

ZONAGEN INC  
Form 10-K  
March 13, 2006

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**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**Form 10-K**

**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES  
EXCHANGE ACT OF 1934**

**For the fiscal year ended December 31, 2005**

**or**

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES  
EXCHANGE ACT OF 1934**

**For the transition period from to  
Commission File No. 0-21198**

**Zonagen, Inc.**

*(Exact name of registrant as specified in its charter)*

**Delaware**

*(State or other jurisdiction of  
incorporation or organization)*

**76-0233274**

*(IRS Employer  
Identification No.)*

**2408 Timberloch Place, Suite B-1**

**The Woodlands, Texas**

*(Address of principal executive offices)*

**77380**

*(Zip Code)*

**(281) 719-3400**

**(Registrant's telephone number, including area code)**

**Securities registered pursuant to Section 12(b) of the Act:**

<b>Title of Each Class</b>	<b>Name of Each Exchange on Which Registered</b>
Common Stock, \$.001 par value	Pacific Exchange, Inc.
Rights to purchase Series One Junior Participating Preferred Stock	Pacific Exchange, Inc.

**Securities registered pursuant to Section 12(g) of the Act:**

<b>Title of Each Class</b>	<b>Name of Each Exchange on Which Registered</b>
Common Stock, \$.001 par value	Nasdaq Capital Market
Rights to purchase Series One Junior Participating Preferred Stock	Nasdaq Capital Market

Indicate by check mark whether the registrant is a well-known seasoned issuer (as defined in Rule 405 of the Securities Act). Yes ☐ No ☒

Indicate by check mark whether the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Securities Act.

Yes ☐ No ☒

## Edgar Filing: ZONAGEN INC - Form 10-K

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐

Accelerated filer ☐

Non-accelerated filer ☒

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

The aggregate market value of the voting stock held by non-affiliates of the registrant was approximately \$38,100,000 as of June 30, 2005, the last business day of the registrant's most recently completed second fiscal quarter, based on the closing sales price of the registrant's common stock on the Nasdaq Capital Market on such date of \$3.83 per share. For purposes of the preceding sentence only, all directors, executive officers and beneficial owners of ten percent or more of the shares of the registrant's common stock are assumed to be affiliates.

As of March 6, 2006, there were 10,145,962 shares of the registrant's common stock outstanding.

**Documents incorporated by reference:** Portions of the registrant's definitive proxy statement relating to the registrant's 2006 Annual Meeting of Shareholders, which proxy statement will be filed under the Exchange Act within 120 days of the end of the registrant's fiscal year ended December 31, 2005, are incorporated by reference into Part III of this Form 10-K.

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**ZONAGEN, INC.**  
**2005 FORM 10-K ANNUAL REPORT**  
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This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. The words may, anticipate, believe, expect, estimate, project, suggest, intend and similar expressions are intended forward-looking statements. Such statements reflect the Company's current views with respect to future events and financial performance and are subject to certain risks, uncertainties and assumptions, including those discussed in Item 1. Description of Business Business Risks. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, expected, estimated, projected, suggested or intended.

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**PART I**

**ITEM 1. BUSINESS**

**Overview**

Zonagen, Inc. ( the Company , Zonagen, or we, us or our ) was organized on August 28, 1987 and is a development stage company. We are a biopharmaceutical company focused on the development of new drugs to treat hormonal and reproductive system disorders. The Board of Directors recently approved changing the company's name to Repros Therapeutics Inc. in order to more appropriately reflect the Company's focus on the reproductive and hormonal health technology market. We anticipate that the name change will be effective immediately after our 2006 annual meeting, subject to stockholder approval.

Our lead product candidate, Proellex™, is an orally available small molecule compound that we are developing for the treatment of uterine fibroids and endometriosis. We are developing Proellex under an exclusive, worldwide license from the National Institutes of Health, or NIH. Proellex 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 Proellex, 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 Proellex may have advantages over treatment with GnRH agonists based on research that has been done to date, which includes a 9-month primate study and data collected from our three-month European human Phase 1b clinical study. Proellex does not appear to induce a low estrogen state and therefore should not promote bone loss, which could make Proellex a better treatment option for patients prior to surgery. In addition, we believe Proellex 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.

