clinical trials will succeed. Initial clinical trials for Progenta and Androxal have been conducted only in small numbers of patients that may not fully represent the diversity present in larger populations, and thus the limited data we have obtained may not predict results from studies in larger numbers of patients drawn from more diverse populations, and therefore may not predict the ability of Progenta to treat uterine fibroids and endometriosis or Androxal to treat testosterone deficiency. We will be required to demonstrate through larger-scale clinical trials that these product candidates are safe and effective for use in a diverse population before we can seek regulatory approvals for their commercial sale. There is typically an extremely high rate of attrition from the failure of drug candidates proceeding through clinical trials. We will also be required to complete a two year rat carcinogenicity study before we are permitted to file a new drug application, or NDA, for Androxal. If Progenta, Androxal, or any other potential future product candidate fails to demonstrate sufficient safety and efficacy in any clinical trial, we would experience potentially significant delays in, or be required to abandon, development of that product candidate. If we delay or abandon our development efforts related to Progenta or Androxal, we may not be able to generate sufficient revenues to continue operations or become profitable.

If we fail to obtain the capital necessary to fund our operations, we will have to delay, reduce or eliminate our research and development programs or commercialization efforts.

We expect to make additional capital outlays and to increase operating expenditures over the next several years to support our preclinical development and clinical trial activities, particularly as we enter into pivotal clinical trials for Progenta and Androxal. Our existing financial resources, together with the expected proceeds of this offering, are expected to be sufficient to fund our operations through at least the end of 2005. Therefore we will need to seek additional funding through public or private financings, including equity or debt financings, and through other means, including collaborations and license agreements. We do not know

whether additional financing will be available when needed, or that, if available, we will obtain financing on terms favorable to our stockholders or us. If adequate funds are not available to us, we may be required to:

- delay, reduce the scope of or eliminate one or more of our development programs;
- relinquish, license or otherwise dispose of rights to technologies, product candidates or products that we would otherwise seek to develop or commercialize ourselves at an earlier stage or on terms that are less favorable than might otherwise be available; or
- liquidate and dissolve our company.

Our future capital requirements will depend upon a number of factors, including:

- the size, complexity, results and timing of our clinical programs;
- the cost to obtain sufficient supply of the compounds necessary for our product candidates at a reasonable cost;
- the time and costs involved in obtaining regulatory approvals;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims; and
- competing technological and market developments.

These factors could result in variations from our currently projected operating and liquidity requirements.

We have a history of operating losses, and we expect to incur increasing net losses and may not achieve or maintain profitability for some time or at all.

We have experienced significant operating losses in each fiscal year since our inception. As of September 30, 2004, we had an accumulated deficit of approximately $86.0 million. We expect to continue incurring net losses and may not achieve or maintain profitability for some time or at all. As we increase expenditures for clinical development of Progenta and Androxal, we expect our operating losses to increase for at least the next few years. Our ability to achieve profitability will depend, among other things, on successfully completing the development of Progenta and Androxal, obtaining regulatory approvals, establishing marketing, sales and manufacturing capabilities or collaborative arrangements with others that possess such capabilities, and raising sufficient funds to finance our activities. There can be no assurance that we will be able to achieve profitability or that profitability, if achieved, can be sustained.

Raising additional funds by issuing securities or through collaboration and licensing arrangements may cause dilution to existing stockholders, restrict our operations or require us to relinquish proprietary rights.

We may raise additional funds through public or private equity offerings, debt financings or corporate collaborations and licensing arrangements. We cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that we raise additional capital by issuing equity securities, our stockholders ownership will be diluted. Any debt financing we enter into may involve covenants that restrict our operations. These restrictive covenants may include limitations on borrowing and specific restrictions on the use of our assets, as well as prohibitions on our ability to create liens, pay dividends, redeem capital stocks or make investments. In addition, if we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish potentially valuable rights to our potential products or proprietary technologies, or grant licenses on terms that are not favorable to us. For example, we might be forced to relinquish all or a portion of our sales and marketing rights with respect to Progenta, Androxal or other potential products or license intellectual property that enables licensees to develop competing products.

We licensed our rights to Progenta from the National Institutes of Health, or NIH, and our inability to fulfill our commitments and obligations under such license may result in forfeiture of our rights.

Our rights to Progenta are licensed exclusively to us from the NIH under a license agreement. This license agreement contains numerous detailed performance obligations, with time sensitive dates for compliance, relating to clinical development and commercialization activities required by us or our designated third-party providers, as well as additional financial milestones and royalties. Failure to achieve the benchmarks specified in the commercial development plan attached to the license agreement or meet payment obligations could result in termination of the license agreement and the loss of our rights to develop and commercialize Progenta. During the period when we were considering redeployment of our assets, we were not in compliance with all of the original requirements stated in the commercial development plan. In July 2002, the license agreement was amended to include a revision of the original commercial development plan relating to the targeted dates for certain objectives. Additional updates of the original commercial development plan have been reached with the NIH thereafter in order to expedite development. There can be no assurance that we will be able to meet any or all of such performance objectives in the future on a timely basis or at all, or that, if we fail to meet any of such objectives, the NIH will again agree to amend such agreement to our satisfaction. The NIH has the ability to terminate the agreement for failure to comply with the material terms contained in the license agreement and for other reasons as outlined in the agreement. Should the NIH terminate the license agreement, we would lose all rights to commercialize Progenta, which would have a material adverse effect on us.

There is a patent holder that claims priority over our patent for Androxal.

U.S. Patent No. 6,391,920 was issued to a competitor on May 21, 2002 and is directed to the use of an anti-estrogen such as clomiphene citrate for use in the treatment of androgen deficiency and disorders related thereto. Androxal is purified from clomiphene citrate. We filed a request for reexamination of this patent with the U.S. Patent and Trademark Office, or PTO. The PTO has since rejected all of such claims of this patent on the grounds that each of the claims are anticipated by, or obvious in view of, a number of printed publications that were already in the public domain. The third party has filed a response to those rejections and the PTO is currently considering that response. Reexamination proceedings, in general, are unpredictable in both their conduct and the results of the proceedings. Because of the nature of the reexamination proceedings, it is difficult to predict with certainty the scope of the claims, if any, which survive the reexamination proceedings. If the other party s response is successful and its patent is upheld, it is possible that the claims of this patent could be construed so as to block our use of Androxal for indications such as the treatment of testosterone deficiency. If this were to occur, we may then be required to obtain a license from the holder of such patent in order to develop Androxal further and such license may not be available on acceptable terms or at all. In this case, we would not be able to develop or commercialize Androxal.

We cannot assure that our manufacture, use or sale of Progenta and Androxal will not infringe on the patent rights of others.

There can be no assurance that the manufacture, use or sale of Progenta or Androxal and any potential future product candidates will not infringe the patent rights of others. The patent holder who claims priority over our patent for Androxal could claim infringement against us, if the PTO upholds his patent. We may be unable to avoid infringement of the patent rights of others and may be required to seek a license, defend an infringement action or challenge the validity of the patents in court. There can be no assurance that a license to the allegedly infringed patents will be available to us on terms and conditions acceptable to us, if at all, or that we will prevail in any patent litigation. Patent litigation is extremely costly and time-consuming, and there can be no assurance that we will have sufficient resources to defend any possible litigation related to such infringement. If we do not obtain a license on acceptable terms under such patents, or are found liable for infringement, or are not able to have such patents declared invalid, we may be liable for significant money damages, may encounter significant delays in bringing Progenta and Androxal to market, or may be precluded from participating in the manufacture, use or sale of Progenta or Androxal, any of which would materially and adversely effect our business.

We face substantial uncertainty in our ability to protect our patents and proprietary technology.

Our ability to commercialize our products will depend, in part, on our or our licensors ability to obtain patents, to enforce those patents and preserve trade secrets, and to operate without infringing on the proprietary rights of others. The patent positions of biopharmaceutical companies are highly uncertain and involve complex legal and factual questions. There can be no assurance that:

- patent applications owned by or licensed to us, such as the patent application for our Progenta compound, will result in issued patents;
- patent protection will be secured for any particular technology;
- any patents that have been or may be issued to us, such as our pending patent for Androxal, or our licensors, such as the patents underlying our Progenta compound, when issued, will be valid or enforceable;
- any patents will provide meaningful protection to us;
- others will not be able to design around the patents; or
- our patents will provide a competitive advantage or have commercial application.

The failure to obtain and maintain adequate patent protection would have a material adverse effect on us and may adversely affect our ability to enter into, or affect the terms of, any arrangement for the marketing of any product.

We cannot assure that our patents will not be challenged by others.

There can be no assurance that patents owned by or licensed to us will not be challenged by others. We could incur substantial costs in proceedings, including interference proceedings before the PTO and comparable proceedings before similar agencies in other countries in connection with any claims that may arise in the future. These proceedings could result in adverse decisions about the patentability of our or our licensors inventions and products, as well as about the enforceability, validity or scope of protection afforded by the patents. Any adverse decisions about the patentability of our product candidates could cause us to either lose rights to develop and commercialize our product candidates or to license such rights at substantial cost to us. In addition, even if we were successful in such proceedings, the cost and delay of such proceedings would most likely have a material adverse effect on our business.

Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and other proprietary information, may not adequately protect our intellectual property, and will not prevent third parties from independently discovering technology similar to or in competition with our intellectual property.

We rely on trade secrets and other unpatented proprietary information in our product development activities. To the extent we rely on trade secrets and unpatented know-how to maintain our competitive technological position, there can be no assurance that others may not independently develop the same or similar technologies. We seek to protect trade secrets and proprietary knowledge, in part, through confidentiality agreements with our employees, consultants, advisors, collaborators and contractors. Nevertheless, these agreements may not effectively prevent disclosure of our confidential information and may not provide us with an adequate remedy in the event of unauthorized disclosure of such information. If our employees, scientific consultants, advisors, collaborators or contractors develop inventions or processes independently that may be applicable to our technologies, product candidates or products, disputes may arise about ownership of proprietary rights to those inventions and processes. Such inventions and processes will not necessarily become our property, but may remain the property of those persons or their employers. Protracted and costly litigation could be necessary to enforce and determine the scope of our proprietary rights. If we fail to obtain or maintain trade secret protection for any reason, the competition we face could increase, reducing our potential revenues and adversely affecting our ability to attain or maintain profitability.

We have not filed an Investigational New Drug application to conduct clinical trials for Progenta in the United States and we may not be able to obtain FDA approval of such application to permit us to conduct clinical trials for Progenta in the United States.

We are currently conducting our Phase Ib clinical trial for Progenta for the treatment of uterine fibroids in Poland. Prior to commencing any clinical trials for Progenta in the United States, we will need to submit an Investigational New Drug, or IND, application to the FDA. Any IND application that we submit to the FDA for Progenta will likely incorporate the results of our clinical trial in Poland. The FDA may not accept the results of this clinical trial and may request further preclinical data before approving the IND. Moreover, the FDA may subject the trial data that we submit to additional scrutiny and we may incur additional costs and delays responding to FDA requests for supplemental information or clarification. If we are unable to obtain FDA approval for an IND for Progenta, we will not be permitted to conduct clinical trials for Progenta in the United States and ultimately seek or obtain regulatory approval for commercialization in the United States. As a result, any delay in an IND becoming effective for Progenta would delay the further development and potential commercialization of our lead product candidate and delay our ability to generate product sales.

Delays in the commencement of clinical testing of our current and potential product candidates could result in increased costs to us and delay our ability to generate revenues.

Our product candidates will require continued preclinical testing and extensive clinical trials prior to the submission of a regulatory application for commercial sales. We recently completed our Phase I/ II clinical trial for Androxal in the United States for the treatment of men with testosterone deficiency and are continuing our Phase Ib clinical trail for Progenta in Poland and, as a result, have very limited experience conducting clinical trials. In part, because of this limited experience, we do not know whether future planned clinical trials will begin on time, if at all. Delays in the commencement of clinical testing could significantly increase our product development costs and delay any product commercialization. In addition, many of the factors that may cause, or lead to, a delay in the commencement of clinical trials may also ultimately lead to denial of regulatory approval of a product candidate.

The commencement of clinical trials can be delayed for a variety of reasons, including delays in:

obtaining approval of an IND application from the FDA for Progenta and any other potential product candidates;

conducting additional animal studies required by the FDA staff before commencement of pivotal clinical trials for Androxal;

conducting and completing a two-year rat carcinogenicity study required by the FDA staff prior to submission of an NDA for Androxal;

demonstrating sufficient safety and efficacy in past clinical trials to obtain regulatory approval to commence a further clinical trial;

reaching agreement on acceptable terms with prospective contract research organizations and clinical trial sites;

manufacturing sufficient quantities of a product candidate; and

obtaining institutional review board approval to conduct a clinical trial at a prospective site.

In addition, the commencement of clinical trials may be delayed due to insufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites, the availability of effective treatments for the relevant disease, and the eligibility criteria for the clinical trial.

Delays in the completion of, or the termination of, clinical testing of our current and potential product candidates could result in increased costs to us, and could delay or prevent us from generating revenues.

Once a clinical trial has begun, it may be delayed, suspended or terminated by us or the FDA, or other regulatory authorities due to a number of factors, including:

ongoing discussions with the FDA or other regulatory authorities regarding the scope or design of our clinical trials;

failure to conduct clinical trials in accordance with U.S. regulatory requirements, particularly for our trials for Progenta conducted in Poland;

lower than anticipated retention rate of patients in clinical trials;

inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;

lack of adequate funding to continue clinical trials;

negative results of clinical trials;

requests by the FDA for supplemental information or clarification of the results of our clinical trials in Poland;

insufficient supply or deficient quality of drug candidates or other materials necessary for the conduct of our clinical trials; or

serious adverse events or other undesirable drug-related side effects experienced by participants.

Many of these factors that may lead to a delay, suspension or termination of clinical testing of a current or potential product candidate may also ultimately lead to denial of regulatory approval of a current or potential product candidate. We experienced a clinical hold beginning in 1999 during our development of VASOMAX and were forced to abandon development of that product candidate. If we experience delays in the completion of, or termination of, clinical testing of any product candidates in the future, our financial results and the commercial prospects for our product candidates will be harmed, and our ability to generate product revenues will be delayed.

Even if we successfully complete clinical trials for Progenta and Androxal, there are no assurances that we will be able to submit, or obtain FDA approval of, a new drug application.

There can be no assurance that, if our clinical trials for Progenta and Androxal are successfully completed, we will be able to submit a new drug application, or NDA, to the FDA or that any NDA we submit will be approved by the FDA in a timely manner, if at all. After completing clinical trials for a product candidate in humans, a drug dossier is prepared and submitted to the FDA as an NDA, and includes all preclinical and clinical trial data that clearly establish both short-term and long-term safety, as well as carcinogenicity studies for a product candidate that will be used as a chronic treatment, and data that establishes the statistically significant efficacy of a product candidate, in order to allow the FDA to review such drug dossier and to consider a product candidate for approval for commercialization in the United States. If we are unable to submit a NDA with respect to Progenta or Androxal, or if any NDA we submit is not approved by the FDA, we will be unable to commercialize that product. The FDA can and does reject NDAs and requires additional clinical trials, even when drug candidates perform well or achieve favorable results in large-scale Phase III clinical trials. If we fail to commercialize Progenta or Androxal, we may be unable to generate sufficient revenues to continue operations or attain profitability and our reputation in the industry and in the investment community would likely be damaged, each of which would cause our stock price to significantly decrease.

If commercialized, our product candidates may not be approved for sufficient governmental or third-party reimbursements, which would adversely affect our ability to market our product candidates.

In the United States and elsewhere, sales of pharmaceutical products depend in significant part on the availability of reimbursement to the consumer from third-party payers, such as government and private insurance plans. Since we have no commercial products, we have not had to face this issue yet; however, third-party payers are increasingly challenging the prices charged for medical products and services. It will be time consuming and expensive for us to go through the process of seeking reimbursement from Medicaid, Medicare and private payers for Progenta and Androxal. Our products may not be considered cost effective, and coverage and reimbursement may not be available or sufficient to allow us to sell our products on a competitive and profitable basis. The passage of the Medicare Prescription Drug and Modernization Act of 2003 imposes new requirements for the distribution and pricing of prescription drugs which may negatively affect the marketing of our potential products.

If we successfully develop products but those products do not achieve and maintain market acceptance, our business will not be profitable.

Even if Progenta and Androxal are approved for commercial sale by the FDA or other regulatory authorities, the degree of market acceptance of any approved product by physicians, healthcare professionals and third-party payers and our profitability and growth will depend on a number of factors, including:

relative convenience and ease of administration;

the prevalence and severity of any adverse side effects;

availability, effectiveness and cost of alternative treatments;

pricing and cost effectiveness of Progenta and Androxal;

effectiveness of our or our collaborators sales and marketing strategy; and

our ability to obtain sufficient third-party insurance coverage or reimbursement.

If Progenta does not provide a treatment regimen that is more beneficial than Lupron, a GnRH agonist and the current therapeutic standard of care for uterine fibroids, or otherwise provide patient benefit, it likely will not be accepted favorably by the market. Similarly, if Androxal does not provide a treatment regime that is more beneficial than Androgel, the current standard of care for the treatment of testosterone deficiency, or otherwise provide patient benefit, it likely will not be accepted favorably by the market. If any products we may develop do not achieve market acceptance, then we will not generate sufficient revenue to achieve or maintain profitability.

In addition, even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if:

new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete;

unforeseen complications arise with respect to use of our products; or

sufficient third-party insurance coverage or reimbursement does not remain available.

We currently rely on third-party manufacturers and other third parties for production of our product candidates, and our dependence on these manufacturers may impair the development of our product candidates.

Currently, we do not have the ability internally to manufacture the product candidates that we need to conduct our clinical trials. We have entered into purchase orders with third-party manufacturers to produce our supplies of Progenta and Androxal; however, we have no long term contracts with suppliers of either product candidate. To date, other than some initial amounts from the NIH, we have obtained all of our supply of Progenta for our clinical trials from Bridge Organics pursuant to purchase orders on an as needed basis.

We are in the process of identifying a manufacturer for a long-term supply contract of the product candidate. There are several potential manufacturers capable of manufacturing Progenta. There can be no assurance that we will be able to successfully negotiate a long-term agreement with any of such potential manufacturers at a reasonable price and on other acceptable terms or will be able to reproduce the results obtained by Bridge Organics in manufacturing Progenta to date. We have obtained all of our supply of Androxal to date from BioVectra. We have not faced any material problems with BioVectra in supplying us with our necessary quantities of Androxal for our clinical trials and anticipate utilizing them for commercial production if Androxal is approved. There are numerous other suitable manufacturers capable of manufacturing Androxal.

For the foreseeable future, we expect to continue to rely on third-party manufacturers and other third parties to produce, package and store sufficient quantities of Progenta, Androxal and any future product candidates for use in our clinical trials. These product candidates are complicated and expensive to manufacture. If our third-party manufacturers fail to deliver our product candidates for clinical use on a timely basis, with sufficient quality, and at commercially reasonable prices, we may be required to delay or suspend clinical trials or otherwise discontinue development and production of our product candidates. While we may be able to identify replacement third-party manufacturers or develop our own manufacturing capabilities for these product candidates, this process would likely cause a delay in the availability of our product candidates and an increase in costs. We may also be required to enter into long-term manufacturing agreements that contain exclusivity provisions and/or substantial termination penalties. In addition, third-party manufacturers may have a limited number of facilities in which our product candidates can be produced, and any interruption of the operation of those facilities due to events such as equipment malfunction or failure or damage to the facility by natural disasters could result in the cancellation of shipments, loss of product in the manufacturing process or a shortfall in available product candidates.

We also depend on outside vendors for the supply of the active pharmaceutical ingredients and raw materials used to produce our product candidates. Although we believe there are numerous third-party suppliers available, if our current third-party suppliers were to cease production or otherwise fail to supply us with quality raw materials and we were unable to contract on acceptable terms for these raw materials with alternative suppliers, our ability to have our product candidates manufactured and to conduct preclinical testing and clinical trials of our product candidates would be adversely affected.

Our product candidates have only been manufactured in small quantities to date, and we may face delays or complications in manufacturing quantities of our product candidates in sufficient quantities to meet the demands of late stage clinical trials and marketing.

We cannot assure that we will be able to successfully increase the manufacturing capacity or scale-up manufacturing volume per batch, whether on our own or in reliance on third-party manufacturers, for any of our product candidates in a timely or economical manner, or at all. To date our product candidates have been manufactured exclusively by third parties in small quantities for pre-clinical and clinical trials. We will need to arrange for the production of significantly larger quantities of our product candidates for future clinical trials and for future commercial sale in the event that our product candidates are approved by the FDA or foreign regulatory bodies. Significant scale-up of manufacturing may require certain additional validation studies, which the FDA must review and approve. If we or our third-party manufacturers are unable to successfully increase the manufacturing capacity for a product candidate, the regulatory approval or commercial launch of that product candidate may be delayed or there may be a shortage in supply of that product candidate.

Our product candidates require precise, high-quality manufacturing which may not be available at acceptable costs.

Progenta is a novel compound that has never been produced in large scale. As in the development of any new compound, there are underlying risks associated with its manufacture. These risks include, but are not limited to, cost, process scale-up, process reproducibility, construction of a suitable process plant, timely availability of raw materials, as well as regulatory issues associated with the manufacture of an active pharmaceutical agent. Any of these risks may prevent us from successfully developing Progenta. Our failure,

or the failure of our third-party manufacturers to achieve and maintain these high manufacturing standards, including the incidence of manufacturing errors and reliable product packaging for diverse environmental conditions, could result in patient injury or death, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could seriously hurt our business.

We may experience delays in the development of our product candidates if the third-party manufacturers of our product candidates cannot meet FDA requirements relating to Good Manufacturing Practices.

Our third-party manufacturers are required to produce our product candidates under FDA current Good Manufacturing Practices in order to meet acceptable standards for our clinical trials. If such standards change, the ability of third-party manufacturers to produce our product candidates on the schedule we require for our clinical trials may be affected. In addition, third-party manufacturers may not perform their obligations under their agreements with us or may discontinue their business before the time required by us to gain approval for or commercialize our product candidates. Any difficulties or delays in the manufacturing and supply of our product candidates could increase our costs or cause us to lose revenue or postpone or cancel clinical trials.

The FDA also requires that we demonstrate structural and functional comparability between the same drug product produced by different third-party manufacturers. Because we may use multiple sources to manufacture Progenta and Androxal, we may need to conduct comparability studies to assess whether manufacturing changes have affected the product safety, identity, purity or potency of any commercial product candidate compared to the product candidate used in clinical trials. If we are unable to demonstrate comparability, the FDA could require us to conduct additional clinical trials, which would be expensive and significantly delay commercialization of our product candidates.

We rely on third parties to conduct clinical trials for our product candidates, and their failure to timely and properly perform their obligations may result in costs and delays that prevent us from obtaining regulatory approval or successfully commercializing our product candidates.

We rely on independent contractors, such as researchers at clinical research organizations and universities, in certain areas that are particularly relevant to our research and product development plans, such as the conduct of clinical trials. Pharm-Olam International Ltd. conducts our clinical trial in Poland for Progenta for the treatment of uterine fibroids and Advanced Biomedical Research, Inc. conducted our clinical trial in the United States for Androxal for the treatment of testosterone deficiency. The competition for these relationships is intense, and we may not be able to maintain our relationships with them on acceptable terms. These independent contractors generally may terminate their engagements with us at any time. As a result, we can control their activities only within certain limits, and they will devote only a certain amount of their time conducting research on and trials of our product candidates and assisting in developing them. If they do not successfully carry out their duties under their agreements with us, fail to inform us if these trials fail to comply with clinical trial protocols, or fail to meet expected deadlines, our clinical trials may need to be extended, delayed or terminated. We may not be able to enter into replacement arrangements without undue delays or excessive expenditures. If there are delays in testing or regulatory approvals as a result of the failure to perform by our independent contractors or other outside parties, our drug development costs will increase and we may not be able to attain regulatory approval for or successfully commercialize our product candidates.

Our liability insurance may not provide adequate coverage nor may it always be available on favorable terms or at all.

Neither Progenta nor Androxal has been approved for commercial sale. However, the current and future use of our product candidates by us and potential corporate collaborators in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims might be made directly by consumers or healthcare providers or indirectly by pharmaceutical companies, potential corporate collaborators or others selling such products. We may experience financial losses in the future due to product liability claims. We have obtained limited general commercial liability insurance coverage for our clinical trials. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing

approval for any of our product candidates. However, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or for liabilities in excess of our insurance limits, our assets may not be sufficient to cover such claims and our business operations could be impaired.

We face significant competition with many companies with substantially greater resources than we have and other possible advantages.

We are engaged in biopharmaceutical product development, an industry that is characterized by extensive research efforts and rapid technological progress. The biopharmaceutical industry is also highly competitive. Our success will depend on our ability to acquire, develop and commercialize products and our ability to establish and maintain markets for Androxal and Progenta or any products for which we receive marketing approval. Potential competitors in North America, Europe and elsewhere include major pharmaceutical companies, specialty pharmaceutical companies and biotechnology firms, universities and other research institutions and government agencies. Many of our competitors have substantially greater research and development and regulatory capabilities and experience, and substantially greater management, manufacturing, distribution, marketing and financial resources, than we do. Accordingly, our competitors may:

develop or license products or other novel technologies that are more effective, safer or less costly than the product candidates that we are developing;

obtain regulatory approval for products before we do; or

commit more resources than we can to developing, marketing and selling competing products.

The main therapeutic products competitive with Progenta for the treatment of uterine fibroids and endometriosis are GnRH agonists, especially Lupron, which is marketed by TAP Pharmaceuticals. There are additional companies developing similar progesterone-blocking technology. Asoprisnil, an anti-progestin being developed by TAP Pharmaceuticals in partnership with Schering AG, is currently in Phase III clinical trials. TAP Pharmaceuticals is a much larger company than we are with greater resources and greater ability to promote their products than we currently have. In addition, surgical treatment of both uterine fibroids and endometriosis competes with Progenta by removing uterine fibroids and by removing misplaced tissue in women with endometriosis.

Our main competitors for the treatment of testosterone deficiency are the testosterone replacement therapies currently being marketed. The current gold standard of care is Androgel, a topical gel for the replacement of testosterone developed by Solvay Pharmaceuticals. Solvay is a much larger company than we are with greater resources and marketing ability. Androxal would also compete with other forms of testosterone replacement therapies such as oral treatments, patches, injectables and a tablet applied to the upper gum. There is another topical gel currently marketed by Auxilium Pharmaceuticals called Testim®, and a transdermal patch marketed by Watson Pharmaceuticals called AndroDerm®. There can be no assurance that our product candidates will be more successful than competitive products. In addition, other potential competitors may be developing testosterone therapies similar to ours.

We are thinly staffed and highly dependent on a limited number of management persons and key personnel, and if we lose these members of our team or are unable to attract and retain additional qualified personnel, our future growth and ability to compete would suffer.

The competition for qualified personnel in the biopharmaceutical field is intense, and our future success depends upon our ability to attract, retain and motivate highly skilled scientific, technical and managerial employees. We have only four full-time employees at the present time, including our President and CEO, Joseph S. Podolski, and our Vice President, Business Development and CFO, Louis Ploth, Jr. We are highly dependent on Messrs. Podolski and Ploth for the management of our company and the development of our technologies. Both Messrs. Podolski and Ploth have employment agreements with us. There can be no assurance that either or both of Messrs. Podolski and Ploth will remain with us through development of our current product candidates. We do not maintain key person life insurance on any of our directors, officers or

employees. The loss of the services of Mr. Podolski or Mr. Ploth could delay or curtail our research and product development efforts.

Additionally, in order to commercialize our products successfully, we will be required to expand our workforce, particularly in the areas of clinical trials management, regulatory affairs, business development, sales and marketing and administrative and accounting functions. These activities will require the addition of new personnel and the development of additional expertise by management. We face intense competition for qualified individuals from numerous biopharmaceutical companies, as well as academic and other research institutions. Our intention is to hire three employees over the next two years. To the extent we are not able to attract and retain employees on favorable terms, we may face delays in the development or commercialization of our product candidates and extensive costs in retaining current employees or searching for and training new employees.

Our plan to use collaborations to leverage our capabilities may not be successful.

As part of our business strategy, we intend to enter into collaboration arrangements with strategic partners to develop and commercialize our product candidates. For our collaboration efforts to be successful, we must identify partners whose competencies complement ours. We must also successfully enter into collaboration agreements with them on terms attractive to us and integrate and coordinate their resources and capabilities with our own. We may be unsuccessful in entering into collaboration agreements with acceptable partners or negotiating favorable terms in these agreements. In addition, we may face a disadvantage in seeking to enter into or negotiating collaborations with potential partners because other potential collaborators may have greater management and financial resources than we do. Also, we may be unsuccessful in integrating the resources or capabilities of these collaborators. In addition, our collaborators may prove difficult to work with or less skilled than we originally expected. If we are unsuccessful in our collaborative efforts, our ability to develop and market product candidates could be severely limited.

Healthcare reform measures could adversely affect our business.

The business and financial condition of pharmaceutical companies are affected by the efforts of governmental and third-party payers to contain or reduce the costs of healthcare. In the United States and in foreign jurisdictions there have been, and we expect that there will continue to be, a number of legislative and regulatory proposals aimed at changing the healthcare system. For example, in some countries other than the United States, pricing of prescription drugs is subject to government control, and we expect proposals to implement similar controls in the United States to continue. The pendency or approval of such proposals could result in a decrease in our stock price or limit our ability to raise capital or to obtain strategic collaborations or licenses.

Risks Relating to this Offering

Our stock price is, and we expect it to remain, volatile, which could limit investors ability to sell stock at a profit.

The volatile price of our common stock makes it difficult for investors to predict the value of their investment, to sell shares at a profit at any given time, or to plan purchases and sales in advance. For example, for the period beginning on the first trading day following completion of our self tender offer (January 8, 2004) and ending on November 29, 2004 (as reported on the Nasdaq National Market through July 7, 2004 and subsequently on the Nasdaq SmallCap Market), a share of our common stock traded at prices ranging between $1.84 to $5.95. A variety of factors may affect the market price of our common stock. These include, but are not limited to:

publicity regarding actual or expected clinical trial results relating to products under development by our competitors or us;

delay or failure in initiating, completing or analyzing preclinical or clinical trials or unsatisfactory design or result of these trials;

achievement or rejection of regulatory approvals by our competitors or us;

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

developments concerning proprietary rights, including patents;

developments concerning our license agreement with the NIH and other current or potential collaborations or licensing arrangements;

regulatory developments in the United States and foreign countries;

economic or other crises and other external factors;

period-to-period fluctuations in our revenue and other results of operations;

changes in financial estimates by securities analysts and our ability to meet or exceed such estimates; and

actual or anticipated sales of debt or equity securities by us.

We will not be able to control many of these factors, and we believe that period-to-period comparisons of our financial results will not necessarily be indicative of our future performance. If our revenues, if any, in any particular period do not meet expectations, we may not be able to adjust our expenditures in that period, which could cause our operating results to suffer further. If our operating results in any future period fail to meet or exceed the expectations of securities analysts or investors, our stock price may decline by a significant amount.

In addition, the stock market in general, and the market for biopharmaceutical companies in particular, has experienced extreme price and volume fluctuations that may have been unrelated or disproportionate to the operating performance of individual companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance.

We expect to sell additional equity securities, which would cause dilution.

We expect to sell more equity securities in the future to obtain operating funds. We may sell these securities at a discount to the market price. Any future sales of equity will dilute the holdings of existing stockholders, possibly reducing the value of their investment.

Recent trading in our common stock has been limited, so investors may not be able to sell significant amounts of our common stock at prevailing prices.

Since the first trading day after completion of our tender offer (January 8, 2004) through November 29, 2004, the average daily trading volume in our common stock was approximately 35,100 shares. In the last 30 days, the average daily trading volume in our common stock was approximately 11,800 shares. Although trading volume in our common stock may increase after this offering, it may be difficult for investors to sell their shares in the public market at any given time at prevailing prices.

Investors in this offering will suffer immediate dilution.

As of September 30, 2004 we had a net tangible book value of approximately $6.3 million, or approximately $1.25 per share of common stock, assuming no exercise of any options. The net tangible book value per share is substantially less than the current market price per share. If investors in this offering pay more than the net tangible book value per share for stock in this offering, they will suffer immediate dilution.

As of September 30, 2004, holders of our outstanding options have the right to acquire 1,836,846 shares issuable on the exercise of stock options, at exercise prices ranging from $1.70 to $33.25 per share. If the holders convert or exercise those stock options, investors in this offering may experience additional dilution in the net tangible book value of our common stock they purchase. In addition, the sale or availability for sale of the underlying shares in the market could depress our stock price. We have registered all of the underlying

shares listed above. Holders of registered underlying shares could resell the shares immediately upon issuance, resulting in significant downward pressure on our stock price.

Anti-takeover provisions could make it more difficult for a third party to acquire us.

Our board of directors has the authority to issue up to 5,000,000 shares of preferred stock and to determine the price, rights, preferences, privileges and restrictions, including voting rights, of those shares without any further vote or action by our stockholders. The rights of holders of our common stock may be subject to, and may be adversely affected by, the rights of the holders of any preferred stock that may be issued in the future. The issuance of preferred stock may have the effect of delaying, deferring or preventing a change of control without further action by the stockholders and may adversely affect the voting and other rights of the holders of common stock. In addition, we have a stockholder Rights Agreement currently in effect until September 2005 which could have the effect of deterring, delaying or preventing a change of control without further action by our board of directors.

Both of the above-described provisions may be waived or removed by action of our board of directors. Therefore, our board of directors, which includes both our President and CEO and our CFO, could delay or prevent a change of control transaction from occurring. While our board of directors has a fiduciary duty to our stockholders, our board of directors could have interests that are at odds with our stockholders in a particular transaction which could delay or prevent a change of control transaction from occurring and could have the effect of creating entrenched management. Finally, state anti-takeover laws in Delaware related to corporate takeovers may deter, prevent or delay a change of control. The prevention or delay of a change of control action also could have a material adverse effect on the price of our common stock.

Our management will have broad discretion in allocating the net proceeds from this offering, and the failure of our management to apply the net proceeds from this offering effectively could harm our business.

We currently intend to use the net proceeds from the sale of the common stock offered hereby for continued clinical development of our Progenta and Androxal product candidates. In addition, we may use a portion of the net proceeds for working capital and general corporate purposes. We have not determined the amount of net proceeds from the sale of our common stock pursuant to this offering that we will use for each of these purposes. Accordingly, our management will retain broad discretion as to the allocation of the net proceeds of this offering. The failure of management to apply these funds effectively could negatively impact our business.

Our common stock could be delisted from the Nasdaq SmallCap Market, which would adversely affect the liquidity of our common stock.

The Nasdaq Stock Market has established rules and policies with respect to the continued listing of securities on the Nasdaq SmallCap Market. In executing these policies, the Nasdaq Stock Market has established standards and identified events following which it will normally consider suspending dealings in or removing a security from listing (delisting) on the Nasdaq SmallCap Market. We were recently required to move to the Nasdaq SmallCap Market because we no longer met the Nasdaq National Market requirement of maintaining stockholders equity of at least $10 million. The Nasdaq SmallCap Market has a requirement that an issuer have at least $2.5 million in stockholders equity for continued listing, among other requirements. If we are able to complete the offering contemplated hereby, we believe that we will continue to meet this listing requirement until the end of 2005; however, we cannot assure that we will be able to do so given the uncertainties of our capital requirements in developing our technologies.

The Nasdaq SmallCap Market also has a minimum bid price per share requirement for listed securities of $1.00. It is possible that our price per share could fall below this minimum amount any time before or following completion of the offering. If we are forced to delist our common stock and we do not qualify for listing on another exchange or in a consolidated quotation system, our common stock might continue to be traded as an unlisted company in an over-the-counter market, such as the Over-the-Counter Bulletin Board or

the pink sheets. There can be no assurance of any trading activity or the level of liquidity or market price of our common stock should it be delisted from the Nasdaq SmallCap Market.

If our common stock were delisted from the Nasdaq SmallCap Market, our common stock would be subject to the penny stock rules, which would adversely affect the liquidity of our common stock.

If Nasdaq delisted our common stock, it could become subject to Rule 15g-9 under the Securities Exchange Act of 1934, as amended, or Exchange Act, which imposes additional sales practice requirements on broker-dealers that sell such securities to persons other than established customers and accredited investors (generally, individuals with net worth in excess of $1,000,000 or annual incomes exceeding $200,000, or $300,000 together with their spouses). For transactions covered by this rule, a broker-dealer must make a special suitability determination for the purchaser and receive the purchaser s written consent to the transaction prior to sale. Consequently, this rule may adversely affect the ability of the holders of our common stock to sell their shares in the secondary market.

Securities and Exchange Commission, or SEC, regulations define a penny stock to be any non-Nasdaq equity security that has a market price (as therein defined) of less than $5.00 per share or with an exercise price of less than $5.00 per share, subject to certain exceptions). For any transaction involving a penny stock, unless exempt, the rules require delivery, prior to any transaction in a penny stock, of a disclosure schedule prepared by the SEC relating to the penny stock market. The SEC also requires disclosure about commissions payable to both the broker-dealer and the registered representative and current quotations for the securities. Finally, the SEC requires monthly statements to be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks.

These penny stock restrictions will not apply to our common stock if it remains listed on Nasdaq and meets certain price and volume requirements on a current and continuing basis or meets certain minimum net tangible assets or average revenue criteria. We cannot ensure that our common stock will qualify for exemption from these restrictions. Even if our common stock were exempt from such restrictions, we would remain subject to Section 15(b)(6) of the Exchange Act, which gives the SEC the authority to prohibit any person engaged in unlawful conduct while participating in a distribution of a penny stock from associating with a broker-dealer or participating in a distribution of a penny stock, if the SEC finds that such a restriction would be in the public interest. If our common stock were subject to the rules on penny stocks, the market liquidity for our common stock could be severely and adversely affected.

Our former independent public accountant, Arthur Andersen LLP, has ceased operations and investors may be unable to exercise effective remedies against it in any legal action.

Arthur Andersen LLP was our independent auditor for the eight years ended December 31, 2001. On June 15, 2002, a jury in Houston, Texas found Arthur Andersen LLP guilty of federal obstruction of justice charges arising from the federal government s investigation of Enron Corp. On June 15, 2002, Arthur Andersen LLP ceased practicing before the SEC and substantially all of its personnel have left the firm, including the individuals responsible for auditing our audited financial statements for the year ended December 31, 2001 that are included in this prospectus. On June 18, 2002 we dismissed Arthur Andersen LLP and on July 10, 2002 appointed PricewaterhouseCoopers LLP as our independent registered public accounting firm.

Arthur Andersen LLP has not reissued its audit report with respect to the audited financial statements included in this prospectus covered by such report. Furthermore, Arthur Andersen LLP has not consented to the inclusion or incorporation by reference of its audit report in the registration statement of which this prospectus forms a part or in any other filings we may make with the SEC. As a result, investors in this offering may not have an effective remedy against Arthur Andersen LLP in connection with a material misstatement or omission with respect to our audited financial statements that are included elsewhere in this prospectus, the registration statement of which this prospectus forms a part or any other filing we may make with the SEC, including any claim under Sections 11 and 12 of the Securities Act of 1933, as amended. Even if such investors were able to assert such a claim, as a result of its conviction and other lawsuits, Arthur

Andersen LLP may fail or otherwise have insufficient assets to satisfy claims made by investors or by us that might arise under federal securities laws or otherwise relating to any alleged material misstatement or omission with respect to our audited financial statements. In addition, in connection with any future capital markets transaction in which we are required to include financial statements that were audited by Arthur Andersen LLP, as a result of the foregoing, investors may elect not to participate in any such offering or, in the alternate, may require us to obtain a new audit with respect to previously audited financial statements. Consequently, our financing costs may increase or we may miss attractive capital market opportunities.

FORWARD-LOOKING STATEMENTS

We make forward-looking statements in this prospectus, including certain information set forth in the sections entitled Prospectus Summary, Business and Management s Discussion and Analysis of Financial Condition and Results of Operations. We have based these forward-looking statements on our current views and assumptions about future events and our future financial performance. You can generally identify forward-looking statements by the appearance in such a statement of words like anticipate, believe, continue, could, estimate, expe intend, may, plan, potential, predict, project, should or will or other comparable words or the negative of these words. When you co forward-looking statements, you should keep in mind the risk factors we describe and other cautionary statements we make in this prospectus.

Among the risks, uncertainties and assumptions to which these forward-looking statements may be subject are:

our ability to have success in the clinical development of our technologies, including Progenta and Androxal;

uncertainty related to our patent portfolio and the possibility of competing patents;

our ability to raise additional capital after this offering on acceptable terms or at all;

the reliability of clinical trials in non-U.S. jurisdictions;

our ability to have Progenta and Androxal manufactured in amounts necessary for our clinical trials at an acceptable cost;

our ability to remain listed on the Nasdaq SmallCap Market; and

our ability to have success in meeting governmental regulations and the costs and time required to meet such regulatory requirements.

Our forward-looking statements are only predictions based on expectations that we believe are reasonable. Actual events or results may differ materially from those described in any forward-looking statement. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. To the extent these risks, uncertainties and assumptions give rise to events that vary from our expectations, the forward-looking events discussed in this prospectus may not occur.

USE OF PROCEEDS

We estimate that we will receive net proceeds of approximately $13.5 million (based on the last reported sale price of our common stock on November 29, 2004) from the sale of 4,000,000 shares in this offering, after deducting the underwriting discount and estimated offering expenses. If the underwriters over-allotment option is exercised in full, we estimate that we will receive an additional $2.2 million. We intend to use the proceeds from this offering as follows:

approximately $4.1 million to fund our planned Phase II clinical trial for Progenta for the treatment of uterine fibroids;

approximately $700,000 to fund a Phase II clinical trial for Progenta for the treatment of endometriosis;

approximately $5.3 million to fund our planned Phase III clinical trial for Androxal for the treatment of testosterone deficiency;

up to an estimated $2.7 million to fund animal studies for Progenta and Androxal; and

the balance for working capital and general corporate purposes.

Pending these uses, the net proceeds will be invested in investment-grade, interest-bearing securities. We believe such proceeds, together with our current resources, will last through at least the end of 2005. Thereafter, we anticipate additional equity financings or strategic collaborations to fund continued development and potential commercialization of our product candidates. In order to reach commercialization, we estimate that we will need to spend an additional $21.2 million to complete development of Progenta for the treatment of uterine fibroids and an additional $10.7 million to complete development of Androxal for the treatment of testosterone deficiency.

DIVIDEND POLICY

We currently intend to retain any future earnings to finance the growth, development and expansion of our business. Accordingly, we do not intend to declare or pay any dividends on our common stock for the foreseeable future. The declaration, payment and amount of future dividends, if any, will be at the sole discretion of our board of directors after taking into account various factors, including our financial condition, results of operations, cash flow from operations, current and anticipated capital requirements and expansion plans, the income tax laws then in effect and the requirements of Delaware corporate law.

PRICE RANGE OF COMMON STOCK

Our common stock is quoted on the Nasdaq SmallCap Market and the Pacific Exchange under the symbol ZONA. The following table shows the high and low sale prices per share of our common stock, as reported by the Nasdaq National Market (prior to July 8, 2004) and by the Nasdaq SmallCap Market (after July 8, 2004), during the periods presented.