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 common condition in the aging male. 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. We believe that Androxal will not cause these adverse effects to the extent that such other replacement therapies do.

We also continue to maintain our patent portfolio on our phentolamine-based products for the treatment of sexual dysfunction. These products were placed on clinical hold in the United States in 1999 after a New Drug Application ( NDA ) was filed with the U.S. Food and Drug Administration ( FDA ) due to brown fat being discovered in a two-year rat carcinogenicity study. The FDA upgraded their clinical hold to a partial clinical hold in 2000. The United States is the only country where phentolamine-based products to treat sexual dysfunction are on partial clinical hold. We continue to try to create value from these assets in various ways which includes product out-licensing and attempting to obtain an end to the clinical hold in the United States.

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Below is a summary of our product candidates and the related stages of development for each:

<b>Product Candidate</b>	<b>Indication</b>	<b>Current Phase of Development</b>	<b>Collaborator</b>	<b>Estimate of Completion of Current Phase(1)</b>
Proellex	- Uterine fibroids - Endometriosis - Breast cancer	- U.S. Phase II - European Phase II - Investigative	None None None	Initial U.S. Phase II uterine fibroid data is not expected before late third quarter 2006; initial 3-month European Phase II endometriosis data anticipated fourth quarter 2006; no development is being done in the area of breast cancer at this time
Androxal	- Testosterone deficiency	U.S. Phase III safety	None	Initial Phase III study data expected end of third quarter of 2006
VASOMAX® Phentolamine-based product	- Male erectile dysfunction (MED)	Previously approved in 8 countries and previously marketed in Mexico and Brazil; partial clinical hold in the U.S.	None	Outlicensing activities ongoing
Other phentolamine-based products	- MED (Bimexes , ERxin ) - Female sexual dysfunction	Non-U.S. Phase II studies completed for all three products; partial clinical hold in the U.S.	None	Outlicensing activities ongoing and currently re-evaluating clinical development requirements

- (1) 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.

**Business Strategy**

Our primary business strategy is to concentrate our resources on the clinical development of Proellex and Androxal. We intend to outsource the clinical development programs for both drugs and we will continue to operate in a near virtual manner. We have no current plans to build manufacturing or sales and marketing capabilities, or to add additional technologies through in-licensing at this time. We will seek to create value by developing our technologies to a point that one or more significant corporate transactions can be completed. We will seek to access the capital markets at appropriate times based on our clinical trial results and development needs.

**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 in the United States.

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

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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.

As a result, 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 other potential disorders associated with low testosterone. 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. 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 U.S. sales of approximately \$310 million in 2005, 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 believe that today the U.S. market is approximately \$460 million and the global market is in excess of \$600 million and could grow to nearly a billion



dollars worldwide within the next several years as the median age increases 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.

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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.

### *Sexual Dysfunction*

Sexual dysfunction is a widespread health problem for both sexes. Studies have reported that more than 50 percent of men over 40 years of age suffer from male erectile dysfunction, or MED. Approximately 45 percent of all sexually active women suffer from female sexual dysfunction, or FSD, according to one study.

#### Male Erectile Dysfunction

Erectile dysfunction has historically been defined as the persistent inability to attain and maintain an erection adequate to permit satisfactory sexual performance. Oral vaso-active drugs can improve sexual function by improving the blood flow to the genitalia via several different biologic pathways. Currently there are existing approved, commercially available drugs, as well as new products in development that can take advantage of a variety of pathways. Drugs that inhibit the enzyme phosphodiesterase, such as Viagra®, act on the nitric oxide pathway and generally require about one hour or more to take effect. In both cases, sexual stimulation is necessary for a normal response.