	Price Range	
	High	**Low**
2002		
First Quarter	$7.44	$4.12
Second Quarter	4.68	0.90
Third Quarter	1.54	0.99
Fourth Quarter	1.42	0.75
2003		
First Quarter	$1.20	$0.87
Second Quarter	1.73	1.15
Third Quarter	1.97	1.28
Fourth Quarter	1.91	1.50
2004		
First Quarter	$4.35	$1.83
Second Quarter	5.40	2.44
Third Quarter	5.95	2.76
Fourth Quarter (through November 29, 2004)	3.94	3.07

All of the foregoing prices reflect interdealer quotations, without retail mark-up, markdowns or commissions, and may not necessarily represent actual transactions in our common stock.

On November 29, 2004, the last sale price of our common stock, as reported by the Nasdaq SmallCap Market, was $3.83 per share. On November 29, 2004, there were 206 holders of record of our common stock.

CAPITALIZATION

The following table sets forth our unaudited actual and as adjusted capitalization at September 30, 2004. The as adjusted column gives effect to the sale of 4,000,000 newly issued shares of common stock in this offering, based on an offering price of $3.83 per share (based on the last reported sale price of our common stock on November 29, 2004) and the receipt of net proceeds of approximately $13.5 million after deducting the underwriting discount and estimated offering expenses payable by us. The actual price at which shares will be sold pursuant to this offering may be more or less than $3.83 per share, and such variation would affect portions of the as adjusted column of the following table. Depending on the extent of such variation, the effect on the as adjusted column could be material.

	September 30, 2004	
	Actual	As Adjusted
	(Unaudited) (In thousands)	
Stockholders equity:		
Undesignated preferred stock, $.001 par value: 5,000,000 shares authorized; none issued and outstanding		
Common stock, $.001 par value: 20,000,000 shares authorized, 11,989,936 shares issued (actual) and 15,989,936 shares issued (as adjusted); and 4,992,901 shares outstanding (actual) and 8,992,901 shares outstanding (as adjusted)	$ 12	$ 16
Additional paid-in capital	114,377	127,899
Deferred compensation	(260)	(260)
Cost of treasury stock, 6,997,035 shares	(21,487)	(21,487)
Deficit accumulated during the development stage	(86,011)	(86,011)
Total stockholders equity	$ 6,631	$ 20,157

The number of shares of common stock immediately outstanding after this offering is based on 4,992,901 shares outstanding as of September 30, 2004 on an actual basis and excludes:

1,836,846 shares of common stock issuable upon exercise of stock options at a weighted average exercise price of $4.84 per share;

381,933 shares available for grant under our 2004 stock option plan and 2000 director plan; and

127,366 shares of common stock reserved for future issuance under our 2000 employee stock purchase plan.

DILUTION

Our net tangible book value as of September 30, 2004, was approximately $6.3 million, or $1.25 per share. Net tangible book value per share represents our tangible net worth (tangible assets less total liabilities) divided by the total number of outstanding shares of our common stock. Dilution in net tangible book value per share represents the difference between the amount per share that investors will pay in this offering and the net tangible book value per share immediately afterwards.

After giving effect to the receipt of $13.5 million of estimated net proceeds from the sale of 4,000,000 shares of our common stock in this offering at an assumed price of $3.83 per share after deducting the underwriting discount and estimated expenses of this offering, our adjusted net tangible book value as of September 30, 2004 would have been $19.8 million or $2.20 per share. This represents an immediate increase in our net tangible book value of $0.95 per share to existing stockholders and an immediate dilution of $1.63 per share to new investors purchasing our common stock in this offering. The following table illustrates this per share dilution to new investors purchasing our common stock in this offering:

Assumed public offering price per share		$3.83
Net tangible book value per share as of September 30, 2004	$1.25	
Increase in net tangible book value per share attributable to new investors	0.95	
Adjusted net tangible book value per share after this offering		2.20
Dilution per share to new investors		$1.63

Assuming the exercise in full of the underwriters over-allotment option, the adjusted net tangible book value per share after this offering would be $2.29, the increase in net tangible book value per share to existing stockholders would be $1.04 and the dilution in net tangible book value per share to new investors would be $1.54.

The table above is based on 4,992,901 shares of common stock outstanding as of September 30, 2004 and excludes:

1,836,846 shares of common stock issuable upon exercise of stock options at a weighted average exercise price of $4.84 per share;

381,933 shares available for grant under our 2004 stock option plan and 2000 director plan; and

127,366 shares of common stock reserved for future issuance under our 2000 employee stock purchase plan.

SELECTED CONSOLIDATED FINANCIAL INFORMATION

The statements of operations data for the three years ended December 31, 2003, 2002 and 2001 and the balance sheet data as of December 31, 2002 and 2003 have been derived from our audited financial statements included elsewhere in this prospectus. The statements of operations data for the nine months ended September 30, 2003 and 2004 and the balance sheet data as of September 30, 2004 have been derived from our unaudited financial statements included elsewhere in this prospectus, and, in the opinion of management, have been prepared on a basis consistent with the audited financial statements and include all adjustments, which consist only of normal recurring adjustments, necessary to present fairly in all material respects the information included in those statements. The statements of operations data for the years ended December 31, 1999 and 2000 and the balance sheet data as of December 31, 1999, 2000, and 2001 have been derived from audited financial statements not included in this prospectus. Our historical results are not necessarily indicative of results to be expected for any future period. The data presented below have been derived from financial statements that have been prepared in accordance with generally accepted accounting principles and should be read in conjunction with our financial statements, including the notes, and with Management s Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this prospectus.

	Year Ended December 31,					Nine Months Ended September 30,	
	1999	2000	2001	2002	2003	2003	2004
	(In thousands except per share amounts					) (unaudited)	
Statement of operations data:							
Revenues and other income							
Licensing fees		$ 2,115	$2,162	$ 4,228			
Products royalties	$ 242	164	58				
Research and development grants		72	115	315	$ 595	$ 459	$ 118
Interest income	2,170	2,239	1,526	711	318	254	75
Gain on disposal of fixed assets					102	102	
Other income					35		
Total revenues and other income	2,412	4,590	3,861	5,254	1,015	815	228
Expenses							
Research and development	12,180	4,495	3,028	6,420	2,161	1,583	1,914
General and administrative	3,249	2,796	1,672	2,716	2,183	1,707	1,268
Interest expense and amortization of intangibles	8						
Total expenses	15,437	7,291	4,700	9,136	4,344	3,290	3,182
Loss from continuing operations	(13,025)	(2,701)	(839)	(3,882)	(3,329)	(2,475)	(2,954)
Loss from discontinued operations	59						
Gain on disposal	1,014						
Net loss before cumulative effect of change in accounting principle	(11,952)	(2,701)	(839)	(3,882)	(3,329)	(2,475)	(2,954)
Cumulative effect of change in accounting principle		(8,454)					
Net loss	$(11,952)	$(11,155)	$ (839)	$(3,882)	$(3,329)	$(2,475)	$(2,954)

	Year Ended December 31,					Nine Months Ended September 30,	
	1999	2000	2001	2002	2003	2003	2004
	(In thousands except per share amounts					) (unaudited)	
Per share information basic and diluted:							
Loss from continuing operations	$ (1.16)	$ (0.24)	$ (0.07)	$ (0.34)	$ (0.29)	$ (0.22)	$ (0.57)
Income (loss) from discontinued operations	0.01						
Gain on disposal	0.09						
Net loss before cumulative effect of change in accounting principle	(1.06)	(0.24)	(0.07)	(0.34)	(0.29)	(0.22)	(0.57)
Cumulative effect of change in accounting principle		(0.75)					
Loss per share basic and diluted	$ (1.06)	$ (0.99)	$ (0.07)	$ (0.34)	$ (0.29)	$ (0.22)	$ (0.57)
Shares used in loss per share calculation:							
Basic	11,244	11,303	11,333	11,412	11,487	11,489	5,159
Diluted	11,244	11,303	11,333	11,412	11,487	11,489	5,159

	As of December 31,					As of September 30, 2004
	1999	2000	2001	2002	2003	
	(In thousands)					(unaudited)
Balance sheet data:						
Cash and cash equivalents	$ 4,106	$ 2,511	$ 1,521	$ 8,683	$20,946	$2,556
Marketable securities	35,030	30,346	28,535	16,455	2,000	4,000
Total assets	46,287	40,374	36,914	27,370	24,028	7,046
Total current liabilities	4,537	5,071	4,231	519	541	415
Total long term debt						
Total stockholders equity	41,750	31,060	30,569	26,851	23,487	6,631

MANAGEMENT S DISCUSSION AND ANALYSIS

OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following management s discussion and analysis should be read in conjunction with our historical consolidated financial statements and their notes included elsewhere in this prospectus. This discussion contains forward-looking statements that reflect our current views with respect to future events and financial performance. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors, such as those set forth under Risk Factors and elsewhere in this prospectus.

Overview

We are a biopharmaceutical company focused on the development of new drugs to treat hormonal and reproductive system disorders. Our lead product candidate, Progenta, is an orally available small molecule compound that we are developing for the treatment of uterine fibroids and endometriosis. We currently are conducting a Phase Ib clinical trial for Progenta in Poland for the treatment of uterine fibroids, which is scheduled to be completed by the end of 2004. We intend to begin a Phase II clinical trial for Progenta in the United States for the treatment of uterine fibroids during 2005, subject to review of our Phase Ib data by the U.S. Food and Drug Administration, or FDA. Based upon the final results of our Phase Ib clinical trial for Progenta for the treatment of uterine fibroids, we plan to conduct a Phase II clinical trial in Poland for Progenta for the treatment of endometriosis. Our second product candidate is Androxal, an orally available small molecule compound being developed for the treatment of testosterone deficiency in men. We recently completed a Phase I/ II clinical trial in the United States for Androxal for the treatment of men with testosterone deficiency and submitted final data to the FDA. We met with FDA staff members on November 10, 2004 to review our clinical plan for the approval of Androxal. The FDA has agreed to review our protocols for our trials in a timely fashion under a special protocol assessment, or SPA. The FDA deems Androxal to be a new chemical entity, and additional lengthy animal studies will be required before long term human studies may be initiated and an NDA may be filed.

We have four full-time employees who utilize the services of contract research organizations, contract manufacturers and various consultants to assist us in performing regulatory services for the clinical development of our products. We are completely dependent on our various contract groups to adequately perform the activities required to obtain regulatory approval of our products.

The clinical development of pharmaceutical products is a complex undertaking, and many products that begin the clinical development process do not obtain regulatory approval. The costs associated with our clinical trials may be impacted by a number of internal and external factors, including the number and complexity of clinical trials necessary to obtain regulatory approval, the number of eligible patients necessary to complete our clinical trials and any difficulty in enrolling these patients, and the length of time to complete our clinical trials. Given the uncertainty of these potential costs, we are unable to estimate the total costs we will incur for the clinical development of our product candidates. We do, however, expect these costs to increase substantially in future periods as we continue later-stage clinical trials, initiate new clinical trials for additional indications and seek to obtain regulatory approvals. Any failure by us to obtain, or any delay in obtaining, regulatory approvals could cause our research and development expenditures to increase and, in turn, have a material adverse effect on our results of operations.

In order to complete the clinical development of our Androxal product candidate, we must achieve a positive conclusion to the current patent issue relating to Androxal described in our risk factor titled There is a patent holder that claims priority over our patent for Androxal. If we were to obtain regulatory approval of Progenta, we will need to develop a long-term, commercially viable source of bulk Progenta to successfully commercialize the product candidate.

We have not generated any revenue from commercial sale of our current product candidates Progenta and Androxal. We will not receive any revenue from commercial sales unless we complete the clinical trial process, obtain regulatory approval, and successfully commercialize one or more of our product candidates.

We cannot be certain when or if any net cash inflow from any of our current product candidates will commence.

We will need to raise additional capital through the sale of equity securities to continue the clinical development of our products. If we are not able to raise capital through the sale of equity securities, or cannot locate an alternative source of financing, the outcome would have a material adverse effect on us and the clinical development timeline of our product candidates. If we are not able to raise adequate capital for our clinical development plans, then we will have to adjust our plans, which will delay the approval process of our product candidates.

Historical Background

Prior to 2004, we focused most of our resources on the development of VASOMAX and related phentolamine-based products for the treatment of male erectile dysfunction. Beginning in 1999, the FDA placed our phentolamine-based products on clinical hold, which was subsequently lifted to a partial clinical hold the following year. As a result of the setbacks associated with this FDA hold, as well as other setbacks with the European regulatory agency in connection with phentolamine, we undertook two separate efforts in 2000 and 2002 to identify strategic alternatives. These efforts culminated in the signing of a definitive merger agreement in October 2002 with a potential strategic partner, which was subsequently terminated in March 2003 for regulatory and other reasons. During the remainder of 2003, the Board continued to review all of the options available to us.

As a result of the numerous Board discussions during 2003, our board of directors approved, on October 17, 2003, a modified Dutch auction self tender offer to purchase up to 9,836,065 shares, or up to 86%, of our then-outstanding common stock at a purchase price not greater than $2.10 nor less than $1.83 per share, which amount was subsequently amended to 8,571,428 shares of our common stock. We intended to continue to develop our earlier stage technologies with a focus on Progenta and Androxal with funds remaining from the tender offer, which at that time was anticipated to be no less than $4 million.

On January 7, 2004, we accepted for purchase 6,547,635 shares (57% of our then-outstanding common stock) at a purchase price of $2.10 per share in accordance with the terms of the tender offer, which included 60,888 shares issuable upon exercise of options tendered by directors, for a total aggregate purchase amount of approximately $14 million, including costs associated with the offer. Four of the five members of our board of directors at that time tendered all of their shares and in-the-money options (except in-the-money options exercisable for 5,000 shares held by one director) in the tender offer. Joseph S. Podolski, our President and CEO, did not tender any of his shares or options. These four board members did not stand for re-election at our 2003 annual meeting of stockholders, which was held on January 14, 2004. At that meeting, four new directors were elected.

We will continue our efforts to out-license our phentolamine-based product candidates, including VASOMAX. We will no longer maintain our current patent portfolio for any of our immunotherapies, including our hCG and zona pellucida immuno-contraceptive vaccines and associated vaccine adjuvants. There can be no assurance that we will be able to create any value from out-licensing activities of our prior development programs.

Results of Operations

Comparison of Nine-Month Periods Ended September 30, 2004 and 2003

Revenues. Total revenues were approximately $228,000 for the nine-month period ended September 30, 2004 as compared to $815,000 for the same period in the prior year.

Research and development grant revenues were $118,000 for the nine-month period ended September 30, 2004 as compared to $459,000 for the same period in the prior year. Grant revenue relate to three Small Business Innovative Research, or SBIR, grants that were awarded to us in the third quarter ended September 30, 2002. We performed a portion of that paid research under our one existing $836,441 Phase II grant during the nine-month period ended September 30, 2004 as compared to the research that was

performed under three SBIR grants during the same period in the prior year. Two of the awarded SBIR grants were depleted during 2003 and the last existing grant for $836,441 has essentially been depleted during the third quarter ended September 30, 2004. We intend to continue applying for additional SBIR grants to offset product development costs. Due to the competitive nature of these grants, there can be no assurance that any grants that are applied for in the future will be awarded to us.

Interest income was $75,000 for the nine-month period ended September 30, 2004 as compared to $254,000 for the same period in the prior year. This decrease is primarily due to the reduction in investment cash on hand as a result of completion of our self tender offer for an approximate aggregate purchase price of $13.7 million, which was exclusive of approximately $289,000 of associated costs.

During the nine-month period ended September 30, 2003, we sold substantially all of our fixed assets, which were not necessary for our current clinical development programs of either Progenta or Androxal for approximate net proceeds of $225,000, which was $102,000 over their book value.

Other revenue included in the nine-month period ended September 30, 2004 of $35,000 was from the sale of some of our preclinical phentolamine data that is to be used for a purpose that does not compete with our sexual dysfunction technologies.

Research and Development Expenses. Research and development, or R&D, expenses include contracted research, regulatory affairs activities and general research and development expenses. R&D expenses increased 21% to $1.9 million for the nine-month period ended September 30, 2004 as compared to $1.6 million for the same period in the prior year. The increase in R&D expenses for the nine-month period ended September 30, 2004, is primarily due to an increase of $804,000 in costs associated with our Phase Ib clinical trial for Progenta for uterine fibroids in Poland and the write-off of our patent portfolio related to our vaccine adjuvants, prostate cancer vaccines and hCG immuno-contraceptive vaccine in the amount of $308,000, offset by a decrease of $336,000 in costs associated with our SBIR grants and a decrease of $208,000 in expenses related to the completion of the in-human portion of Phase I/II clinical trial for Androxal for testosterone deficiency in the United States. Reimbursed R&D expenses relating to our SBIR grants were $336,000 less for the nine-month period ended September 30, 2004 as compared to the same period in the prior year. In addition, during the nine-month period ended September 30, 2003, we reduced our research staff and incurred a $122,000 severance charge.

General and Administrative Expenses. General and administrative, or G&A, expenses decreased 26% to $1.3 million for the nine-month period ended September 30, 2004 as compared to $1.7 million for the same period in the prior year. The decrease in expenses for the and nine-month period ended September 30, 2004 is primarily due to a decrease in costs associated with the search for a potential strategic alternative and a reduction in directors and officers insurance costs, offset by an increase in professional fees and non cash stock option compensation expense.

Comparison of Years Ended December 31, 2003 and 2002

Revenues. Total revenues for 2003 were $1.0 million as compared with $5.3 million for 2002. Licensing fees for 2003 were $0 as compared with $4.2 million in the prior year. Due to the termination of our Schering-Plough agreements in July 2002, we recognized the remaining $3.2 million of deferred revenue in the quarter ended September 30, 2002. Research and development grants for 2003 were $595,000 as compared with $315,000 for 2002 relating to our SBIR grants. We did not receive any milestone payments from Schering-Plough in 2002 for VASOMAX under the agreements that were mutually terminated in July 2002. Product royalties from sales of VASOMAX in Latin America were $0 for 2002. Due to the termination of the Schering-Plough agreements, we do not expect to receive any royalties in the foreseeable future.

Interest income decreased 55% to $318,000 for 2003 as compared with $711,000 for 2002 primarily due to a reduction in interest rates and lower cash balances.

We sold substantially all of our fixed assets for approximate net proceeds of $225,000 and recognized a gain of $102,000 over their book value. These proceeds were collected in July 2003.

Research and Development Expenses. Following the April 2002 withdrawal by Schering-Plough of its application for regulatory approval of VASOMAX in the United Kingdom, we continued scaling back R&D spending activities to maintain our cash reserves for future redeployment. R&D expenses decreased 66% to $2.2 million in 2003, as compared with $6.4 million in 2002, which included net non-cash expenses of $4.1 million related to our VASOMAX product. Due to the termination of the Schering-Plough agreements in July 2002, the future uncertainty surrounding the VASOMAX product and the fact that we are not presently committing resources toward the approval of VASOMAX, we wrote off non-cash expenses for our bulk phentolamine inventory previously valued at $4.4 million and our VASOMAX patent estate previously valued at approximately $1.0 million in the quarter ended June 30, 2002, and in July 2002, a liability due to Schering-Plough of $1.3 million relating to a prior joint clinical development program for VASOMAX was forgiven and taken as a reduction to R&D expenses. In addition, R&D expenses in the quarter ended June 30, 2002 were reduced by $188,000 due to a reimbursement of prior clinical expenses for VASOMAX that was received from a clinical research organization after a reconciliation was completed comparing actual expenses to payments made by us. R&D expenses excluding the four adjustments listed above would have been $2.5 million in 2002.

General and Administrative Expenses. G&A expenses decreased 20% to $2.2 million in 2003 as compared with $2.7 million in 2002. The decrease in expenses is primarily due to the decrease in costs associated with potential strategic alternative opportunities, professional services and non-cash compensation expenses offset by an increase in insurance expense.

We incurred $284,000 in the three month period ended December 31, 2003 relating to transaction costs associated with our tender offer that was completed in January 2004. These costs were recorded as other assets on the balance sheet and were charged to treasury stock in January 2004 when the tender offer was completed.

Comparison of Years Ended December 31, 2002 and 2001

Revenues. Total revenues for 2002 were $5.3 million as compared with $3.9 million for 2001. Licensing fees for 2002 were $4.2 million as compared with $2.2 million for 2001. Research and development grants for 2002 were $315,000 as compared with $115,000 for 2001 relating to our SBIR grants. We did not receive any milestone payments from Schering-Plough in either 2002 or 2001 for VASOMAX. Product royalties from sales of VASOMAX in Latin America were $0 for 2002 as compared to $58,000 for 2001. Under the terms of the Schering agreements, we received quarterly royalty payments based on net product sales by Schering-Plough. These quarterly payments had lagged current quarter sales by up to sixty days.

Interest income decreased 53% to $711,000 for 2002 as compared with $1.5 million for 2001 primarily due to a reduction in interest rates and lower cash balances.

Research and Development Expenses. R&D expenses increased 112% to $6.4 million in 2002 as compared with $3.0 million in 2001. Due to the termination of the Schering-Plough agreements in July 2002, the future uncertainty surrounding the VASOMAX product and the fact that we are no longer committing resources toward the approval of VASOMAX, we wrote off non-cash expenses for our bulk phentolamine inventory previously valued at $4.4 million and our VASOMAX patent estate previously valued at approximately $1.0 million in the quarter ended June 30, 2002, and in July 2002 a liability due to Schering-Plough of $1.3 million relating to a prior joint clinical development program for VASOMAX was forgiven and taken as a reduction to R&D expenses. In addition, R&D expenses in the quarter ended June 30, 2002 were reduced by $188,000 due to a reimbursement of prior clinical expenses for VASOMAX that was received from a clinical research organization after a reconciliation was completed comparing actual expenses to payments made by us. R&D expenses excluding the four adjustments listed above would have been $2.5 million in 2002.