#### Female Sexual Dysfunction

Female sexual disorders include five major categories: lack of desire, arousal disorder (problems with lubrication and sensation), failure to achieve orgasm, pelvic pain disorder and vaginismus (involuntary contraction of vaginal muscles). The causes of female sexual dysfunction are multi-faceted and complicated; both physiological as well as psychological problems such as depression, stress and fatigue are among the causes. Circulatory problems due to menopause, diabetes and hysterectomies are also believed to contribute to the problem.

### **Our Product Candidates**

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

#### ***Proellex***

##### *Uterine Fibroids and Endometriosis*

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 Proellex 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 Proellex on a long-term, or chronic, basis without the bone loss problems associated with GnRH agonists. Although we believe Proellex may be 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. Proellex is a once-a-day oral therapy.

Our investigational new drug, or IND, application for the U.S. study of Proellex became effective in December 2005. The first U.S. study of Proellex in uterine fibroids will enroll 150 patients at up to 20 clinical sites in the United States, beginning in the first quarter of 2006. The study is designed to assess both improvement of symptoms associated with uterine fibroids as well as effects on the fibroid itself. The study will test two doses of Proellex versus placebo in a double-blind design. The study is 12 weeks in duration and initial data is not expected before late third quarter 2006. Pharm-Olam International Ltd. (Pharm-Olam) was awarded the contract for this study. Sixteen clinical sites have been selected to date. We held the pre-IND meeting with the FDA regarding this study in May 2005. Doses to be used in this trial were previously tested in a 30 patient, 12-week 2005 European Phase 1b study of Proellex in women with uterine fibroids. In the 2005 study, Proellex exhibited positive effects on fibroid size reduction, as well as reductions in bleeding and pain associated with the condition. The drug was well tolerated over the course of the 2005 study. Longer term open label studies, where both patients and physicians know what drug is used are conducted to fulfill the safety requirements for chronically administered drugs. We hope the 2006 clinical study will serve as the first of two required pivotal trials of efficacy and we plan on enrolling the participants of these studies into a subsequent long-term open label study.

In September 2005, we released results of the effects observed on endometrial and breast tissue after nine months of dosing of Proellex in cynomolgus monkeys. In this study, the effects of Proellex were compared to Lupron<sup>®</sup>, an approved GnRH agonist, and mifepristone, an extensively studied antiprogestational agent. In this study, Proellex and mifepristone suppressed progesterone's effects on tissues without any suppression of estrogen's effects on bone. Lupron, on the other hand, suppressed the hormonal activities

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of both progesterone and estrogen. This inhibitory effect on estrogen is similar to that seen in human trials and leads to Lupron's adverse effects on bone.

Our preclinical studies with Proellex have shown that its pharmacology is uniquely different from Lupron and mifepristone in that only Proellex has antiproliferative and apoptotic effects. The combination of these anti-proliferative and apoptotic effects seen in the primate uterus suggests that Proellex may have the potential to suppress endometrial hyperplasia, and therefore, we believe the concern associated with other antiprogesterone therapies that result in estrogen being unopposed by progesterone is lessened with the use of Proellex. The doses used in the study were equivalent to doses used in our previous human studies as well as those planned for the 2006 European endometriosis Phase II clinical study.

We have received all required regulatory approvals to dose in our Phase II clinical study of Proellex in women suffering from endometriosis. Initial three-month data from this six-month trial is anticipated to be available fourth quarter of 2006.

Proellex is a new chemical entity which means that the compound will be required to go through the full clinical approval process. Amongst other requirements, lengthy animal studies will be required before long-term human studies may be initiated. In addition, a two-year carcinogenicity study will be required before an NDA can be submitted. We have completed a six-month rat study and a nine-month dog study testing the safety of Proellex in response to our May 2005 meeting with the U.S. Food and Drug Administration, or FDA. The two-year carcinogenicity study is scheduled to begin in the first half of 2006. We anticipate filing an NDA in 2008.

### *Breast Cancer*

We believe Proellex may possess the potential capability to treat breast cancers that are resistant to Tamoxifen® therapy, a commonly used anti-estrogen breast cancer therapy. Our initial rodent studies showed a strong dose dependent effect on the reduction and elimination of tumors in a well accepted breast cancer model. These studies were funded with an SBIR grant that was completed in 2004. Moreover, enhanced apoptosis in the breast with Proellex may indicate suppression of nascent hyperplasia or neoplasia, extending the possible benefit of the drug into the treatment of breast cancer. Currently, no resources are being applied by us to conduct breast cancer trials due to capital constraints.

### *Hormone Replacement Therapy*

We believe Proellex 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, Proellex 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 Proellex combinations. No resources have been applied by us to investigate this theory, to date, nor are any expected in the near future, due to capital constraints.

### *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 brought about by Androxal avoids the 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 U.S. Phase I/II clinical trial results indicate that Androxal does not cause abnormal peaks in blood testosterone levels which has been observed with some current testosterone replacement therapies;

our recently completed 13 patient two-week open-label study, that was designed to evaluate the effects of Androxal on men with normal, borderline or low testosterone showed that all study subjects, including those that had normal testosterone levels at the start of the study, exhibited testosterone levels within the normal range and after the dosing period had concluded, all of the study subjects had returned to their baseline testosterone levels; and

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the data so far indicate that Androxal therapy is not associated with the elevated levels of dihydroxytestosterone, or DHT, unlike those 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.

In January 2006, we received Investigational Review Board, or IRB, approval for the start of our Phase III study of Androxal. The 200 patient trial will be conducted in the United States under an existing IND and will enroll patients at up to 20 clinical sites. This 200 patient study is designed to assess both the safety of Androxal and its efficacy in restoring normal pituitary and testicular function in men that are hypogonadal due to secondary hypogonadism. Secondary hypogonadism is a failure of appropriate signaling from the pituitary to the testes. The condition is most common in aging males but can result from a variety of causes, including the use of androgens.

The double-blind study will test two doses of Androxal versus placebo and will include an open-label arm of the commercially available drug Androgel®. The dosing is of 24-week duration with an efficacy assessment made at 12 weeks. Initial data after 12 weeks of dosing is anticipated in the third quarter of 2006. The extension of the trial dosing to 24 weeks is to satisfy an FDA request regarding the safety of restoring normal testicular function as compared to placebo or the currently approved testosterone replacement therapies. We believe that at least two additional Phase III pivotal studies beyond the currently planned study will be required before an NDA can be submitted.

Doses to be used in the U.S. Phase III trial were previously tested in a 52 patient, 2-week study of Androxal in men in the U.S. with low testosterone. We released the results of this study in July 2004. In the prior study, Androxal demonstrated statistically significant positive effects on restoring normal pituitary signaling to the testes resulting in the achievement of normal testosterone levels within 2 weeks. In contrast, that study also found that Androgel, while replacing testosterone levels, further suppressed normal pituitary secretions. Additionally, men on Androgel experienced more deviations above the normal range of testosterone than men on Androxal. Androxal was also well tolerated over the course of the study. Similar to our Proellex clinical trial, this study was of a small sample size. The primary purpose of the study was to show that the drug was safe, over the period and number of patients exposed, and to determine whether the drug warranted further development. We caution that the results may be reversed by the results of our Phase III study. Pharm-Olam was awarded the contract for the study.

Initial review of our special protocol assessment, or SPA, filing for a Phase III efficacy/pivotal study was completed by the FDA, and we are in the process of responding to their comments. The FDA suggested that certain endpoints in our SPA filing, such as effects of Androxal therapy on libido, were insufficient on their own in the form of a simple questionnaire response. Rather the FDA has requested that we incorporate a validated assessment tool as a clinical endpoint before being used in a Phase III efficacy/pivotal study. A decision on commencement of the SPA protocol is dependent on successful completion of our current Phase III study.