General and Administrative Expenses. G&A expenses increased 62% to $2.7 million in 2002 as compared with $1.7 million in 2001. This increase in expenses was primarily due to an increase in costs associated with potential strategic alternative opportunities and increases in insurance rates and non-cash

personnel expenses, offset by a discontinuation of quarterly amortization expenses relating to a non-cash compensation charge for stock options previously issued in December 1996 that were fully amortized by December 31, 2001.

Liquidity and Capital Resources

As of September 30, 2004, we had an accumulated deficit of $86.0 million. Losses have resulted principally from costs incurred in conducting clinical trials for VASOMAX, our discontinued product for the oral treatment of male erectile dysfunction, and our related discontinued female sexual dysfunction product candidate, in research and development activities related to efforts to develop our current product candidates and from the associated administrative costs required to support those efforts.

We have incurred losses since our inception in 1987 and expect to continue to incur losses for at least the foreseeable future. Since inception, we have financed our operations primarily with proceeds from private placements and public offerings of equity securities, with funds received under collaborative agreements and SBIR grants. Our primary use of cash to date has been in operating activities to fund research and development, including preclinical studies and clinical trials, and general and administrative expenses. We believe our current financial resources are adequate to complete our Phase Ib clinical trial for Progenta for uterine fibroids in Europe and to complete our ongoing data management of our Phase I/ II clinical trial for Androxal for testosterone deficiency in men in the United States. We will continue to apply for SBIR grants to fund internal research, but we do not have any committed funding at this time. We believe that our existing capital resources, excluding this offering, will be sufficient to fund our operations under our current operating plan through the end of June 2005. We believe that our existing resources, together with the expected net proceeds from this offering, will be sufficient to fund our accelerated clinical development plans for Progenta and Androxal through at least the end of 2005. In order to reach commercialization, we estimate that we will need to spend an additional $21.2 million to complete development of Progenta for the treatment of uterine fibroids and an additional $10.7 million to complete development of Androxal for the treatment of testosterone deficiency. We do not have any other committed sources of funding at this time. If we are unable to complete this offering and derive sufficient funding from alternative sources, we would be required to delay or abandon our clinical development programs which would have a material adverse effect on our business.

We will require substantial additional funds to continue the development of Progenta and Androxal. Our ability to raise additional funds will depend on many factors, including the progress of our clinical development programs, the condition of the equity capital markets generally and the market for biopharmaceutical stocks specifically. There can be no assurance that we will be able to obtain financing on favorable terms in the public or private capital markets, or at all. Our failure or inability to obtain additional financing on acceptable terms could force us to discontinue the clinical development of Progenta and/or Androxal.

In January 2004, we purchased 6,547,635 shares of our common stock (approximately 57% of our then-outstanding common stock) at a purchase price of $2.10 per share in accordance with the terms of our self tender offer, which expired on January 7, 2004. This purchase included 60,888 shares issuable upon exercise of options for a total aggregate purchase price of approximately $13.7 million, exclusive of approximately $289,000 of costs associated with the offer. As of September 30, 2004, we had 4,992,901 shares outstanding.

Cash and cash equivalents and marketable securities were $6.6 million at September 30, 2004 as compared to $22.9 million at December 31, 2003.

Excluding purchases of investment marketable securities of $2.0 million, we used $2.3 million during the nine-month period ended September 30, 2004 for operating activities. The major uses of cash for operating activities during the nine-month period ended September 30, 2004 was to fund operating losses of approximately $3.0 million partially offset by a non-cash write-off of $308,000 relating to our patent portfolio of our vaccine adjuvants, prostate cancer vaccines and hCG immuno-contraceptive vaccine and a $274,000 decrease in other assets which primarily related to the costs associated with our self tender offer that was completed in January 2004. Excluding maturities of investment marketable securities, cash used in operating activities was $2.4 million in the nine-month period ended September 30, 2003. The major uses of cash in the

nine-month period ended September 30, 2003 was to fund operating losses of $2.5 million, partially offset by depreciation expense of $75,000.

Cash used in investing activities was $148,000 in the nine-month period ended September 30, 2004, primarily for investments in technology rights related to our Progenta and Androxal patent portfolios. Cash provided by investing activities was $1.2 million in the nine-month period ended September 30, 2003 which was primarily related to the collection of a $1.0 million note receivable.

Cash used in financing activities was approximately $14.0 million in the nine-month period ended September 30, 2004, relating to the purchase of treasury stock through our self tender offer which was completed in January 2004. Cash used in financing activities in the nine-month period ended September 30, 2003 was $49,000 relating to the purchase of treasury stock.

Cash and cash equivalents and marketable securities were $22.9 million at December 31, 2003 and $25.1 million at December 31, 2002.

Excluding maturities of marketable securities, cash used in operating activities was $3.3 million in 2003 and $3.6 million in 2002. The major use of cash in 2003 was to fund operating losses of $3.3 million in 2003, partially offset by a decrease in prepaid expenses of $297,000. The major use of cash in 2002 was to fund operating losses of $3.9 million, which included noncash charges of $4.4 million related to inventory impairment and $1.0 million related to patent impairment, partially offset by a noncash gain of $1.3 million related to the forgiveness of debt.

Cash provided by investing activities was $1.2 million in 2003. Cash used in investing activities was $1.3 million in 2002. In 2003, we received $1.0 million from the collection of a note receivable, the issuance of which was the primary use of cash in 2002. Cash used in financing activities was $49,000 in 2003, relating to the purchase of treasury stock. Cash provided by financing activities was $27,000 in 2002, relating to the issuance of common stock from option exercises.

Off-Balance Sheet Arrangements and Contractual Obligations

As of December 31, 2003, we did not have any off-balance sheet financing arrangements or contractual obligations.

Critical Accounting Policies and the Use of Estimates

The preparation of our financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in our financial statements and accompanying notes. Please see Note 2 to our audited financial statements, Summary of Significant Accounting Policies, for a discussion of our critical accounting policies. Actual results could differ materially from those estimates. The items in our financial statements requiring significant estimates and judgments are as follows:

We maintain an inventory of bulk phentolamine which is the active ingredient in VASOMAX, our oral treatment for male erectile dysfunction, or MED. Due to the termination of our Schering-Plough agreements in July 2002, the future uncertainty surrounding the VASOMAX product and the fact that we are not presently committing resources toward the approval of VASOMAX, we recorded a reserve for both our bulk phentolamine inventory previously valued at $4.4 million and our patent estate valued at approximately $1.0 million in the quarter ended June 30, 2002.

During 2000, we adopted U.S. Securities and Exchange Commission Staff Accounting Bulletin No. 101, Revenue Recognition in Financial Statements, or SAB 101, which requires up-front, non-refundable license fees to be deferred and recognized over the performance period. In situations where we receive payment in advance of the performance of services, such amounts are deferred and recognized as revenue as the related services are performed. We recognize revenue from non-refundable, up-front license and milestone payments, not specifically tied to a separate earnings process, ratably over the performance period of the agreement. When payments are specifically tied to

a separate earnings process, revenue is recognized when earned. Prior to January 1, 2000, we had recognized revenue from non-refundable fees when we had no obligation to refund the fees under any circumstances, and there were no additional contractual services to be provided or costs to be incurred by us in connection with the non-refundable fees. The cumulative effect of adopting SAB 101 at January 1, 2000 resulted in a one-time, non-cash charge of $8.5 million, with a corresponding increase to deferred revenue that will be recognized in future periods. The $8.5 million represents portions of 1997 and 1998 payments received from Schering-Plough in consideration for the exclusive license of our VASOMAX product for the treatment of MED. For the years ended December 31, 2003 and 2002, we recognized $0 and $4.2 million, respectively, of licensing fees revenue that was included in the cumulative effect adjustment as of January 1, 2000. Due to the mutual termination of our Schering-Plough agreements in July 2002, we recognized the remaining $3.2 million of deferred revenue in the quarter ended September 30, 2002.

We have had losses since inception and, therefore, have not been subject to federal income taxes. We have accumulated approximately $2.9 million of research and development tax credits. As of December 31, 2003 and 2002, we had approximately $75.6 million and $72.3 million, respectively, of net operating loss, or NOL, carry- forwards for federal income tax purposes. Additionally, approximately $614,000 of NOLs, and approximately $34,000 of research and development tax credits will expire in 2004. Under SFAS No. 109, Accounting for Income Taxes, an NOL requires the recognition of a deferred tax asset. As we have incurred losses since inception, and there is no certainty of future revenues, our deferred tax assets have been reserved in full in the accompanying consolidated financial statements.

Recent Accounting Pronouncements

In January 2003, the Financial Accounting Standards Board, or FASB, issued FASB Interpretation No. 46, or FIN 46, Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51. In December 2003, the FASB issued a revised version of this interpretation, FIN 46(R). FIN 46(R) addresses the requirements for business enterprises to consolidate certain variable interest entities who are the primary beneficiary of the entity if the equity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. FIN 46 and FIN 46(R) are effective immediately for all new variable interest entities created or acquired after January 31, 2003. The revised provisions of the interpretation will become applicable for the first reporting period ending after March 15, 2004 for variable interest entities created before February 1, 2003. The adoption of FIN 46 did not impact our financial statements. The adoption of FIN 46(R) is not anticipated to have a material effect on our results of operations or financial position.

In May 2003, the FASB issued Statement of Financial Accounting Standards, or SFAS, No. 150, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity. SFAS No. 150 establishes how an issuer classifies and measures certain financial instruments that have characteristics of both liabilities and equity. The statement requires that an issuer classify financial instruments that are within its scope as a liability and requires disclosure regarding the terms of those instruments and settlement alternatives. Previously, many of these instruments were classified as equity or as mezzanine instruments (between the liabilities and the equity section). SFAS No. 150 is effective immediately for qualifying financial instruments issued after May 31, 2003 and was effective for existing issuances as of the third quarter ended September 30, 2003. Adoption of SFAS No. 150 did not have a material effect on our results of operations or financial position.

BUSINESS

Overview

We are a biopharmaceutical company focused on the development of new drugs to treat hormonal and reproductive system disorders. Our lead product candidate, Progenta, is an orally available small molecule compound that we are developing for the treatment of uterine fibroids and endometriosis. We are developing Progenta under an exclusive, worldwide license from the National Institutes of Health, or NIH. Progenta is being developed to alleviate adverse symptoms associated with both uterine fibroids and endometriosis by selectively blocking the progesterone receptor in women. We believe it may have advantages over the current standards of care for the treatment of uterine fibroids and endometriosis, which include surgery and treatment with gonadotropin releasing hormone agonists, or GnRH agonists, such as Lupron. Unlike Progenta, GnRH agonists create a low estrogen, menopausal-like state in women, and estrogen is necessary for the maintenance of bone mineral density. Therefore, GnRH agonists tend to promote bone loss and cannot be used for more than six months at a time. When women cease treatment with GnRH agonists, fibroids rapidly regenerate and symptoms associated with endometriosis quickly reappear. We believe Progenta may have advantages over treatment with GnRH agonists because, in our animal research to date, Progenta does not appear to induce a low estrogen state and therefore should not promote bone loss, which could make Progenta a better treatment option for patients prior to surgery. In addition, we believe Progenta may provide an attractive alternative to surgery because of its potential to treat these conditions in a chronic fashion resolving the symptoms that most commonly lead to surgical treatment. We currently are conducting a Phase Ib clinical trial for Progenta in Poland for the treatment of uterine fibroids, which is scheduled to be completed by the end of 2004. We intend to begin a Phase II clinical trial for Progenta in the United States for the treatment of uterine fibroids during 2005, subject to review of our Phase Ib data by the U.S. Food and Drug Administration, or FDA. We have not yet filed an investigational new drug application, or IND, with the FDA. If the FDA approves our IND, only then would we be permitted to conduct a clinical trial in the United States for Progenta. Based upon the final results of our Phase Ib clinical trial for Progenta for the treatment of uterine fibroids, we plan to conduct a Phase II clinical trial in Poland for Progenta for the treatment of endometriosis. However, we have not yet conducted any clinical trials for Progenta for the treatment of endometriosis, and any clinical trials we may conduct may not produce positive results.

Our second product candidate is Androxal, an orally available small molecule compound being developed for the treatment of testosterone deficiency in men. Androxal, our proprietary compound, is designed to restore normal testosterone production in males with functional testes and diminished pituitary function, a condition commonly referred to in the aging male as andropause. We believe Androxal may have advantages over current therapies because it is being designed as an oral therapy that acts centrally to restore normal testosterone function in the body, rather than simply replacing diminished testosterone. The administration of replacement testosterone has been linked to numerous potential adverse effects, including shrinkage of the testes. In addition, a safe and effective oral treatment for testosterone deficiency has to date been unavailable. We recently completed a Phase I/II clinical trial for Androxal in the United States for the treatment of men with testosterone deficiency and submitted final data to the FDA. We met with the staff of the Division of Reproductive and Urologic Products of the FDA on November 10, 2004 to review our clinical plan for the approval of Androxal. The FDA has agreed to review our protocols for our trials in a timely fashion under a special protocol assessment, or SPA. The FDA deems Androxal to be a new chemical entity, and additional lengthy animal studies will be required before long term human studies may be initiated or an NDA may be filed.

Business Strategy

Our primary business strategy is to concentrate our resources on the clinical development of Progenta and Androxal. We intend to outsource our activities required to conduct these clinical trials and to continue to operate in a near-virtual manner until we complete our pivotal trials. We have no current intentions to build manufacturing or acquire sales and marketing capabilities but will seek to create value by developing our technology and realizing such value, if successful, by securing licensing fees, milestone payments and

royalties through corporate collaborations. We also intend to out-license our phentolamine-based sexual dysfunction products or in-license other product candidates for the treatment of hormonal and reproductive system disorders if the right opportunity presents itself.

Market Overviews

Uterine Fibroids

Uterine fibroids are common non-cancerous tumors that arise from the smooth muscle layer of the uterus. The National Uterine Fibroid Foundation estimates that possibly as many as 80% of all women in the United States have uterine fibroids, and one in four of these women have symptoms severe enough to require treatment. The two most common symptoms are abnormal uterine bleeding and pelvic pressure. Uterine fibroids may also cause fetal malpresentations and complications with labor. Pressure on internal organs caused by fibroids can cause difficulty in bowel movements, constipation, urinary frequency and incontinence.

In general, fibroids only need to be treated if they are causing symptoms. Currently, the primary treatment for patients with large or symptomatic fibroids is surgery. Hysterectomy, or surgical removal of the entire uterus, is the most frequent operative technique used to treat this disorder. In fact, fibroids are the most common indication for hysterectomy, accounting for approximately one-third of hysterectomies, or about 200,000 procedures annually, in the United States, according to the Center for Uterine Fibroids, or CUF. We estimate that the costs associated with these procedures reaches approximately $1 to $1.5 billion annually.

When women wish to preserve childbearing potential, a myomectomy may be performed. Unlike hysterectomy in which the entire uterus is removed, myomectomy is a surgical procedure in which individual fibroid(s) are removed. The CUF reports that approximately 18,000 myomectomies are performed annually in the United States, and this procedure, in general, diminishes menorrhagia, or prolonged and/or profuse menstrual flow, in roughly 80% of patients presenting with this symptom. Unfortunately, there is a significant risk of recurrence of fibroids after myomectomy. The CUF has also stated that, in some studies, up to 10% of women who underwent an initial myomectomy required a second major operative procedure, and one-quarter to one-half of women who underwent myomectomies had evidence of recurrence of their fibroids within one to ten years.

Drugs can help control fibroid-related symptoms. The most effective medications for the treatment of fibroids are GnRH agonists, including Lupron and Zoladex®, which are marketed by TAP Pharmaceuticals and AstraZeneca PLC, respectively. GnRH agonists induce a low-estrogen, menopause-like state. Because fibroids are dependent on estrogen for their development and growth, induction of a low estrogen state causes reduction of tumor and uterus mass, resolving pressure symptoms. Specifically, uterine volume has been shown to decrease approximately 50% after three months of GnRH agonist therapy. In addition to decreasing the size of the uterus, treatment with GnRH agonists also stops menstrual flow, a disorder known as amenorrhea, allowing women with bleeding-induced anemia to significantly increase their iron stores.

However, there are two significant problems with GnRH agonists:

1. Bones require estrogen. GnRH agonists induce a low estrogen state in women, and estrogen is necessary for the maintenance of bone mineral density. Therefore, GnRH agonists tend to promote bone loss and cannot be used for more than six months at a time, usually in preparation for a surgical procedure.

2. When women cease treatment with GnRH agonists, their fibroids rapidly regenerate.

Therefore, use of GnRH agonists alone for treatment of fibroids is usually limited to a short one to three month preoperative course to shrink the uterus to facilitate a surgical procedure or to induce amenorrhea to improve hematologic condition before surgery.

Endometriosis

Endometriosis occurs when endometrial tissue, which is tissue that normally lines the inside of the uterus, is found outside of the uterus. This misplaced tissue develops into growths or lesions which react to

the menstrual cycle the same way that the endometrium reacts, which results in internal bleeding and inflammation and can cause pain, infertility, scar tissue formation and bowel problems. According to the Endometriosis Association, endometriosis affects 5.5 million women in the United States and Canada and millions more worldwide.

Surgery is the current customary standard of care for endometriosis, either through laparoscopy or laparotomy. Conservative surgery seeks to remove or destroy the growths, relieve pain, and may allow pregnancy to occur in some cases. Hormonal therapy may be prescribed along with conservative surgery. Radical surgery, which may be necessary in severe cases, involves hysterectomy, removal of all growths, and removal of ovaries.

Physicians often prescribe pain medications, such as aspirin, acetaminophen, ibuprofen and naproxen, to reduce the pain associated with endometriosis. Hormonal treatments, such as the GnRH agonists described earlier, are designed to stop ovulation for as long as possible. Other hormonal treatments include oral contraceptives, progesterone drugs and danazol (a testosterone derivative). Surgery is expensive and invasive. GnRH agonists are currently the most effective form of treatment for endometriosis other than surgery but suffer from the same problems as described above when used for treating uterine fibroids, namely, bone loss and recurrence of the condition after cessation of treatment.

Testosterone Deficiency

Low testosterone is linked to several negative physical and mental conditions in the aging male population, including loss of muscle tone, reduced sexual desire and deterioration of memory and certain other cognitive functions. Testosterone plays an essential role in the development of the normal male and in the maintenance of many male characteristics, including muscle mass and strength, bone mass, libido, potency, and spermatogenesis. Testosterone deficiency occurs with disorders that damage the testes, including traumatic or surgical castration (primary testicular failure) or disorders in which the gonadotropin stimulation of the testes is reduced, a condition known as hypogonadotropic hypogonadism. Men with hypogonadotropic hypogonadism have low plasma testosterone levels and luteinizing hormone levels that may be low or low-normal. This condition is a normal part of aging and is commonly referred to as andropause. According to the Urology Channel, recent estimates show that approximately 13 million men in the United States experience testosterone deficiency.

Current therapies focus on testosterone replacement. They deliver testosterone to the blood stream either transdermally or via injection. The current standard therapy in the industry is Androgel, a topical gel with sales of approximately $283 million in 2003, marketed by Solvay Pharmaceuticals. Testim is another topical gel currently sold and marketed by Auxilium Pharmaceuticals. Watson Pharmaceuticals markets a transdermal patch called AndroDerm. There are several other companies attempting to get FDA approval for testosterone gels and at least two companies attempting to obtain generic approval for a topical testosterone gel. We anticipate that the global market could grow to nearly a billion dollars within the next several years as aging and the resulting effects on lifestyle become increasingly important.

However, there are two significant problems with the current therapies:

1. The use of any of the current therapies, including the transdermal therapies, may create high peaks of testosterone levels. Such high peaks can lead to excitation and aggressive behavior, sleeplessness, anxiety, depression and headaches and have been associated with prostate disease.

2. While transdermal delivery through gels and patches produces a more constant drug level in the blood stream, transdermal delivery also results in elevated levels of dihydrotestosterone, or DHT. Elevated levels of DHT in the blood stream also have been associated with prostate disease.

Our Product Candidates

We intend to address the markets described above with our novel small molecule compounds that we believe may have advantages over the current common standards of care in each respective market.

Progenta

We believe that current therapies for uterine fibroids and endometriosis are less than ideal and leave room for improved drugs with different modes of action. Particularly, we believe that anti-progestational agents like Progenta may have advantages over GnRH agonists because they are designed to selectively block progesterone without inducing a low estrogen state. Therefore, it may be possible to use Progenta on a long-term, or chronic, basis without the bone loss problems associated with GnRH agonists. Although we believe Progenta may be an effective as an alternative six month pre-treatment to surgery for uterine fibroids, we also believe this product candidate may hold the potential to eventually become a chronic therapy for uterine fibroids and endometriosis that could eliminate the need for uterine fibroid surgery.

We currently have rights, under the terms of our license from the NIH, to a U.S. patent application and a foreign filing made by the NIH regarding Progenta. The U.S. patent application has been allowed. Please see Agreement with National Institutes of Health for a description of the current status of our license with the NIH.