Androxal is deemed a new chemical entity by the FDA which means that the compound will be required to go through the full clinical approval process. Amongst other requirements, lengthy animal studies will be required before long-term human studies may be initiated. In addition, a two-year carcinogenicity study will be required before an NDA can be submitted. We are currently completing a six-month rat study and a nine-month dog study testing the safety of Androxal. The two-year carcinogenicity study was initiated in September 2005. We anticipate filing an NDA in 2008.

On February 3, 2006, we announced positive top-line results of an open-label study that was designed to evaluate the effect of Androxal on the testosterone levels of 13 men with normal, borderline or low testosterone. The open-label study enrolled eight patients with normal testosterone levels (greater than 350 and less than 1,100 ng/dL), four with borderline testosterone levels (250-350 ng/dL) and one with low testosterone (less than 250 ng/dL). Study subjects received 25 mg of Androxal orally for two weeks and were monitored at the end of the dosing period and four weeks after dosing had stopped. After two weeks on Androxal, all study subjects, including those that had normal testosterone levels at the start of the study, exhibited average testosterone levels within the normal range. The average change from baseline was 297.5 ng/dL of testosterone. Four weeks after the dosing period had concluded, all of the

study subjects had returned to their baseline testosterone levels.

We have met with a major European regulatory agency to review our program for the clinical development of Androxal. Preliminary assessment of the outcome from that discussion suggests that our current 200 patient U.S. Phase III trial of Androxal would serve as the first pivotal trial for approval of the drug in that country. We plan to meet with other major countries within the European Union to determine whether a parallel program to our U.S. effort should be commenced.

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### ***Phentolamine-Based Products***

Our phentolamine-based products for the treatment of sexual dysfunction include VASOMAX<sup>®</sup>, an oral therapy for MED; an oral therapy for FSD; Bimexes<sup>®</sup>, an oral combination drug therapy for MED; and ERxin<sup>®</sup>, an injectable combination drug therapy for MED. All of our phentolamine-based products have been tested in humans, though each is at a different stage of development.

VASOMAX was previously approved for sale in eight non-U.S. countries (primarily in Latin American), but before VASOMAX would be permitted to be sold in these countries again, the product would have to be re-registered. There is no assurance that a re-registration would be allowed in all or any countries where VASOMAX was previously approved. Even though our products that were 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. Before the FDA will consider the approval to market of any of our phentolamine-based products, the partial clinical hold must first be lifted. While the results of a November 2000 mechanistic study designed to address the FDA's concerns over phentolamine causing the formation of brown fat proliferations were positive, 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. There can be no assurance that even if we were to complete an additional study that the FDA would lift its partial clinical hold on phentolamine. The U.S. is the only country where phentolamine-based products are on clinical hold.

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 mutually 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 and milestone obligations in the event we have any sales of VASOMAX or our other phentolamine-based products.

We recently met with the Ministry of Health in Mexico regarding our second generation phentolamine-based products for the treatment of erectile dysfunction: Bimexes<sup>®</sup>, an oral therapy for men with mild to moderate impotence, and ERxin<sup>®</sup>, an injectable therapy for the treatment of severe erectile dysfunction. Initial assessment of the outcome from that meeting suggests that both drugs could be approved in Mexico after completion of a successful single positive controlled registration trial to the satisfaction of the Mexican Ministry of Health. Previously, we conducted Phase II studies in Mexico comparing Bimexes against 100 mg Viagra<sup>®</sup> and ERxin against a full one ml injection of the highest approved dose of Caverject<sup>®</sup>, the current leading injectable therapy for the treatment of MED, marketed by Pfizer. In the completed studies Bimexes performed at least as well in efficacy measurements as Viagra with fewer moderate grade side effects than Viagra. We believe that Bimexes would not be contraindicated for men on nitrates unlike the currently approved phosphodiesterase drugs which include Viagra. ERxin was able to effectively treat 41% of men that failed full high dose Caverject treatment. Caverject is the most aggressive approved therapy on the market today.

Our Board of Directors is evaluating its options before proceeding with Mexican approval trials for Bimexes or ERxin. Mexico is viewed as the gold standard for regulatory efforts in Latin America. Approval in Mexico can lead to approvals in other Latin American countries. For example, VASOMAX, our former lead erectile dysfunction drug was approved in seven additional countries in Latin America after approval in Mexico. The Latin American market for erectile dysfunction therapies now exceeds \$230 million.

### **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 research and development, or R&D, expenses for 2005 were for the payment of consultants and contract research organizations in connection with our clinical trials for Proellex for the treatment of uterine fibroids and for Androxal for testosterone deficiency. In addition, we anticipate incurring expenses relating to the clinical development of Proellex for endometriosis and in obtaining regulatory approval, and release of clinical hold, for VASOMAX and its related products. We believe that these expenses will continue to be our primary R&D expenses in the near future.

### **Agreement with National Institutes of Health**



In 1999, we licensed rights to Proellex 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 Proellex for the treatment of uterine fibroids. We provide annual updates to the NIH on the progress of our development of Proellex. Based on our interaction with the NIH to date, we believe our license and relationship with NIH 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. 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 agree to amend this agreement to our satisfaction.

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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 Proellex and severely harm our business prospects. 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 Proellex 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.

### **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. Our process to manufacture Proellex and, to a certain extent, Androxal, is highly complex, costly, and involves numerous steps with multiple parties. We believe we have refined the process to eradicate unnecessary and potentially adverse complications, and expect to have acceptable suppliers engaged in the near future on satisfactory terms for all steps in the process. Other than some initial amounts from the NIH, we have used the same outside supplier, Bridge Organics, for all of the Proellex 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 that any potential manufacturer will be able to reproduce the results obtained by Bridge Organics in manufacturing Proellex to date. We have obtained all of our supply of Androxal to date from BioVectra.

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 an 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. We anticipate that we will outlicense such activities, as well as possibly later stage pivotal trials of our product candidates, to larger pharmaceutical companies more capable of distributing the products to the market place, and we are presently engaged in exploring possible partnerships with several companies. 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. We have previously written off capitalized patents relating to the zona pellucida immuno-contraceptive vaccine and our phentolamine-based products, which include VASOMAX, our hCG immuno-contraceptive vaccine, our two vaccine adjuvants and our two prostate cancer vaccines. However, we continue to maintain 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 recently has issued, and a foreign filing made by the NIH regarding Proellex. We also have the following patent applications pending relating to Androxal and methods of use: eight pending patent applications in the United States, and 19

foreign pending patent applications. All of these applications relate to methods and materials for the treatment of testosterone deficiency in men.

Androxal is purified from clomiphene citrate. 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. In our prior filings with the Securities and Exchange Commission, or SEC, we have described our request to the U.S. Patent and Trademark Office, or PTO, for re-examination of this third party's patent based on several printed publications previously available in the public domain. The third party amended the claims in the reexamination proceedings, which has led the PTO to determine that the amended claims are patentable in view of the publications under consideration. We believe that the amended claims are invalid based on, among other things, additional

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prior publications not yet considered by the PTO. We intend to seek further reexamination of the third party's patent in light of a number of these publications. There is no assurance that the patent ultimately will be reversed. If such patent is not cancelled, 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 may not be able to develop or commercialize Androxal.

All of our employees and consultants have signed assignment of invention and confidentiality agreements, and each corporate partner we enter into discussions with or engage to assist in our clinical trials or manufacturing process is also required to execute appropriate confidentiality and assignment agreements protecting our intellectual property.

### **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 may 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 2003 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 Proellex 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 Proellex 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, with 2005 sales of \$310 million. Androgel 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.

The erectile dysfunction market is well established and intensely competitive. Our main competitors are already existing products such as Viagra, which is marketed by Pfizer; Levitra®, which is being marketed by Bayer AG outside the United States and GlaxoSmithKline and Schering-Plough Corporation in the United States; and Cialis, which is being marketed by Icos Lilly. In addition, there are several other biopharmaceutical companies that are also developing products that would directly compete with our phentolamine-based products.

### **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.

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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 IND 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

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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 PTO, in consultation with the FDA, reviews and approves or rejects the application for patent term extension.