We recently completed enrollment of a three-month, 30-patient, randomized Phase Ib clinical trial in Poland comparing Progenta to placebo and Lucrin® (the trade name for leucrolide acetate in Poland) in treating uterine fibroids, and anticipate final data from the trial to be available by early 2005. Patients enrolled in the trial are randomly distributed across five parallel groups. Each group consists of six patients, and each group is dosed with a different medication: placebo, 12.5 mg Progenta, 25 mg Progenta, 50 mg Progenta, or Lucrin. The placebo and Progenta groups are administered in a double-blind fashion, meaning that the attending physician and the patient are both unaware of which medication is administered. The placebo contains no active ingredient, and is used to assess the psychological impact of treatment and to assure that the positive or negative effects experienced by patients receiving medication in a clinical study are in fact drug-related. The Lucrin group is included in the clinical trial so that the effects of Progenta can be compared against a drug currently approved and marketed for the indication. This is referred to as having a positive control in the clinical trial. The study consists of three phases. One day dosing is conducted for both initial safety and pharmacokinetics. Patients then enter a one-week washout period, during which no drug is administered. This period is included as a safety assessment to determine how long the positive or negative effects of the drug are observed, as well as to determine if the drug has the potential to accumulate within the patient. Following the one week washout and safety assessment, women take the drug for an additional 30 days after which time they are readmitted into the clinic to evaluate steady state pharmacokinetics, effects on fibroid size, bone mineral density and hemoglobin. Women showing positive effects on fibroid volume and hemoglobin without adverse reactions are allowed to continue in the trial for an additional two months. Women not experiencing a benefit with the study drug are allowed to switch to the GnRH agonists for the duration of the study. At the end of the study, women on Progenta are evaluated for changes in bone mineral density, hemoglobin levels and fibroid size and compared against the changes experienced by the positive control group dosed with GnRH agonists.

We have already announced preliminary data from this study. All clinical trial results are subject to review by the FDA, and the FDA may disagree with our conclusions about safety or efficacy. As of November 8, 2004, all women have completed the thirty-day chronic exposure to Progenta or Lucrin. None of the women in the double blinded portion of this cohort have elected to switch to Lucrin. Furthermore, none of the women in the study have experienced any side effects or changes in clinical chemistry. To date, the drug has been well tolerated. The women in the high dose Progenta group of the study have experienced reduction in fibroid size, as measured by ultrasound, at least numerically equivalent to GnRH agonists. Because the effects of a GnRH agonist, which is approved for this indication, are best evaluated after at least three months of dosing, these preliminary results may be reversed by the final results of this clinical trial or from later stage clinical trials with significantly larger and more diverse patient populations treated for longer periods of time.

This study is of a small sample size (n=6 per group). The primary purpose of the study is to show that the drug is safe, over the period and number of patients exposed, and to determine whether the drug warrants further development. Only drugs with significant therapeutic effects could be expected to exhibit statistically

significant separation from placebo ($p<0.05$, a statistical calculation that suggests the result is 95% probable to reoccur if tested in a similar manner) for any endpoints in such a small study. The purpose of including a positive control is to provide further information regarding the activity of the drug and to not over- or under-interpret the results from the study. For example, if an approved drug does not achieve statistical significance in a given study it suggests that the product candidate, if equally not significant, should not be abandoned. Typically, after such a small study is undertaken, a larger Phase II or Phase III trial is performed. In cases where the subsequent trial achieves statistical significance and shows an adequate dose response, it may be used as one of the two pivotal trials necessary to obtain regulatory approval for the product candidate. Longer term open label studies, where both patients and physicians know what drug is used, are usually conducted to fulfill the safety requirements for chronically administered drugs.

We intend to begin a Phase II clinical trial for Progenta in the United States for the treatment of uterine fibroids during 2005, subject to the review of our Phase Ib data by the U.S. Food and Drug Administration, or FDA. We have not yet filed an investigational new drug application, or IND, with the FDA. If the FDA approves our IND, only then would we be permitted to conduct a clinical trial in the United States for Progenta.

Several animal studies, including a nine-month primate study, were previously conducted exploring both the safety and activity of the product candidate, which were funded by a SBIR grant. The data from those studies currently are being analyzed. Based upon the final results of our Phase Ib clinical trial for Progenta for uterine fibroids, we intend to conduct a Phase II clinical trial for Progenta in Poland for the treatment of endometriosis. However, we have not yet conducted any clinical trials for Progenta for the treatment of endometriosis, and any clinical trials we may conduct may not produce positive results.

Androxal

We are developing Androxal as a once a day oral therapy for the treatment of men with testosterone deficiency. Androxal is being designed to act centrally, thereby causing an increase in certain hormones that stimulate increased production of testosterone by the testes. We believe that the endogenous production of testosterone through a compound like Androxal would not provide the significant negative feedback that occurs with the administration of high concentrations of exogenous testosterone (as with Androgel). This negative feedback signals the body to stop producing testosterone naturally, and has been linked to numerous potential adverse effects, including shrinkage of the testes. We believe that Androxal has the potential to restore near normal levels of testosterone, in as close to a natural process as possible, by restoring testicular production of testosterone, rather than simply replacing testosterone, and that Androxal could be the first significant therapy approved in this market that treats testosterone deficiency in this manner. In addition, a safe and effective oral treatment for testosterone deficiency has to date been unavailable.

Because Androxal induces naturally occurring cycles of testosterone production internally, we believe it may have advantages over the current therapies on the market for the following reasons:

Our Phase I/II clinical trial results indicate that Androxal does not cause abnormal peaks in blood testosterone levels which can be caused by some current testosterone replacement therapies; and

the data so far do not indicate the elevated levels of DHT associated with transdermal therapies.

All clinical trial results are subject to review by the FDA, and the FDA may disagree with our conclusions about safety or efficacy. In addition, these results are from early stage clinical trials, and may be reversed by the results of larger or later stage clinical trials with significantly larger and more diverse patient populations treated for longer periods of time.

Our Androxal product candidate is covered by five pending patent applications in the United States, 13 foreign pending patent applications and one Patent Cooperation Treaty application. All of these applications relate to methods and materials for the treatment of testosterone deficiency in men. A third party holds an issued patent related to the use of an anti-estrogen such as clomiphene citrate for use in the treatment of androgen deficiency and disorders related thereto. Androxal is purified from clomiphene citrate. We believe that the claims of the other s party patent are invalid over several printed publications previously

available in the public domain. On that basis, we filed a request for reexamination of the patent with the USPTO in light of a number of these publications. The USPTO has since rejected all of such claims of patent on the grounds that each of the claims are anticipated by, or obvious in view of, a number of printed publications that were already in the public domain. The third party has filed a response to those rejections and the USPTO is currently considering that response. We do not believe that the third party will overcome the rejections made by the USPTO. Even if the other party s response is successful and its patent is upheld, we believe that our contemplated use of Androxal may not infringe any valid claims of the patent. However, it is possible that the claims of this patent could be construed so as to block our use of Androxal for indications such as the treatment of testosterone deficiency. If this were to occur, we may then be required to obtain a license from the holder of such patent in order to develop Androxal further, and such license may not be available on acceptable terms or at all. In this case, we would be not be able to develop or commercialize Androxal.

In July 2004, we released results from a randomized Phase I/ II clinical trial in the United States comparing Androxal to placebo and to Androgel in hypogonadal men. All clinical trial results are subject to review by the FDA, and the FDA may disagree with our conclusions about safety and efficacy. We caution that these results may be reversed by the results of later stage clinical trials with significantly larger and more diverse patient populations treated for longer periods of time. The trial tested 52 clinically diagnosed hypogonadal men with testosterone levels less than 300 ng/dL, whereas normal levels range from 298 to 1034 ng/dL. Patients were randomized into five different arms and each arm was dosed with a different medication: three dose levels of Androxal, placebo, or the low dose of Androgel. Upon completion of these arms of the trial, a sixth arm comprised of 10 men from the initial group was formed to test the high dose of Androgel. The placebo and Androxal doses were administered in a double-blind fashion, meaning that the attending physician and the patient are both unaware of which medication is administered. Androgel was administered as an open label treatment, where both patient and physician know what drug is being administered. Following a two week drug treatment, patients were followed for an additional seven to 10 days to evaluate their testosterone levels. There were no side effects noted in either the Androxal or Androgel arms of the study that were statistically different than placebo. Furthermore, all three dose levels of Androxal produced statistically significant changes in testosterone from baseline testosterone levels. The low, mid and high dose levels achieved mean increases of 169, 247 and 294 ng/dL, respectively (p=0.0053, 0.0002 and 0.0005) as compared to baseline. There were no statistically significant changes within the placebo group (mean decrease from baseline of -1 ng/dL, p=0.96). Seven of 10 men in the low dose group, 10 of 11 in the mid dose group and 10 of 10 men in the high dose group had restoration of normal testosterone levels.

We met with members of the staff of the Division of Reproductive and Urologic Products of the FDA on November 10, 2004 to review our clinical plan for the approval of Androxal. We are awaiting the written record of this meeting, but based on our discussions, we believe that the FDA will require an additional endpoint, for example, improved libido or increased muscle mass, associated with the primary endpoint of increased testosterone levels. The FDA has agreed to review our protocols for our trials in a timely fashion under a special protocol assessment, or SPA. In the SPA process, the FDA reviews the design, size and planned analysis of our Phase III clinical trial and provides comments regarding the trial s adequacy to form a basis with respect to effectiveness for approval of a NDA, if the trial is successful in meeting its predetermined objectives. The FDA s written agreement is binding on its review decision, except in limited circumstances, such as when a substantial scientific issue essential to determining the safety or effectiveness of a product candidate is identified after the Phase III clinical trial is commenced. Even if a NDA is filed, there is no guarantee that the application will be approved. Any change to the protocol for our Phase III clinical trial included in the SPA would require prior FDA approval, which could delay our ability to implement such change. The FDA deems Androxal to be a new chemical entity, and additional lengthy animal studies will be required before long term human studies may be initiated. In particular, a twelve week study in dogs and rats must be completed before humans may be dosed in a Phase III clinical trial. In addition, before we can submit our NDA for Androxal, we will be required to successfully complete a two-year carcinogenicity study in rats.

Comparing average testosterone levels during the trial period, all three doses of Androxal achieved blood levels of total testosterone that were statistically indistinguishable from the high dose of Androgel. In each patient studied, Androxal also produced average testosterone levels below 1000 ng/dL at day 14, whereas several Androgel patients had average testosterone levels far above the normal range. In the subset of men whose blood testosterone levels were measured six times over a 24-hour period, three of five men on the high dose of Androgel had multiple measurements above the normal range. In contrast, only one man out of 15 on Androxal had a single measurement above the normal range. Similar to our Progenta clinical trial, this study is of a small sample size. The primary purpose of the study is to show that the drug is safe, over the period and number of patients exposed, and to determine whether the drug warrants further development. We caution that these results may be reversed by the results of later stage clinical trials with significantly larger patient populations treated for longer periods of time.

Product Candidate Development Timeline

Below is a summary of our product candidates and the related stages of development for each. The information in the column labeled Estimate of Completion of Current Phase contains forward-looking statements regarding timing of completion of product development phases. The successful development of our product candidates is highly uncertain. Estimated completion dates and R&D expenses can vary significantly for each product candidate and are difficult to predict. The actual timing of completion of those phases could differ materially from the estimates provided in the table.

Product Candidate	Indication	Current Phase of Development	Collaborator	Estimate of Completion of Current Phase	Estimated Cost to Complete Current Phase (3)
Progenta (1)	Uterine fibroids	Phase Ib (Poland)	None	2004-2005	$ 200,000
Androxal (2)	Testosterone deficiency	Phase I/II (United States)	None	2004	$ 25,000

(1) Female health small molecule opportunity. This technology was in-licensed from the NIH in 1999. Meetings have not yet been held with the FDA regarding further clinical effort. Based upon final results of our Phase Ib clinical trial in Poland, we may also initiate a Phase II clinical trial for the treatment of endometriosis in Poland.

(2) Internal small molecule program. We have described a patent potentially competitive with our patent on Androxal. We met with FDA staff members on November 10, 2004 to review our clinical plan for the approval of Androxal.

(3) We cannot estimate the total cost to complete beyond the current phase.

Additional Potential Indications for Progenta

We believe Progenta may be effective for the treatment of breast cancer and as a hormone replacement therapy but are not actively developing Progenta for these indications at this time.

Breast Cancer

We believe Progenta may possess the potential capability to treat breast cancers that are resistant to Tamoxifin therapy, a commonly used anti-estrogen breast cancer therapy. Our initial rodent studies funded by a SBIR grant showed a strong dose dependent effect on the reduction and elimination of tumors in a well accepted breast cancer model.

Hormone Replacement Therapy

We believe Progenta may have the potential to eliminate many of the side effects, particularly endometrial cancer, seen with estrogen-only therapies in women with low hormone levels. The side effects of estrogen-only hormone replacement therapies for women are alleviated with estrogen-progestin combination therapies. However, recent data have shown that such combination therapies may increase the risk of breast cancer, heart attacks, strokes and blood clots. Unlike progestins, Progenta is devoid of progesterone-like activity and instead opposes its actions. The result of this action could lead to a new class of hormone replacement therapies with Progenta combinations.

Out-Licensing Opportunities

Our phentolamine-based products for the treatment of sexual dysfunction include VASOMAX, an oral therapy for male erectile dysfunction, or MED; an oral therapy for female sexual arousal disorder; Bimexes™, an oral combination drug therapy for MED; and ERxin™, a multi-drug component injection therapy for MED. Although VASOMAX was previously approved for sale in eight non-U.S. countries, some approvals have lapsed and the existing approvals may be difficult to transfer to another entity or could also lapse. Although the products previously being developed to treat sexual dysfunction are our most advanced in terms of clinical development, they all contain phentolamine which the FDA has on partial clinical hold. The interim results of a November 2000 mechanistic study were positive, but in October 2002, the FDA decided to require us to perform an additional two-year rat study in order to lift the partial clinical hold. At this time, we do not intend to conduct this additional study. There can be no assurance that even if we were to complete this additional study that the FDA would remove its partial clinical hold on phentolamine. All of our phentolamine-based products have been tested in humans, though each is at a different stage of development. Before the FDA will consider the approval to market any of our phentolamine-based products, the partial clinical hold must first be lifted.

In addition, Schering-Plough, Ltd. and Schering Corporation, the previous licensees of our phentolamine-based products, decided to withdraw their December 2001 submission to the Medicines Control Agency in the United Kingdom after receipt and review of comments from the Committee on Safety of Medicines on such submission. In July 2002, the Schering group agreed to terminate its worldwide licensing agreements with us. Schering returned all rights to our phentolamine-based product candidates to us for a nominal up front cash fee and certain continuing royalty obligations in the event we have any sales of VASOMAX or our other phentolamine-based products. We intend to outlicense some or all of this technology if the right opportunity presents itself, although we may not be able to realize any value from this technology.

Research and Development

We have limited resources and utilize consultants and outside entities to perform clinical development and limited research activities in connection with preclinical studies and clinical trials. Our primary R&D expenses for 2004 are for the payment of consultants and contract research organizations in connection with our clinical trials for Progenta for the treatment of uterine fibroids and for Androxal for testosterone deficiency. We believe that these expenses will continue to be our primary R&D expenses in the near future. In addition, we may have additional expenses should we undertake a clinical trial for Progenta for endometriosis and a nominal amount of R&D expenses associated with our development of Progenta as a treatment for breast cancer under an SBIR grant that we applied for under this indication, assuming we are awarded such grant.

Agreement with National Institutes of Health

In 1999, we licensed rights to Progenta from the NIH under an exclusive, worldwide license in the field of treatment of human endocrinologic pathologies or conditions in steroid sensitive tissues which expires upon the expiration of the last licensed patent. Under the terms of the agreement, we are obligated to meet developmental milestones as outlined in a commercial development plan. This development plan outlines a preclinical and clinical program leading to the stated objective of submitting an NDA for regulatory approval of Progenta for the treatment of uterine fibroids in 2008. We provide annual updates to the NIH on the progress of our development of Progenta. Based on our interaction with the NIH to date, we believe our license and relationship are in good standing. The NIH has the ability to terminate the agreement for lack of payment or if we are not meeting milestones as outlined in the commercial development plan and for other reasons as outlined in the agreement. The NIH retains, on behalf of the government, a nonexclusive, nontransferable, worldwide license to practice the inventions licensed under the licensed patents by or on behalf of the government. For the purpose of encouraging basic research, the NIH retains the right to grant nonexclusive research licenses to third parties. Due to the work that was done on Progenta at the NIH prior to our license agreement, the government also has certain rights to use the product in the event of a national emergency pursuant to the Patent and Trademark Laws Amendments Act of 1980, as amended. During the

period when we were considering redeployment of our assets, we were not in compliance with all of the original requirements stated in the commercial development plan. In July 2002, we and the NIH amended the license agreement to include a revision of the original commercial development plan relating to the targeted dates for certain objectives. Additional updates of the original commercial development plan have been reached with the NIH thereafter in order to expedite development. Although we believe that we have a good working relationship with the NIH, there can be no assurance that all of the objectives and conditions in the commercial development plan will be met on a timely basis or at all, or that, if we fail to meet any of such objectives, the NIH will again agree to amend this agreement to our satisfaction. Failure to comply with the material terms contained in the license agreement could result in termination of such agreement, which would prohibit us from further development of Progenta and severely harm our business prospects.

Manufacturing

We do not have any facilities to manufacture products necessary for clinical trials or commercial sales and do not expect to establish any of our own manufacturing capacity in the foreseeable future. We have in the past relied and intend to continue to rely on third parties for the foreseeable future for the manufacture and supply of commercial quantities of any compounds or products that we may develop. Other than some initial amounts from the NIH, we have used the same outside supplier, Bridge Organics, for all of the Progenta needed for our clinical trials to date. We are in the process of seeking a suitable source for a long-term manufacturing agreement for the product candidate. There can be no assurance that we will be able to successfully negotiate a long-term agreement with any of such potential manufacturers at a reasonable price and on other acceptable terms or will be able to reproduce the results obtained by Bridge Organics in manufacturing Progenta to date. We have obtained all of our supply of Androxal to date from BioVectra. Also, our dependence on third parties for the manufacture of any products we may develop may adversely affect our product margins and our ability to develop and to deliver products in a timely manner. Any such third-party suppliers or any manufacturing facility we establish will be required to meet FDA manufacturing requirements. FDA certification of manufacturing facilities for a drug, and compliance with current Good Manufacturing Practices requirements, is a prerequisite to approval of a NDA for that drug. We may encounter significant delays in obtaining supplies from third-party manufacturers or experience interruptions in our supplies. The effects of any such delays or interruptions will be more severe if we rely on a single source of supply. If we were unable to obtain adequate supplies, our business would be materially adversely affected.

Sales and Marketing

We have no experience in the sales, marketing and distribution of pharmaceutical products. If in the future we fail to reach or elect not to enter into an arrangement with a collaborative partner with respect to the sales and marketing of any of our future potential product candidates, we would need to develop a sales and marketing organization with supporting distribution capability in order to market such products directly. Significant additional expenditures would be required for us to develop such a sales and marketing organization.

Patents and Proprietary Information

Our ability to compete effectively with other companies is materially dependent on the proprietary nature of our patents and technologies. We actively seek patent protection for our proprietary technology in the United States and abroad. Although we have previously written off capitalized patents relating to the zona pellucida immuno-contraceptive vaccine and our phentolamine-based products, which includes VASOMAX, our hcG immuno-contraceptive vaccine, our two vaccine adjuvants and our two prostate cancer vaccines, we are still maintaining our phentolamine-based patents relating to these technologies and include these costs in R&D expenses.

Under a license agreement with the NIH, we have exclusive rights to a U.S. patent application, which was recently allowed by the PTO, and a foreign filing made by the NIH regarding Progenta. We also have the following patent applications pending: five pending patent applications in the United States, 13 foreign

pending patent applications, and one Patent Cooperation Treaty application related to methods and materials for the treatment of testosterone deficiency in men.

A third party holds an issued patent related to the use of an anti-estrogen such as clomiphene citrate for use in the treatment of androgen deficiency and disorders related thereto. Androxal is purified from clomiphene citrate. We believe that the claims of the other s party patent are invalid over several printed publications previously available in the public domain. On that basis, we filed a request for reexamination of the patent with the USPTO in light of a number of these publications. The USPTO has since rejected all of such claims of patent on the grounds that each of the claims are anticipated by, or obvious in view of, a number of printed publications that were already in the public domain. The third party has filed a response to those rejections and the USPTO is currently considering that response. We do not believe that the third party will overcome the rejections made by the USPTO. Even if the other party s response is successful and its patent is upheld, we believe that our contemplated use of Androxal may not infringe any valid claims of the patent. However, it is possible that the claims of this patent could be construed so as to block our use of Androxal for indications such as the treatment of testosterone deficiency. If this were to occur, we may then be required to obtain a license from the holder of such patent in order to develop Androxal further, and such license may not be available on acceptable terms or at all. In this case, we would be not be able to develop or commercialize Androxal.

Competition

We are engaged in pharmaceutical product development, an industry that is characterized by extensive research efforts and rapid technological progress. Many established pharmaceutical and biotechnology companies, universities and other research institutions with financial, scientific and other resources significantly greater than ours are marketing or may develop products that directly compete with any products we may develop. These entities may succeed in developing products that are safer, more effective or less costly than products we may develop. Even if we can develop products which should prove to be more effective than those developed by other companies, other companies may be more successful than us because of greater financial resources, greater experience in conducting preclinical studies and clinical trials and in obtaining regulatory approval, stronger sales and marketing efforts, earlier receipt of approval for competing products and other factors. If we commence significant commercial sales of any products, we or our collaborators will compete in areas in which we have no experience, such as manufacturing and marketing. There can be no assurance that our products, if commercialized, will be accepted and prescribed by healthcare professionals.