### **Litigation**

We are not currently a party to any material legal proceedings.

### **Exchange Listings**

In July 2004, our common stock was transferred from the Nasdaq National Market to the Nasdaq Capital Market, and in August 2004, our common stock was moved for trading from Tier I to Tier II of the Pacific Exchange.

### **Employees and Consultants**

#### *Employees*

At March 11, 2006, we had 6 full-time employees and anticipate hiring several new employees during 2006 to assist in the clinical development of our products and the associated administrative requirements. We also 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. We intend to increase the number of employees we have, particularly in the area of research and development, upon successful completion of further financings. 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, provide advice about 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 advisors 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 advisors are otherwise affiliated with us.

In addition to the advisors described above, we have engaged two U.S. contract research organizations to conduct our clinical trials. Pharm-Olam International Ltd. conducts our clinical trials in the United States and Europe for Proellex for the treatment of uterine fibroids and for Androxal for the treatment of testosterone deficiency, and Synergos to assist in the assessment and preparation of the data for resubmission to the FDA. 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. Both Pharm-Olam and Synergos have agreed that we own all of the data associated with the clinical trials.

### **ITEM 1A. RISK FACTORS**

*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 that are in clinical trials, and our phentolamine-based products, VASOMAX, Bimexes and ERxin, on partial clinical hold in the United States and under review in certain non-United States countries. Androxal is in a Phase III, 200-patient safety study in the United States for the treatment of men with testosterone deficiency, and Proellex is presently in a Phase II, 150-patient study in the United States for the treatment of uterine fibroids and in a Phase Ib/II study in Europe for the treatment of endometriosis. We have expended significant time, money and effort in the development of Proellex, Androxal

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and our phentolamine products, and we will have to spend considerable additional time, money and effort before seeking regulatory approval to market these product candidates.

Our business depends primarily on our ability to successfully complete clinical trials, obtain required regulatory approvals and successfully commercialize our product candidates. If we fail to commercialize one or more of our product candidates, 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 our product candidates are not necessarily predictive of future results, we can provide no assurances that any of them 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 Proellex 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 Proellex 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 and Proellex. If Proellex, 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 Proellex 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 with respect to pivotal clinical trials for Proellex and Androxal. Our existing financial resources are expected to be sufficient to fund our operations through December 31, 2006, depending on the timing and success of our clinical trials. Therefore we will need to seek additional funding through public or private financings, including equity or debt financings, and/or 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.

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*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 December 31, 2005, we had an accumulated deficit of approximately \$94.1 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 Proellex 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 Proellex, Androxal and our phentolamine product family, 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 propriety 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 stock 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 Proellex, Androxal or other potential products or license intellectual property that enables licensees to develop competing products.

*We licensed our rights to Proellex 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 Proellex 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 Proellex. 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 as development plans have evolved. 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 such revised objectives. 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 Proellex, which would have a material adverse effect on us.

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

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. In our prior filings with the SEC, we have described our request to the U.S. Patent and Trademark Office, or PTO, for re-examination of this third party's patent based on several printed publications previously available in the public domain. The third party amended the claims in the reexamination proceedings, which has led the PTO to determine that the amended claims are patentable in view of the publications under consideration. We believe that the amended claims are invalid based on, among other things, additional prior publications not yet considered by the PTO. We intend to seek further reexamination of the third

party's patent in light of a number of these publications. There is no assurance that the patent ultimately will be reversed. If such patent is not cancelled, 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 may not be able to develop or commercialize Androxal.

*We cannot assure that our manufacture, use or sale of our product candidates will not infringe on the patent rights of others.*

There can be no assurance that the manufacture, use or sale of any of our product candidates will not infringe the patent rights of others. 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

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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 our product candidates to market, or may be precluded from participating in the manufacture, use or sale of any such product candidates, any of which would materially and adversely affect 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 for our product Androxal 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 application for Androxal, or our licensors, such as the patent(s) and application(s) underlying our Proellex 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.