Our main competitors for the treatment of uterine fibroids and endometriosis are GnRH agonists, especially Lupron, the current most common therapeutic standard of care for uterine fibroids with annual sales of $787.8 million in the United States and Canada for all indications. Lupron is marketed by TAP Pharmaceuticals, which has far greater resources and marketing capabilities than we have. In addition, surgical treatment of both uterine fibroids and endometriosis competes with Progenta by removing uterine fibroids and by removing misplaced tissue in women with endometriosis. We believe we can potentially compete with Lupron and other GnRH agonists because we believe that Progenta will not present the same side effect of a decrease in bone mineral density given its specific focus on progesterone inhibition, which differentiates it from GnRH agonists that create a low estrogen state. There are additional companies developing similar progesterone-blocking technology. Asoprisnil, an anti-progestin being developed by TAP Pharmaceuticals in partnership with Schering AG, is currently in Phase III clinical trials.

Our main competitors for the treatment of testosterone deficiency are the testosterone replacement therapies currently being marketed. The current most common standard of care is Androgel, a topical gel for the replacement of testosterone, which is marketed by Solvay Pharmaceuticals, a considerably larger company than we are. There is another topical gel, Testim, currently marketed by Auxilium Pharmaceuticals, and a transdermal patch, AndroDerm, marketed by Watson Pharmaceuticals. We believe we can compete with Androgel and the other replacement therapies because we believe that Androxal avoids the abnormally high peaks of testosterone levels and elevated levels of DHT which can be associated with current testosterone

replacement therapies like Androgel. Based on our clinical trial supply cost to date, we currently expect that Androxal, if approved, can compete favorably on a cost basis with current testosterone replacement therapies.

Governmental Regulation

Our research and development activities, preclinical studies and clinical trials, and ultimately the manufacturing, marketing and labeling of any products we may develop, are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries. The U.S. Federal Food, Drug and Cosmetic Act and the regulations promulgated thereunder and other federal and state statutes and regulations govern, among other things, the testing, manufacture, storage, record keeping, labeling, advertising, promotion, marketing and distribution of any products we may develop. Preclinical study and clinical trial requirements and the regulatory approval process take many years and require the expenditure of substantial resources. Additional government regulation may be established that could prevent or delay regulatory approval of our product candidates. Delays in obtaining or rejections of regulatory approvals would adversely affect our ability to commercialize any product candidate we develop and our ability to receive product revenues or to receive, milestone payments or royalties from any product rights we might license to others. If regulatory approval of a product candidate is granted, the approval may include significant limitations on the indicated uses for which the product may be marketed or may be conditioned on the conduct of post-marketing surveillance studies.

The standard process required by the FDA before a pharmaceutical agent may be marketed in the United States includes: (1) preclinical tests; (2) submission to the FDA of an investigational new drug application which must become effective before human clinical trials may commence; (3) adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug for its intended application; (4) submission of an NDA to the FDA; and (5) FDA approval of the NDA prior to any commercial sale or shipment of the drug.

Even if regulatory approvals for any products we may develop are obtained, we, our potential collaborators, our products, and the facilities manufacturing our products would be subject to continual review and periodic inspection. The FDA will require post-marketing reporting to monitor the safety of our products. Each U.S. drug-manufacturing establishment must be registered with the FDA. Domestic manufacturing establishments are subject to biennial inspections by the FDA and must comply with the FDA s requirements regarding current Good Manufacturing Practices. To supply drug products for use in the United States, foreign manufacturing establishments must comply with the FDA s Good Manufacturing Practices and are subject to periodic inspection by the FDA or by regulatory authorities in those countries under reciprocal agreements with the FDA. In complying with current Good Manufacturing Practices, manufacturers must expend funds, time and effort in the area of production and quality control to ensure full technical compliance. We do not have any drug manufacturing capabilities and must rely on outside firms for this capability. The FDA stringently applies regulatory standards for manufacturing. Identification of previously unknown problems with respect to a product, manufacturer or facility may result in restrictions on the product, manufacturer or facility, including warning letters, suspensions of regulatory approvals, operating restrictions, delays in obtaining new product approvals, withdrawal of the product from the market, product recalls, fines, injunctions and criminal prosecution.

Before any products we may develop could be marketed outside of the United States, they would be subject to regulatory approval similar to FDA requirements in the United States, although the requirements governing the conduct of clinical trials, product licensing, pricing, and reimbursement vary widely from country to country. No action can be taken to market any drug product in a country until the regulatory authorities in that country have approved an appropriate application. FDA approval does not assure approval by other regulatory authorities. The current approval process varies from country to country, and the time spent in gaining approval varies from that required for FDA approval. In some countries, the sale price of a drug product must also be approved. The pricing review period often begins after market approval is granted. Even if a foreign regulatory authority approves any products we may develop, no assurance can be given that it will approve satisfactory prices for the products.

Our research and development involves the controlled use of hazardous materials and chemicals. Although we believe that our procedures for handling and disposing of those materials comply with state and federal regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. If such an accident occurs, we could be held liable for resulting damages, which could be material to our financial condition and business. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens, and the handling of biohazardous materials. Additional federal, state and local laws and regulations affecting us may be adopted in the future. Any violation of, and the cost of compliance with, these laws and regulations could materially and adversely affect us.

Third-Party Reimbursement and Pricing Controls

In the United States and elsewhere, sales of pharmaceutical products depend in significant part on the availability of reimbursement to the consumer from third-party payers, such as government and private insurance plans. Since we have no commercial products, we have not had to face this issue yet. However, third-party payers are increasingly challenging the prices charged for medical products and services. It will be time consuming and expensive for us to go through the process of seeking reimbursement from Medicaid, Medicare and private payers. Our products may not be considered cost effective, and coverage and reimbursement may not be available or sufficient to allow us to sell our products on a competitive and profitable basis. The passage of the Medicare Prescription Drug and Modernization Act of 2003 imposes new requirements for the distribution and pricing of prescription drugs which may affect the marketing of our products.

In many foreign markets, including the countries in the European Union, pricing of pharmaceutical products is subject to governmental control. In the United States, there have been, and we expect that there will continue to be, a number of federal and state proposals to implement similar governmental pricing control. While we cannot predict whether such legislative or regulatory proposals will be adopted, the adoption of such proposals could have a material adverse effect on our profitability.

The Hatch-Waxman Act

Under the U.S. Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act, newly approved drugs and indications benefit from a statutory period of non-patent marketing exclusivity. The Hatch-Waxman Act provides five year marketing exclusivity to the first applicant to gain approval of an NDA for a new chemical entity, or NCE, meaning that the FDA has not previously approved any other new drug containing the same active ingredient. Both of our current product candidates are considered NCEs. The Hatch-Waxman Act prohibits an abbreviated new drug application, or ANDA, where the applicant does not own or have a legal right of reference to all the data required for approval, to be submitted by another company for another version of such drug during the five year exclusive period. Protection under the Hatch-Waxman Act will not prevent the filing or approval of another full NDA, however, the applicant would be required to conduct its own adequate and well-controlled clinical trials to demonstrate safety and effectiveness. The Hatch-Waxman Act also provides three years of marketing exclusivity for the approval of new NDAs with new clinical trials for previously approved drugs and supplemental NDAs, for example, for new indications, dosages, or strengths of an existing drug, if new clinical investigations are essential to the approval. This three year exclusivity covers only the new changes associated with the supplemental NDA and does not prohibit the FDA from approving ANDAs for drugs containing the original active ingredient or indications.

The Hatch-Waxman Act also permits a patent extension term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent extension cannot extend the remaining term of a patent beyond a total of 14 years. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and it must be applied for prior to

expiration of the patent. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves or rejects the application for patent term extension.

Employees and Consultants

Employees

At September 30, 2004, we had four full-time employees, a number which we believe is currently sufficient to advance the clinical development of our Progenta product candidate for the treatment of uterine fibroids and endometriosis and our Androxal product candidate for the treatment of testosterone deficiency. We utilize part-time consultants as well as contract research organizations and other outside specialty firms for various services such as clinical trial support, manufacturing and regulatory approval advice. Upon completion of this offering, we intend to increase the number of employees we have, particularly in the area of research and development. We believe our relationship with our employees is good.

Scientific Advisors and Consultants

We benefit from consultation with prominent scientists active in fields related to our technology. For this purpose, we have part-time consulting relationships with a number of scientific advisors. At our request, these advisors review the feasibility of product development programs under consideration, advise concerning advances in areas related to our technology, and aid in recruiting personnel. All of the advisors are employed by academic institutions or other entities and may have commitments to or advisory agreements with other entities that limit their availability to us. Our consultants are required to sign an agreement providing that they are to disclose and assign to us any ideas, discoveries and inventions they develop in the course of providing consulting services. We also use consultants for various administrative needs. None of our consultants are otherwise affiliated with us.

In addition to the consultants described above, we have engaged two contract research organizations to conduct our clinical trials. Pharm-Olam International Ltd. conducts our clinical trial in Poland for Progenta for the treatment of uterine fibroids and Advanced Biomedical Research, Inc. conducted our clinical trial in the United States for Androxal for the treatment of testosterone deficiency. Under our arrangements with these contract research organizations, we design the protocols for the clinical trials and direct the contract research organizations in their efforts. We have agreements with both of these companies pursuant to which we have agreed to pay $325,000 plus expenses to Pharm-Olam and have no further obligation to pay Advanced Biomedical, respectively, and both have agreed that we own all of the data associated with the clinical trials.

Litigation

We are not currently party to any material legal proceedings.

Nasdaq SmallCap Market Listing

In January 2004, we purchased 6,547,635 shares of our common stock (approximately 57% of our then-outstanding common stock) at a purchase price of $2.10 per share in accordance with the terms of our self tender offer, which expired on January 7, 2004. This purchase included 60,888 shares issuable upon exercise of options for a total aggregate purchase price of approximately $13.7 million, exclusive of approximately $289,000 of costs associated with the offer. As of September 30, 2004, we had 4,992,901 shares outstanding.

On July 8, 2004, our common stock transferred from the Nasdaq National Market to the Nasdaq SmallCap Market after Nasdaq approved our application for this transfer. We applied for a Nasdaq SmallCap Market listing after Nasdaq informed us that we no longer met the $10,000,000 minimum stockholders equity listing requirement for the Nasdaq National Market. This shortfall was a result of the previously concluded January 2004 self tender offer.

Properties

We executed a new 74 month lease effective May 1, 2004, for 4,800 square feet of laboratory and office space located in its current building in The Woodlands, Texas. The cost of this lease is approximately $3,300 per month. We expect this space will be adequate for our needs for the remainder of the lease term.

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MANAGEMENT

Our Management

The names of our directors and executive officers, and certain additional information with respect to each of them, are set forth below.

Name	Age	Position with the Company	Year First Became Director
Joseph S. Podolski	57	President and Chief Executive Officer and Director	1992
Louis Ploth, Jr.	50	Vice President, Business Development and Chief Financial Officer, Secretary and Director	2004
Daniel F. Cain	59	Director	2004
Jean L. Fourcroy, M.D., Ph.D., M.P.H.	74	Director	2004
Zsolt Lavotha	54	Director	2004
Nola Masterson	57	Director	2004
David Poorvin, Ph.D.	58	Director	2004

Joseph S. Podolski. Mr. Podolski joined us in 1989 as Vice President of Operations and has served as our President and Chief Executive Officer and as a director since 1992. Previously, Mr. Podolski spent twelve years in various engineering, product development and manufacturing positions at G.D. Searle, a subsidiary of Monsanto Company. Before joining Monsanto, Mr. Podolski held positions in manufacturing, engineering, quality control and development of fine chemicals, antibiotics, pharmaceuticals and hospital products with Abbott Laboratories, Dearborn Chemical Company and Baxter Pharmaceuticals. Mr. Podolski holds a B.S. degree in chemistry and a M.S. degree in chemical engineering from the Illinois Institute of Technology.

Louis Ploth, Jr. Since January 2001, Mr. Ploth has served as our Chief Financial Officer, Vice President, Business Development and Secretary. Mr. Ploth joined us in 1993 and was elected a director at our 2003 annual meeting of stockholders, which was held on January 14, 2004. He served as Vice President, Finance from March 1999 to January 2001. He had previously served as Chief Financial Officer and Vice President, Business Development from 1993 to 1998 and as Chief Financial Officer from 1998 to March 1999 at which time he also served as General Manager of Fertility Technologies, Inc., a former subsidiary of ours. Previously, Mr. Ploth was employed by Unisyn Technologies where he served concurrently as Chief Financial Officer and as Vice President of Finance and Administration. Mr. Ploth was also Corporate Controller of Synbiotics Corporation. Mr. Ploth has over 21 years of corporate financial and business development experience, with over 17 years experience in the biotechnology industry. Mr. Ploth has a B.S. degree from Montclair State College.

Daniel F. Cain. Mr. Cain was elected a director at our 2003 annual meeting of stockholders, which was held on January 14, 2004. Since October 1994, Mr. Cain has provided consulting services for small businesses. Since May 2000, he has also served as acting CEO of Wireless Medical, Inc., a Colorado-based medical device company, and Enet Biz, a Colorado-based consulting firm. From 1969 to 1994, Mr. Cain held various positions with Miles Laboratories, Inc., Hexcel Corporation, Scripps-Miles, Inc., Synbiotics Corporation and Heska Corporation. Mr. Cain has 35 years of broad business experience including 26 years with medical companies. Sixteen of these years were with three different biotech startup companies, one of which he co-founded. Mr. Cain has held a wide variety of executive level management positions including CEO/ President and CFO. Mr. Cain earned a B.S. degree in business from LeTourneau College and a M.B.A. degree from Indiana University.

Jean L. Fourcroy, M.D., Ph.D., M.P.H. Dr. Fourcroy was elected a director at our 2003 annual meeting of stockholders, which was held on January 14, 2004. Dr. Fourcroy was engaged as a Medical Officer with the FDA from 1988 to 2001. Since leaving the FDA, Dr. Fourcroy has been a consultant to the industry and a featured speaker and panel member in numerous meetings and symposia. Dr. Fourcroy is a member of the Board of Directors of the U.S. Anti-Doping Agency and is a Past President of the American Medical

Women s Association. Dr. Fourcroy is the recipient of a 1998 American Urological Association Presidential Citation Award, the 1999 Camille Mermod Award from the American Medical Women s Association, and an Outstanding Service Award from the American Society of Andrology in April 2000. Dr. Fourcroy received her M.D. from the Medical College of Pennsylvania and her Ph.D. from the University of California at San Francisco. Her surgery and urology residencies were completed at George Washington University Medical Center with Board Certification in Urology in 1981. In 1999, she received her Masters in Public Heath from the Medical College of Wisconsin.

Zsolt Lavotha. Mr. Lavotha was elected a director at our 2003 annual meeting of stockholders, which was held on January 14, 2004. Mr. Lavotha has served as the President and CEO of Orexo AB, a privately held Swedish biotechnology company since April 2004. Since April 2003, Mr. Lavotha has served on the boards of directors of NeuroNova AB, a privately held company, and Orexo. Mr. Lavotha served as President and Chief Executive Officer of Lavipharm Corp. from December 1998 to April 2003. He has more than 25 years of experience in the pharmaceutical industry. Before joining Lavipharm, he served as head of Wyeth s Europe/ Africa/ Middle East operations. He has also held a variety of positions with Pfizer, Rhone-Poulene Rorer and Wyeth. Mr. Lavotha earned a degree in science from Uppsala University in Sweden.

Nola Masterson. Ms. Masterson was elected a director at our 2004 annual meeting of stockholders, which was held on September 29, 2004. Ms. Masterson has 29 years of experience in the life science industry. Ms. Masterson has been the CEO of Science Futures, Inc., an investment and advisory firm, since 1982. Ms. Masterson is currently Managing Member and General Partner of Science Futures LLC, I, II and III, which are all venture capital funds invested in life science funds and companies. She also serves as a Senior Advisor to TVM Techno Venture Management, an international venture capital company. She was the first biotechnology analyst on Wall Street, working with Drexel Burnham Lambert and Merrill Lynch. She is co-founder of Sequenom, Inc., a genetic analysis company located in San Diego and Hamburg, Germany. She started the BioTech Meeting in Laguna Nigel, California and the annual Biopharmaceutical Conference in Europe. She was nominated to the 100 Irish American Business List in 2003. Ms. Masterson began her career at Ames Company, a division of Bayer, and spent eight years at Millipore Corporation in sales and sales management. She received her Masters in Biological Sciences from George Washington University, and continued Ph.D. work at the University of Florida.

David Poorvin, Ph.D. Dr. Poorvin was elected a director at our 2004 annual meeting of stockholders. Dr. Poorvin has over 30 years of experience in the pharmaceutical industry and is currently an Executive-in-Residence at Oxford Bioscience Partners, a venture capital company. Dr. Poorvin also is engaged in private consulting for biotech companies. At the end of 2003, Dr. Poorvin retired from Schering-Plough Corporation as Vice President of their Business Development operations where he negotiated licenses, joint ventures and acquisitions of pharmaceutical products and research technologies. Dr. Poorvin s career at Schering Plough from 1981 to 2003 included 14 years in Business Development as well as tenure as the Director of Clinical Research at Schering-Plough, a position he also held at Pfizer Pharmaceuticals from 1977 to 1981. He was responsible for several NDA programs and product approvals at both companies, including such drugs as Procardia and Imdur. Dr. Poorvin started his career in the pharmaceutical industry at Lederle Laboratories from 1973 to 1977, where he directed pre-clinical research in the cardiovascular area. He received his B.A. degree from Hunter College of the City University of New York. He received his Ph.D. from Rutgers University.

Directors Meetings and Compensation

Our operations are managed under the broad supervision of the board of directors, which has ultimate responsibility for the establishment and implementation of our general operating philosophy, objectives, goals and policies. During 2003, the board of directors convened on twenty five occasions (due to our activities in searching for strategic alternatives and activities associated with our decision to complete a Dutch auction self tender offer) and took certain additional actions by unanimous written consent in lieu of meetings. Each director attended at least 75% of the meetings held by the board and any committee of the board on which he served during his tenure in 2003. Our current policy is to have our directors attend our annual meeting of

stockholders. Because all of our then non-employee directors were replaced at the 2003 annual meeting of stockholders, only Mr. Podolski was present at such meeting.

Employee directors do not receive additional compensation for service on the board of directors or its committees. We reimburse each non-employee director for travel expenses incurred in connection with attendance at board meetings. For board and committee meetings attended in person or telephonically, non-employee directors currently receive $1,000 per meeting in cash. Employee directors are eligible to participate in our 2004 stock option plan. Non-employee directors are also entitled to participate in our 2000 non-employee directors stock option plan.

Under the 2000 director plan, (1) each non-employee director who is first elected to the board is entitled to receive an option to purchase 40,000 shares of our common stock on the date on which he or she first becomes a non-employee director, and (2) each non-employee director in office immediately after our annual meeting of stockholders will receive an option to purchase 5,000 shares of common stock effective on such date. Additionally under the 2000 director plan, the Chairman of the board (if a non-employee) who is first elected to the board is entitled to receive an option to purchase 10,000 shares of common stock on the date on which he or she first becomes Chairman, and the Chairman (if a non-employee) in office immediately after each of our annual meetings of stockholders will receive an option to purchase 10,000 shares of common stock effective on such date. During 2003, we paid an aggregate of $93,000 to the directors, issued stock awards totaling 10,871 shares of common stock to two directors, and granted options to purchase an aggregate of 12,972 shares of common stock under the 2000 director plan to one director, for their attendance at board and committee meetings.

Board Committees

Pursuant to delegated authority, various board functions are discharged by the standing committees of the board. The board of directors has appointed three principal standing committees: the Compensation and Option Committee, the Nominating and Corporate Governance Committee and the Audit Committee. Copies of the Audit Committee Charter, Compensation and Option Committee Charter and the Nominating and Corporate Governance Committee Charter are available in the Corporate Governance section of our web site at http://www.zonagen.com. In addition, we have adopted a Code of Business Conduct and Ethics for directors, officers and employees and a Code of Ethics for Senior Financial Officers, which are available in the Corporate Governance Section of our website at http://www.zonagen.com. If any substantive amendments are made to either code, the nature of such amendment will be disclosed on our website. In addition, if a waiver from either code is granted to an executive officer, director or principal accounting officer, the nature of such waiver will be disclosed on our website.

Audit Committee. The Audit Committee, currently comprised of Mr. Cain, as Chairman, Mr. Lavotha, Ms. Masterson and Dr. Poorvin (Ms. Masterson and Dr. Poorvin were elected on September 29, 2004), provides assistance to the board in fulfilling its responsibilities relating to corporate accounting and reporting practices, recommends to the board the engagement by us of our independent registered public accounting firm, approves services performed by our independent registered public accounting firm, including fee arrangements and the range of audit and non-audit services, maintains a direct line of communication between the board and our independent registered public accounting firm and performs such other functions as may be prescribed with respect to audit committees under applicable rules, regulations and policies of The Nasdaq Stock Market, Inc. The Audit Committee also evaluates our system of internal controls, the internal audit function and other related areas. As required by Nasdaq Stock Market and SEC rules regarding audit committees, the board has reviewed the qualifications of its Audit Committee and has determined that none of the current members of the Audit Committee have a relationship with us that might interfere with the exercise of their independence from us or our management and has determined that each member of the Audit Committee is independent, as independence is defined in the listing standards for the Nasdaq Stock Market. The board has determined that Mr. Cain, Chairman of the Audit Committee, is an audit committee financial expert as described in Item 401(h) of Regulation S-K.

Compensation and Option Committee. The Compensation and Option Committee, currently comprised of Mr. Lavotha, as Chairman, and Ms. Masterson and Dr. Poorvin, who were elected on September 29, 2004, selects the employees to whom stock options are to be granted, determines the terms and conditions provided for in each option grant and reviews and recommends to the board of directors the amount of compensation to be paid to our officers. The board of directors has determined that each member of the Compensation and Option Committee is independent, as independence is defined in the listing standards for the Nasdaq Stock Market.

Nominating and Corporate Governance Committee. The Nominating and Corporate Governance Committee is currently comprised of Drs. Fourcroy and Poorvin (elected on September 29, 2004), Messrs. Cain and Lavotha and Ms. Masterson (elected on September 29, 2004). The Nominating and Corporate Governance Committee investigates and makes recommendations to the board with respect to qualified candidates to be nominated for election to the board and reviews and makes recommendations to the board with regard to candidates for directors nominated by stockholders in accordance with our bylaws. This committee also investigates and makes recommendations to the board with regard to all matters of corporate governance, including the structure, operation and evaluation of the board and its committees. The board has determined that each member of the Nominating and Corporate Governance Committee is independent, as independence is defined in the listing standards for the Nasdaq Stock Market.

EXECUTIVE COMPENSATION

Compensation of Executive Officers

Summary Compensation Table

The following table provides certain summary information concerning compensation paid or accrued during the last three years to our President and Chief Executive Officer and to our only other officer who had compensation in excess of $100,000 during the last fiscal year, Louis Ploth, Jr.:

		Annual Compensation		Long-Term Compensation		
Name and Principal Position	Year	Salary	Bonus	Restricted Stock Awards ($)	Securities Underlying Options (#)	All Other Compensation (1)
Joseph S. Podolski	2003	$280,000				$6,000(2)
President and Chief Executive Officer	2002	$272,708		$26,500	275,000	$6,000(2)
	2001	$235,000			25,000	$6,000(2)
Louis Ploth, Jr.	2003	$150,000				
Vice President, Business Development,	2002	$150,000		$26,500		
Chief Financial Officer and Secretary	2001	$139,133			30,000	

(1) During the periods indicated, perquisites for each individual named in the summary compensation table aggregated less than 10% of the total annual salary and bonus reported for such individual in the summary compensation table. Accordingly, no such amounts are included in the summary compensation table.

(2) Represents car allowance.

Option Grants in 2003

There were no options granted to Messrs. Podolski and Ploth during the fiscal year ended December 31, 2003 under our stock option plan. During 2004, Messrs. Podolski and Ploth were granted options to purchase 272,866 shares of our common stock and 165,383 shares of our common stock, respectively.

Option Exercises and Holdings

The following table sets forth information concerning option exercises and the value of unexercised options held by Messrs. Podolski and Ploth as of the end of the last fiscal year:

Aggregated Option Exercises in 2003

and Option Values at December 31, 2003

			Number of Securities Underlying Unexercised Options Held at December 31, 2003		Value of Unexercised In-The-Money Options Held at December 31, 2003 (1)
Name	Exercised (#)	Realized ($)	Exercisable	Unexercisable	

Joseph S. Podolski	248,000	287,000
Louis Ploth, Jr.	102,700	24,000

(1) Computed based on the difference between aggregate fair market value and aggregate exercise price. The fair market value of our common stock on December 31, 2003 was $1.85, based on the closing sales price on the Nasdaq Stock Market on December 31, 2003. Neither Messrs. Podolski nor Ploth have sold any shares of common stock they have received upon the exercise of options or shares purchased on the open market during their respective tenures as executive officers and directors of the company.

Equity Compensation Plan Information

The following table provides information as of December 31, 2003, regarding compensation plans (including individual compensation arrangements) under which equity securities are authorized for issuance:

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Shown in the First Column)
Equity compensation plans approved by stockholders (1)	1,225,470	$5.98	380,397
Equity compensation plans not approved by stockholders			
Total	1,225,470	$5.98	380,397

(1) Consists of shares of common stock issued or remaining available for issuance under all of our stock option plans. The material terms of the 2000 director plan are described above under Directors Meetings and Compensation.

Employment Agreements

We have employment agreements with Messrs. Podolski and Ploth which provide for current annual salaries of $300,000 and $190,000, respectively. The agreements provide that we will pay Messrs. Podolski and Ploth an annual incentive bonus as may be approved by the board of directors and that they are entitled to participate in all employee benefit plans sponsored by us.

We initially entered into an employment agreement with Mr. Podolski on January 1, 1993, which was subsequently amended on January 31, 2001 and October 29, 2002. Mr. Podolski s employment agreement provides for automatic annual renewals each January unless terminated in writing by either party. If terminated for reasons other than cause, Mr. Podolski is entitled to receive his annual base salary and certain employment benefits for one year following termination. In addition, he is entitled to the following severance payments in the event he is terminated without cause or resigns for good reason within 12 months following a change of control: a cash lump sum payment equal to the present value of the aggregate amount of payments set forth below, in which the present value is determined as of the closing date of the change of control transaction (as if he was terminated or had resigned on such date). Mr. Podolski has agreed to defer payment of such amount, and in lieu of such lump sum payment, he will receive the payments listed in the following table. All of the payments listed below, other than the first payment made at the closing of a change of control, would be made out of an irrevocable Rabbi Trust which would be funded by the company immediately prior to the closing of a change of control transaction:

Amount of Payment	Payment Due Date
Current base salary	On the closing of the change of control transaction
$150,000	1st anniversary after closing
$150,000	2nd anniversary after closing
$150,000	3rd anniversary after closing
$150,000	4th anniversary after closing
$125,000	5th anniversary after closing
$ 75,000	6th anniversary after closing

Finally, Mr. Podolski is entitled to acceleration of all unvested options and an extension of the period of exercisability of his options for a two year period following the closing of a change of control transaction and is entitled to receive benefits coverage for a period of 12 months

following his termination.

We initially entered into an employment agreement with Mr. Ploth on October 16, 1993, which was subsequently amended on January 31, 2001 and October 29, 2002. Mr. Ploth s employment agreement

automatically renews each October unless otherwise terminated by either party. If terminated for reasons other than cause, Mr. Ploth is entitled to salary and certain employment benefits for six months following termination.

Mr. Ploth is entitled to receive a lump sum payment upon the closing of a change of control transaction, regardless of whether he is terminated or continues with the combined company, in an amount equal to his current base salary at the time of the closing. In addition, Mr. Ploth is entitled to acceleration of all unvested options and an extension of the period of exercisability of his options for a two year period following the closing of a change of control, and he is entitled to receive benefits coverage for a period of 12 months following closing.

Compensation and Option Committee Interlocks and Insider Participation

The Compensation and Option Committee currently consists of Messrs. Lavotha and Cain, who were elected to this committee on January 16, 2004, and Ms. Masterson, who was elected to this committee on September 29, 2004. During fiscal 2003, none of our executive officers served as (i) a member of the compensation committee (or other board committee performing equivalent functions) of another entity, one of whose executive officers served on the Compensation and Option Committee of our board of directors, (ii) a director of another entity, one of whose executive officers served on the Compensation and Option Committee of our board of directors or (iii) a member of the compensation committee (or other board committee performing equivalent functions) of another entity, one of whose executive officers served as our director.

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

Zsolt Lavotha previously served as President and Chief Executive Officer and a director of Lavipharm Corp., a private corporation wholly owned by Lavipharm S.A., a publicly traded Greek corporation, from December 1998 to April 2003. We entered into a definitive merger agreement with Lavipharm Corp. in October 2002. In addition, immediately following execution of the definitive merger agreement, we loaned $1 million to Lavipharm. The merger agreement terminated in March 2003, and Lavipharm paid off the loan with interest in its entirety in April 2003. Mr. Lavotha served in the capacities described above during these transactions.

All future affiliated transactions and loans will be made or entered into on terms that are no less favorable to us than those that can be obtained from unaffiliated third parties. All future affiliated transactions and any forgiveness of loans must be approved by a majority of our independent directors who do not have an interest in the transactions and who had access, at our expense, to our or independent legal counsel.

PRINCIPAL STOCKHOLDERS

The following table presents certain information regarding the beneficial ownership of common stock as of September 30, 2004 by (i) each person who is known by us to own beneficially more than 5% of the outstanding shares of common stock, (ii) each of our directors, (iii) our executive officers, and (iv) all directors and executive officers as a group. Except as described below, each of the persons listed in the table has sole voting and investment power with respect to the shares listed. Each stockholder s percentage ownership before this offering is based on 4,992,901 shares of our common stock outstanding as of September 30, 2004. Each stockholder s percentage ownership after this offering is based on 8,992,901 shares of our common stock outstanding as of September 30, 2004, assuming no exercise of the underwriters over-allotment option.

Name of Beneficial Owner	Amount and Nature of Beneficial Ownership of Common Stock (1)	Percentage of Shares Beneficially Owned Before Offering (2)	Percentage of Shares Beneficially Owned After Offering (2)
BVF Partners L.P. 227 West Monroe, Suite 4800 Chicago, Illinois 60606	582,743(3)	11.7%	6.5%
Daniel F. Cain	6,666(4)	*	*
Jean L. Fourcroy, M.D., Ph.D., M.P.H.	6,666(4)	*	*
Zsolt Lavotha	6,666(4)	*	*
Nola E. Masterson			
Joseph S. Podolski	290,898(5)	5.6%	3.2%
Louis Ploth, Jr.	164,573(6)	3.2%	1.8%
David Poorvin, Ph.D.			
All directors and executive officers as a group (7 persons)	475,469(4) - (6)	8.9%	5.1%

* Does not exceed 1%.

(1) Unless otherwise noted, we believe that all persons named in the table have sole voting and investment power with respect to all shares of common stock beneficially owned by such persons.

(2) In accordance with the rules of the Securities and Exchange Commission, each beneficial owner s percentage ownership assumes the exercise or conversion of all options, warrants and other convertible securities held by such person and that are exercisable or convertible within 60 days after September 30, 2004.

(3) Based on information contained in a Schedule 13G/A dated February 13, 2004, BVF Partners L.P. shares voting and dispositive power with respect to all of the shares listed above with its general partner, BVF Inc., on behalf of the following entities with which it shares voting and dispositive power in the following amounts: Biotechnology Value Fund, L.P., 221,443 shares; Biotechnology Value Fund II, L.P., 116,138 shares; BVF Investments, L.L.C., 217,862 shares; and Investment 10, L.L.C., 27,300 shares. Mark Lampert acts as manager of these funds.

(4) Includes 6,666 shares issuable upon exercise of options, all with exercise prices of $2.40 per share.

(5) Includes (i) 300 shares of common stock which are held by certain of Mr. Podolski s family members and (ii) 198,717 shares of common stock issuable upon the exercise of options with exercise prices per share ranging between $2.72 to $8.38 and a weighted average of $5.79 per share. Mr. Podolski disclaims beneficial ownership of the shares owned by his family members.

(6) Includes 134,776 shares of common stock issuable upon the exercise of options with exercise prices per share ranging between $2.72 to $30.00 and a weighted average of $10.16 per share.

DESCRIPTION OF CAPITAL STOCK

Our authorized capital stock consists of 20,000,000 shares of common stock, par value $0.001 per share, and 5,000,000 shares of preferred stock, par value $0.001 per share.

As of September 30, 2004, we had 4,992,901 outstanding shares of common stock and no outstanding shares of preferred stock. As of September 30, 2004, we had outstanding stock options to purchase 1,836,846 shares of common stock at prices ranging from $1.70 to $33.25. Upon completion of this offering,

assuming the sale of 4,000,000 shares of our common stock, we will have 8,992,901 outstanding shares of common stock.

Common Stock

Subject to any special voting rights of any series of preferred stock that we may issue in the future, each share of common stock has one vote on all matters voted on by our stockholders, including the election of our directors. Because holders of common stock do not have cumulative voting rights, the holders of a majority of the shares of common stock can elect all of the members of the board of directors standing for election, subject to the rights, powers and preferences of any outstanding series of preferred stock.

No share of common stock affords any preemptive rights or is convertible, redeemable, assessable or entitled to the benefits of any sinking or repurchase fund. Holders of common stock will be entitled to dividends in the amounts and at the times declared by our board of directors in its discretion out of funds legally available for the payment of dividends.

Holders of common stock will share equally in our assets on liquidation after payment or provision for all liabilities and any preferential liquidation rights of any preferred stock then outstanding. All outstanding shares of common stock are fully paid and non-assessable.

Preferred Stock

Our certificate of incorporation provides that shares of preferred stock may be issued from time to time in one or more series. Our board of directors has authority to issue up to 5,000,000 shares of preferred stock and to determine the price, rights, preferences, privileges and restrictions, including voting rights, of those shares without any further vote or action by our stockholders. The rights of holders of our common stock may be subject to, and adversely affected by, the rights of the holders of any preferred stock that may be issued in the future. The issuance of preferred stock may have the effect of delaying, deferring or preventing a change of control and may adversely affect the voting and other rights of holders of our common stock. We have no present plans to issue any shares of preferred stock after this offering. We may not offer preferred stock to our directors and officers except on the same terms as it is offered to all other existing shareholders or to new shareholders.

Rights Agreement

Pursuant to our rights agreement we entered into in September 1999, each share of our common stock has one preferred stock purchase right attached to it, including those being issued in this offering. Each right entitles the holder to purchase from us one one-hundredth of a share of Series One Junior Participating Preferred Stock at a price of $20.00, subject to adjustment.

The rights will separate from our common stock and a distribution date will occur upon the earlier of (i) 10 days following the date of public announcement that a person or group of persons has become an acquiring person (defined below) or (ii) 10 business days (or such later date as may be determined by action of the board of directors prior to the time a person becomes an acquiring person) following the commencement of, or the announcement of an intention to make, a tender offer or exchange offer upon consummation of which the offeror would, if successful, become an acquiring person (the earlier of such dates being called the distribution date). The term acquiring person means any person who or which, together with all of its affiliates and associates, shall be the beneficial owner of 20% or more of our outstanding common stock.

The rights are not exercisable until the distribution date. The rights will expire on September 13, 2005.

In the event that following the date of public announcement that an acquiring person has become such, we are acquired in a merger or other business combination transaction or more than 50% of our consolidated assets or earning power are sold, proper provision will be made so that each holder of a right will thereafter have the right to receive, upon the exercise thereof at the then current exercise price of the right, that number

of shares of common stock of the acquiring company which at the time of such transaction will have a market value of two times the exercise price of the right. This is known as a flip-over right.

In the event that a person who is not exempt becomes an acquiring person, proper provision shall be made so that each holder of a right (other than the acquiring person and its affiliates and associates) will thereafter have the right to receive upon exercise that number of shares of our common stock (or, under certain circumstances, cash, other equity securities or property) having a market value equal to two times the purchase price of the rights. This is known as a flip-in right. Upon the occurrence of the foregoing event giving rise to the exercisability of the rights, any rights that are or were at any time owned by an acquiring person shall become void.

We may redeem the rights in whole, but not in part, at a price of $0.01 per right prior to the earlier of the expiration of the rights or their triggering; provided, that (i) if the board authorizes redemption on or after the time a person becomes an acquiring person, then such authorization must be with the approval of a majority of our directors and (ii) the period for redemption may, upon approval of a majority of our directors, be extended by amending the rights agreement.

The terms of the rights may be amended by the board without the consent of the holders of the rights at any time and from time to time provided that such amendment does not adversely affect the interests of the holders of the rights. In addition, during any time that the rights are subject to redemption, the terms of the rights may be amended by approval of a majority of our directors, including an amendment that adversely affects the interests of the holders of the rights, without the consent of the holders of rights.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Investor Services LLC.

Anti-Takeover Effects of Certificate, Bylaws, Stockholder Rights Plan and Delaware Law

General. Our certificate of incorporation, bylaws and stockholder rights plan contain provisions that are designed in part to make it more difficult and time-consuming for a person to obtain control of our company. The provisions of our certificate of incorporation, bylaws and stockholder rights plan reduce the vulnerability of our company to an unsolicited takeover proposal. These provisions may also have an adverse effect on the ability of stockholders to influence the governance of our company and may result in entrenchment of management. This may adversely affect the liquidity and price of our common stock in certain situations. We have summarized the material terms of our certificate of incorporation and bylaws below and the terms of our stockholder rights plan above. You may read our certificate of incorporation, bylaws and stockholder rights plan in their entirety for the full terms of the rights of holders of our common stock.

Delaware Business Combination Statute. Section 203 of the Delaware General Corporation Law provides that, subject to specified exceptions, an interested stockholder of a Delaware corporation may not engage in any business combination, including general mergers or consolidations or acquisitions of additional shares of the corporation, with the corporation for a three-year period following the time that such stockholder becomes an interested stockholder unless:

before such time, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;

upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding specified shares; or

on or after such time, the business combination is approved by the board of directors of the corporation and authorized not by written consent, but at an annual or special meeting of stockholders, by the affirmative vote of at least 66 2/3% of the outstanding voting stock not owned by the interested stockholder.

Under Section 203, the restrictions described above also do not apply to specified business combinations proposed by an interested stockholder following the announcement or notification of a transaction specified in Section 203 and involving the corporation and a person who:

had not been an interested stockholder during the previous three years; or

became an interested stockholder with the approval of a majority of the corporation s directors,

if such transaction is approved or not opposed by a majority of the directors who were directors prior to any person becoming an interested stockholder during the previous three years or were recommended for election or elected to succeed such directors by a majority of such directors.

Except as otherwise specified in Section 203, an interested stockholder is defined to include:

any person that is the owner of 15% or more of the outstanding voting stock of the corporation, or is an affiliate or associate of the corporation and was the owner of 15% or more of the outstanding voting stock of the corporation at any time within three years immediately before the date of determination; and

the affiliates and associates of any such person.

Under some circumstances, Section 203 makes it more difficult for an interested stockholder to effect various business combinations with a corporation for a three-year period.

Advance Notice Requirements for Director Nominations and Other Stockholder Proposals. In order to nominate a director at an annual meeting, our bylaws require that a stockholder follow certain procedures. In order to recommend a nominee for director, a stockholder must be a stockholder of record at the time the stockholder gives notice of its recommendation and the stockholder must be entitled to vote for the election of directors at the meeting at which such nominee will be considered. Stockholder recommendations must be made pursuant to written notice delivered to our principal executive offices no less than 50 days nor more than 75 days prior to the date of the annual or special meeting at which directors are to be elected; provided, that if the date of the annual or special meeting was not publicly announced more than 65 days prior to the annual or special meeting, such notice by the stockholder will be timely if delivered to our secretary no later than the close of business on the 15th day following the day on which such announcement of the date of the meeting was communicated to the stockholders.

The stockholder notice must set forth the following:

1. As to each person the stockholder proposes to nominate for election as a director, all information relating to such person that would be required to be disclosed in solicitations of proxies for the election of such nominees as directors pursuant to rules promulgated under the Securities Exchange Act of 1934;

2. The written consent to serve as a director if elected by each person nominated;

3. Name and address of the stockholder as they appear on our books; and

4. The class and number of shares of our common stock beneficially owned by such stockholder.

In addition to complying with the foregoing procedures, any stockholder nominating a director must also comply with all applicable requirements of the Securities Exchange Act of 1934 and the rules and regulations thereunder.

Additionally, with respect to other stockholder proposals, notice of the proposal must be received no less than 50 nor more than 75 days prior to the annual meeting at which such proposal is to be considered, or the notice will be untimely and the proposal will not be considered at such annual meeting.

Authorized But Unissued Shares. Our authorized but unissued shares of common stock and preferred stock are available for future issuances without stockholder approval and could be utilized for a variety of corporate purposes, including future offerings to raise additional capital, corporate acquisitions and employee benefit plans. The existence of authorized but unissued and unreserved common stock and preferred stock

could render more difficult or discourage an attempt to obtain control of us by means of a proxy contest, tender offer, merger or otherwise.

Indemnification of Directors and Officers

Our certificate of incorporation provides for indemnification of directors and officers under the circumstances and to the full extent permitted by Delaware law.

SHARES ELIGIBLE FOR FUTURE SALE

Upon completion of this offering, we will have outstanding 8,992,901 shares of common stock, assuming the underwriters over-allotment option is not exercised. Of these shares, 4,000,000 shares, or 4,600,000 shares if the underwriters exercise the over-allotment option in full, of the common stock sold in this offering will be freely tradable without restriction under the Securities Act of 1933 unless purchased by our affiliates as that term is defined in Rule 144 under the Securities Act.

Pursuant to lock-up agreements, our directors and executive officers have agreed that they will not sell any of the 475,469 shares of our common stock collectively and beneficially owned by them for a period of 90 days from the date of this prospectus without the prior written consent of Punk, Ziegel & Company. As a result of these lock-up agreements and the rules under the Securities Act, the restricted shares will be available for sale in the public market, subject in most cases to volume and other restrictions, as follows:

Days after the Effective Date	Number of Shares Eligible for Sale	Comment
Upon effectiveness	0	Restricted shares not locked up and eligible for sale under Rule 144
90 days	475,469	Lock-up released; restricted shares eligible for sale under Rules 144 and 701

Rule 144

In general, under Rule 144 of the Securities Act as currently in effect, a person who has beneficially owned restricted shares for at least one year, including the holding period of any prior owner other than an affiliate of ours, is permitted to sell, within any three-month period, the number of such restricted shares that does not exceed the greater of:

one percent of the then-outstanding shares of our common stock; or

the average weekly trading volume of our common stock during the four calendar weeks preceding such sale.

Sales under Rule 144 are subject to restrictions relating to manner of sale, notice and the availability of current public information about us.

Rule 144(k)

In addition, under Rule 144(k) of the Securities Act, a person who was not an affiliate of our company at any time within the three months preceding a sale, and who has beneficially owned shares for at least two years, including the holding period of any prior owner other than an affiliate of ours, may sell such shares at any time without having to comply with volume limitations, manner of sale provisions, notice or other requirements of Rule 144.

UNDERWRITING

We, Punk, Ziegel & Company, L.P. and WR Hambrecht + Co, LLC, as representatives of the underwriters, intend to enter into an underwriting agreement with respect to the shares being offered. Subject to the terms and conditions of the underwriting agreement, the underwriters have severally agreed to purchase from us the number of shares of our common stock set forth on the cover page of this prospectus at the public offering price, less the underwriting discount, set forth on the cover page of this prospectus. Subject to the terms and conditions stated in the underwriting agreement, each underwriter has agreed to purchase, and we have agreed to sell to that underwriter, the number of shares of our common stock set forth opposite each underwriter s name below.

Underwriter	Number of Shares
Punk, Ziegel & Company, L.P.	
WR Hambrecht + Co, LLC	
Total	4,000,000

The underwriting agreement provides that the obligations of the underwriters to purchase the shares of common stock offered hereby are conditional and may be terminated at their discretion based on their assessment of the state of the financial markets. The obligations of the underwriters may also be terminated upon the occurrence of other events specified in the underwriting agreement. The underwriters are committed to purchase all of the shares of common stock being offered by us if any shares are purchased.

The underwriters propose to offer the shares of common stock to the public at the public offering price set forth on the cover page of this prospectus. The underwriters may offer the common stock to securities dealers at the price to the public less a concession not in excess of $ per share. Securities dealers may reallow a concession not in excess of $ per share to other dealers. After the shares of common stock are released for sale to the public, the underwriters may vary the offering price and other selling terms from time to time.

We have granted to the underwriters an option, exercisable not later than 30 days after the date of this prospectus, to purchase up to an aggregate of 600,000 additional shares of common stock at the public offering price set forth on the cover page of this prospectus, less the underwriting discount. The underwriters may exercise this option only to cover over-allotments, if any, made in connection with the sale of common stock offered hereby.

The following table summarizes the compensation to be paid to the underwriters by us and the proceeds, before expenses, payable to us.

		Total	
	Per Share	Without Over-Allotment	With Over-Allotment
Public Offering Price	$	$	$
Underwriting Discount			
Proceeds to Us (before expenses)			

We estimate that the total expenses of this offering, excluding the underwriting discount, will be approximately $875,000. This includes an expense allowance of up to $150,000 which we have agreed to pay to the underwriters to reimburse them for expenses they incur in connection with this offering.

We have agreed to indemnify the underwriters against certain civil liabilities, including liabilities under the Securities Act of 1933, and to contribute to payments the underwriters may be required to make in respect of any such liabilities.

Our directors and executive officers have agreed with the underwriters that, for a period of 90 days from the date of this prospectus, they will not offer, sell, assign, transfer, pledge, contract to sell or otherwise dispose of or hedge any shares of our common stock or any securities convertible into or exchangeable for shares of common stock. However, so long as the transferee agrees to be bound by the terms of the lock-up

agreement, a director, executive officer or other holder may transfer his or her securities by gift or for estate planning purposes and in some other circumstances. Punk, Ziegel & Company may, in its sole discretion, release all or any portion of the shares from the restrictions in any such agreement at any time without prior notice. We have entered into a similar agreement with the underwriters. Currently, we are not aware of any agreements between the underwriters and any of our stockholders, option holders or affiliates releasing them from these lock-up agreements prior to the expiration of the 90-day period. In considering any request to release shares subject to a lock-up agreement, Punk, Ziegel & Company will consider the facts and circumstances relating to a request at the time of that request.

The underwriters may engage in over-allotment, stabilizing transactions, syndicate-covering transactions and passive market making in accordance with Regulation M under the Securities Exchange Act of 1934. Over-allotment involves syndicate sales in excess of the offering size, which creates a syndicate short position. Covered short sales are sales made in an amount not greater than the number of shares available for purchase by the underwriters under the over-allotment option. The underwriters may close out a covered short sale by exercising the over-allotment option or purchasing shares in the open market. Naked short sales are sales made in an amount in excess of the number of shares available under the over-allotment option. The underwriters must close out any naked short sale by purchasing shares in the open market. Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum. Syndicate-covering transactions involve purchases of the shares of common stock in the open market after the distribution has been completed in order to cover syndicate short positions. In passive market making, market makers in the shares of common stock who are underwriters or prospective underwriters may, subject to certain limitations, make bids for or purchases of the shares of common stock until the time, if any, at which a stabilizing bid is made. These stabilizing transactions and syndicate-covering transactions may cause the price of the shares of common stock to be higher than it would otherwise be in the absence of these transactions. These transactions may be commenced and discontinued at any time.

WR Hambrecht + Co may distribute preliminary prospectuses electronically to prospective investors who have previously consented to receive electronic delivery of preliminary prospectuses. An electronic prospectus is available on the websites maintained by underwriters Punk, Ziegel & Company, at www.pzk.com, and WR Hambrecht + Co, at www.wrhambrecht.com. Other than the prospectus in electronic format, the information on these websites is not part of this prospectus or the registration statement of which this prospectus forms a part, has not been approved or endorsed by us or any underwriter in its capacity as underwriter, and should not be relied upon by investors.

LEGAL MATTERS

The validity of the common stock offered hereby will be passed on for us by Winstead Sechrest & Minick P.C., The Woodlands, Texas. Certain legal matters in connection with this offering will be passed on for the underwriters by Morrison & Foerster LLP, New York, New York.

NOTICE REGARDING ARTHUR ANDERSEN LLP

Section 11(a) of the Securities Act provides that if any part of a registration statement at the time it becomes effective contains an untrue statement of a material fact or an omission to state a material fact required to be stated therein or necessary to make the statements therein not misleading, any person acquiring a security pursuant to such registration statement (unless it is proved that at the time of such acquisition such person knew of such untruth or omission) may sue, among others, every accountant who has consented to be named as having prepared or certified any part of the registration statement or as having prepared or certified any report or valuation which is used in connection with the registration statement with respect to the statement in such registration statement, report or valuation which purports to have been prepared or certified by the accountant.

Our financial statements for the eight years ended December 31, 2001 were audited by Arthur Andersen LLP. Prior to the date of this prospectus, the Arthur Andersen LLP partners who audited those financial

statements resigned from Arthur Andersen LLP. As a result, after reasonable efforts, we have been unable to obtain Arthur Andersen LLP s written consent to the inclusion in this registration statement of its audit reports with respect to our financial statements for the year ended December 31, 2001. Under these circumstances, Rule 437a under the Securities Acts permits us to file this registration statement without written consents from Arthur Andersen LLP. Accordingly, Arthur Andersen LLP may not be liable to you under Section 11(a) of the Securities Act because it has not consented to being named as an expert in the registration statement.

EXPERTS

Our financial statements for the eight years ended December 31, 2001 included in this prospectus have been audited by Arthur Andersen LLP. Arthur Andersen LLP has not reissued its report with respect to those financial statements and we have not been able to obtain, after reasonable efforts, Arthur Andersen LLP s written consent to the inclusion in this prospectus of said report. Accordingly, Arthur Andersen LLP will not be liable to investors under Section 11(a) of the Securities Act because it has not consented to being named as an expert in this registration statement. As a result, you may not have an effective remedy against Arthur Andersen LLP in connection with any material misstatement or omission in the financial statements to which its audit report relates. In addition, even if you were able to assert such a claim, as a result of its recent conviction of federal obstruction of justice charges and other lawsuits, Arthur Andersen LLP may fail or otherwise have insufficient assets to satisfy claims made by investors that might arise under federal securities laws or otherwise with respect to its audit report.

The consolidated financial statements as of December 31, 2003 and 2002 and for each of the two years in the period ended December 31, 2003 included in this prospectus and registration statement have been so included in reliance on the report of PricewaterhouseCoopers LLP, independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act of 1933 related to the common stock offered by this prospectus. As allowed by SEC rules, this prospectus does not contain all of the information contained in the registration statement. The complete registration statement and the documents filed as exhibits to the registration statement are available to the public over the Internet at the SEC s website at *http://www.sec.gov.* If you have a question on any contract, agreement or other document filed as an exhibit to the registration statement, please see the exhibits for a more complete description of the matter involved. We have been filing with the SEC annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K. The reports that we file with the SEC are available free of charge at the SEC s website named above, as well as at our website at *http://www.zonagen.com.*

You may also read and copy any document we have filed with the SEC at its public reference facilities at 450 Fifth Street, N.W., Washington, D.C. 20549. You may obtain copies of these documents at prescribed rates by writing to the Public Reference Section of the SEC at 450 Fifth Street, N.W., Washington, D.C. 20549. Please call the SEC at 1-800-732-0330 for further information on the operation of the public reference facilities.

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders of Zonagen, Inc.:

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, stockholders equity, and cash flows present fairly, in all material respects, the financial position of Zonagen, Inc., and subsidiaries (a development stage company) at December 31, 2003 and 2002 and the results of their operations and their cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company s management; our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States), which require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion. The financial statements of Zonagen, Inc. for the year ended December 31, 2001 were audited by other independent auditors who have ceased operations. Those independent auditors expressed an unqualified opinion on those financial statements and included an explanatory paragraph that described the change in accounting described in Note 2 to the financial statements in their report dated February 6, 2002.

/s/ PRICEWATERHOUSECOOPERS LLP

Houston, Texas
March 19, 2004, except for Note 12,
as to which the date is
March 29, 2004

THIS REPORT IS A COPY OF THE REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS PREVIOUSLY ISSUED BY ARTHUR ANDERSEN LLP, AND IT HAS NOT BEEN REISSUED BY ARTHUR ANDERSEN LLP.

REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS

To Zonagen, Inc.:

We have audited the accompanying consolidated balance sheets of Zonagen, Inc. (a Delaware corporation in the development stage), and subsidiary (collectively, the Company) as of December 31, 2001 and 2000, and the related consolidated statements of operations, stockholders equity and cash flows for each of the three years in the period ended December 31, 2001. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Zonagen, Inc., and subsidiary as of December 31, 2001 and 2000, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2001, in conformity with accounting principles generally accepted in the United States.

As explained in Note 2 to the consolidated financial statements, effective January 1, 2000, the Company changed its method of accounting for revenue recognition.

/s/ ARTHUR ANDERSEN LLP

Houston, Texas
February 6, 2002

ZONAGEN, INC. AND SUBSIDIARY

(A development stage company)

CONSOLIDATED BALANCE SHEETS

	December 31, 2003	December 31, 2002	September 30, 2004
	(In thousands except share amounts)		(Unaudited)
ASSETS			
CURRENT ASSETS			
Cash and cash equivalents	$ 20,946	$ 8,683	$ 2,556
Marketable securities	2,000	16,455	4,000
Note receivable		1,000	
Prepaid expenses and other current assets	235	532	86
Total current assets	23,181	26,670	6,642
FIXED ASSETS, net		191	17
OTHER ASSETS, net	847	509	387
Total assets	$ 24,028	$ 27,370	$ 7,046
LIABILITIES AND STOCKHOLDERS EQUITY			
CURRENT LIABILITIES			
Accounts payable	$ 126	$ 86	$ 190
Accrued expenses	415	433	225
Total current liabilities	541	519	415
COMMITMENTS & CONTINGENCIES			
STOCKHOLDERS EQUITY			
Undesignated Preferred Stock, $.001 par value, 5,000,000 shares authorized, none issued and outstanding			
Common Stock, $.001 par value, 20,000,000 shares authorized, 11,929,048, 11,918,177 and 11,989,936 (unaudited) shares issued, respectively, 11,479,648, 11,502,877 and 4,992,901 (unaudited) shares outstanding, respectively	12	12	12
Additional paid-in capital	114,065	114,051	114,377
Deferred compensation			(260)
Cost of treasury stock, 449,400, 415,300 and 6,997,035 (unaudited) shares, respectively	(7,533)	(7,484)	(21,487)
Deficit accumulated during the development stage	(83,057)	(79,728)	(86,011)
Total stockholders equity	23,487	26,851	6,631
Total liabilities and stockholders equity	$ 24,028	$ 27,370	$ 7,046

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

ZONAGEN, INC. AND SUBSIDIARY

(A development stage company)

CONSOLIDATED STATEMENTS OF OPERATIONS

	For the Year Ended December 31,			For the Nine Months Ended September 30,		From Inception (August 20, 1987) Through September 30,
	2003	2002	2001	2004	2003	2004
				(Unaudited)		(Unaudited)
			(In thousands except per share amounts)			
REVENUES AND OTHER INCOME						
Licensing fees	$	$ 4,228	$ 2,162	$	$	$ 28,755
Product royalties			58			627
Research and development grants	595	315	115	118	459	1,215
Interest income	318	711	1,526	75	254	13,097
Gain on disposal of fixed assets	102				102	102
Other Income				35		35
Total revenues and other Income	1,015	5,254	3,861	228	815	43,831
EXPENSES						
Research and development	2,161	6,420	3,028	1,914	1,583	93,703
General and administrative	2,183	2,716	1,672	1,268	1,707	26,408
Interest expense and amortization of intangibles						388
Total expenses	4,344	9,136	4,700	3,182	3,290	120,499
Loss from continuing operations	(3,329)	(3,882)	(839)	(2,954)	(2,475)	(76,668)
Income (loss) from discontinued operations						(1,828)
Gain on disposal						939
Net loss before cumulative effect of change in accounting principle	(3,329)	(3,882)	(839)	(2,954)	(2,475)	(77,557)
Cumulative effect of change in accounting principle						(8,454)
NET LOSS	$ (3,329)	$ (3,882)	$ (839)	$ (2,954)	$ (2,475)	$ (86,011)
NET LOSS PER SHARE BASIC AND DILUTED	$ (0.29)	$ (0.34)	$ (0.07)	$ (0.57)	$ (0.22)	
Shares used in net loss per share calculation:						
Basic	11,487	11,412	11,333	5,159	11,489	
Diluted	11,487	11,412	11,333	5,159	11,489	

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

ZONAGEN, INC. AND SUBSIDIARY

(A development stage company)

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

	Preferred Stock		Common Stock		Additional Paid-In	Deferred	Treasury Stock		Deficit Accumulated During the Development	Total Stockholders
	Shares	Amount	Shares	Amount	Capital	Compensation	Shares	Amount	Stage	Equity
					(In thousands except share amounts)					
Exchange of common stock ($.004 per share) for technology rights and services from founding stockholders		$	245,367	$	$ 1	$		$	$	$ 1
Net Loss									(28)	(28)
BALANCE AT DECEMBER 31, 1987 (unaudited)			245,367		1				(28)	(27)
Net Loss									(327)	(327)
BALANCE AT DECEMBER 31, 1988 (unaudited)			245,367		1				(355)	(354)
Proceeds from issuance of common stock			65,431		3					3
Net Loss									(967)	(967)
BALANCE AT DECEMBER 31, 1989 (unaudited)			310,798		4				(1,322)	(1,318)
Proceeds from issuance of common stock			467							
Net Loss									(1,426)	(1,426)
BALANCE AT DECEMBER 31, 1990 (unaudited)			311,265		4				(2,748)	(2,744)
Net Loss									(1,820)	(1,820)
BALANCE AT DECEMBER 31, 1991 (unaudited)			311,265		4				(4,568)	(4,564)
Conversion of 391,305 shares of Series C preferred stock into common stock			91,442		360					360
Purchase of retirement of common stock			(23,555)		(1)					(1)
Proceeds from issuance of common stock			16,946		7					7

Net Loss								(1,583)	(1,583)
BALANCE AT DECEMBER 31, 1992 (unaudited)			396,098	1	370			(6,151)	(5,781)
Issuance of common stock for cash, April 1, 1993, and May 12, 1993 ($5.50 per share), net of offering costs of $1,403			1,534,996	2	7,037				7,039
Issuance of common stock for cash and license agreement, December 9, 1993 ($10.42 per share), net of offering costs of $47			239,933		2,453				2,453
Conversion of Series A preferred stock to common stock			179,936		600				600

	Preferred Stock		Common Stock		Additional		Treasury Stock		Deficit Accumulated	Total
	Shares	Amount	Shares	Amount	Paid-In Capital	Deferred Compensation	Shares	Amount	During the Development Stage	Stockholders Equity
					(In thousands except share amounts)					
Conversion of Series B preferred stock to common stock			96,013		378					378
Conversion of Series C preferred stock to common stock			876,312	1	3,443					3,444
Conversion of Series D preferred stock to common stock			280,248		599					600
Conversion of bridge loan to common stock			64,000		256					256
Net Loss									(2,532)	(2,532)
BALANCE AT DECEMBER 31, 1993 (unaudited)		$	3,667,536	$ 4	$15,136	$		$	$ (8,683)	$ 6,457
Deferred compensation resulting from grant of options					188	(188)				
Amortization of deferred compensation						38				38
Exercise of warrants to purchase common stock for cash, June 30, 1994 ($3.94 per share)			39,623		156					156
Issuance of common stock for purchase of FTI, October 13, 1994			111,111		1,567					1,567
Net loss									(3,970)	(3,970)
BALANCE AT DECEMBER 31, 1994		$	3,818,270	$ 4	$17,047	$ (150)			(12,653)	$ 4,248
Amortization of deferred compensation						37				37
Exercise of options to purchase common stock for cash, January and April 1995 ($.10 to $6.13 per share)			4,546		14					14
Issuance of common stock for cash and a financing charge, March 9, 1995			16,000		76					76
	598,850	1			5,336					5,337

Issuance of Series A preferred stock for cash, October 4, 1995, and October 19, 1995 ($10.00 per share), net of offering costs of $651										
Conversion of warrants to purchase common stock as a result of offering under antidilution clause, October 19, 1995 ($3.63 per share)										
Conversion of Series A preferred stock into common stock, November and December 1995	(94,000)		259,308							
Net loss									(4,287)	(4,287)
BALANCE AT DECEMBER 31, 1995	504,850	$ 1	4,098,124	$ 4	$22,473	$ (113)			(16,940)	$ 5,425

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	Preferred Stock		Common Stock		Additional		Treasury Stock		Deficit Accumulated	Total
	Shares	Amount	Shares	Amount	Paid-In Capital	Deferred Compensation	Shares	Amount	During the Development Stage	Stockholders Equity
	(In thousands except share amounts)									
Deferred compensation resulting from grant of options					86	(86)				
Amortization of deferred compensation						54				54
Exercise of warrants to purchase common stock for cash, January through December 1996 ($3.63 per share)			227,776		827					827
Conversion of Series A preferred stock into common stock, January through November 1996	(507,563)	(1)	1,396,826	2	(1)					99
Issuance of options for services, January 12, 1996					99					75
Exercise of options to purchase common stock for cash, February through November 1996 ($.001 to $5.50 per share)			23,100		75					
Issuance of common stock for agreement not to compete, April 13, 1996			19,512		200					200
Exercise of warrants to purchase Series A preferred stock under cashless exercise provision, June 5, 1996	2,713									
Issuance of Series B preferred stock for cash, September 30, 1996, and October 11, 1996 ($10.00 per share), net of offering costs of $2,557	1,692,500	2			14,366					14,368
Conversion of Series B preferred stock into common stock, November through December 1996	(177,594)		268,058							

Net loss									(9,470)	(9,470)
BALANCE AT DECEMBER 31, 1996	1,514,906	$ 2	6,033,396	$ 6	$38,125	$ (145)		$	$(26,410)	$11,578
Deferred compensation resulting from grant of options					2,110	(2,110)				
Amortization of deferred compensation						854				854
Exercise of options to purchase common stock for cash, January through December 1997 ($0.00 to $22.25 per share)			90,955		522					522

	Preferred Stock		Common Stock		Additional Paid-In	Deferred	Treasury Stock		Deficit Accumulated During the Development	Total Stockholders
	Shares	Amount	Shares	Amount	Capital	Compensation	Shares	Amount	Stage	Equity
					(In thousands except share amounts)					
Exercise of warrants to purchase common stock for cash, January through December 1997 ($3.63 and $3.07 per share)			22,368		75					75
Issuance of common stock for a cashless exercise of Series A preferred stock warrants, February through September 1997			81,294							
Exercise of Series A preferred stock warrants to purchase common stock for cash, April 1997 ($11.00 per share)			818		3					3
Issuance of common stock for a cashless exercise of Series B preferred stock warrants, April through November 1997			88,223							
Exercise of Series B preferred stock warrants to purchase common stock for cash, April through July 1997 ($11.00 per share)			17,169		125					125
Issuance of common stock as final purchase price for acquisition of FTI, January 31, 1997 ($9.833 per share)			305,095	1						1
Issuance of common stock as final debt payment on FTI acquisition, January 31, 1997 ($9.833 per share)			19,842		94					94
Conversion of Series B preferred stock into common stock, January through	(1,514,906)	(2)	2,295,263	2	(1)					(1)

October 1997									
Issuance of common stock for cash, July 25, 1997 ($30.00 per share), net of offering costs of $5,439		2,587,500	3	72,183					72,186
Purchase of treasury stock, December 1997						61,500	(1,287)		(1,287)
Net loss								(13,174)	(13,174)
BALANCE AT DECEMBER 31, 1997	$	11,541,923	$ 12	$113,236	$(1,401)	61,500	$(1,287)	$(39,584)	$ 70,976
Deferred compensation resulting from grant of options				55					55
Amortization of deferred compensation					422				422
Forfeiture of stock options, December 1998				(21)	21				
Exercise of options to purchase common stock for cash, January through October 1998 ($0.43 to $22.25 per share)		63,022		344					344

	Preferred Stock		Common Stock		Additional		Treasury Stock		Deficit Accumulated	Total
	Shares	Amount	Shares	Amount	Paid-In Capital	Deferred Compensation	Shares	Amount	During the Development Stage	Stockholders Equity
					(In thousands except share amounts)					
Issuance of common stock for services, January 15, 1998			5,000		103					103
Issuance of common stock for a cashless Exercise of Series B preferred stock warrants, May through July 1998			11,195							
Purchase of treasury stock, January through September 1998 ($13.00 to $20.65 per share)							353,800	(6,197)		(6,197)
Net loss									(12,316)	(12,316)
BALANCE AT DECEMBER 31, 1998		$	11,621,140							