*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 commenced our Phase III clinical trial for Androxal in the United States for

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the treatment of men with testosterone deficiency and our Phase II clinical trial for Proellex in the United States for the treatment of symptoms associated with uterine fibroids. We also recently commenced a Phase II clinical trial in Europe for the treatment of women suffering from endometriosis. We have limited experience conducting clinical trials for these product candidates. 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:

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

- 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 manufacturers for 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;

- the FDA may not accept data obtained from clinical studies conducted in Europe or other non-United States jurisdictions as meeting all applicable FDA clinical trial standards;

- 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;

- 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, which has resulted in our delaying development of that product candidate. We have not yet been able to have the partial clinical hold removed. In addition, while VASOMAX was previously approved in eight countries in Latin America, such approval



is not current. We cannot assure that we will be able to (i) have the partial clinical hold removed by the FDA in the United States, (ii) develop VASOMAX or our other phentolamine-based products to a point where they are attractive acquisition candidates by third parties or (iii) re-establish approval status in any of the Latin American countries in which we were previously approved.

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.

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*Even if we successfully complete clinical trials for Proellex 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 Proellex 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 an NDA with respect to Proellex 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 Proellex 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.

*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 Proellex 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 our product candidates 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 our drugs;

effectiveness of our or our collaborators' sales and marketing strategies; and

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

If Proellex 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. And if VASOMAX, Bimexes or ERxin do not provide a treatment regime more beneficial than Viagra, Cialis or other drugs already on the market for male erectile dysfunction, they will likely 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

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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 Proellex 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 Proellex 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 Proellex. There are several potential manufacturers capable of manufacturing Proellex. However, 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 that any potential manufacturer will be able to reproduce the results obtained by Bridge Organics in manufacturing Proellex 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 Proellex, 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 non-phentolamine-based 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 such 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.*

Proellex and Androxal are novel compounds that have 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 Proellex or Androxal. 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.

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*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 Proellex 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, including 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. conducted our previous clinical trial in Poland for Proellex for the treatment of uterine fibroids and has been engaged to conduct our clinical trials in the United States for Proellex for uterine fibroids and 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. Independent contractors generally may terminate their engagements at any time, subject to notice. 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.*

Proellex, Androxal and the phentolamine-based product family have not 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 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:

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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 Proellex for the treatment of uterine fibroids and endometriosis are GnRH agonists, including 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 Proellex 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 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.

The erectile dysfunction market is well established and intensely competitive. Our main competitors are already existing products such as Viagra®, which is marketed by Pfizer; Levitra®, which is being marketed by Bayer AG outside the United States and GlaxoSmithKline and Schering-Plough Corporation in the United States; and Cialis, which is being marketed by Icos Lilly. In addition, there are several other biopharmaceutical companies that are also developing products that would directly compete with our phentolamine-based products.

*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 6 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 up to seven 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.

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*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.

*We face high volatility in our stock price.*

We are a development stage company and the market prices for securities of development companies in the biotechnology sector have been highly volatile and may continue to be very volatile in the future.

The following listed factors as well as other factors may have a significant impact on the price of our common stock:

announcements of technology innovations and new products developed by other competitors;

developments relating to proprietary rights and patents;

publicity relating to actual or potential medical results relating to products under development or being commercialized by our other competitors;

regulatory developments concerning our products in the United States and foreign countries;

issues concerning the safety of our products in development or similar products being developed by our competitors; and

economic and other external factors or a disaster or crisis.

**ITEM 2. PROPERTIES**

The Company executed a 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 Company has amended this lease to increase the amount of space to approximately 7,100 square feet. The lease term is not being affected as a result of this amendment.

**ITEM 3. LEGAL PROCEEDINGS**

We are not currently a party to any material legal proceedings.

**ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

No matters were submitted to a vote of the Company's security holders in the fourth quarter of 2005.

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**Table of Contents****PART II****ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES**

The Company's common stock is quoted on The Nasdaq Capital Market and the Pacific Exchange under the symbol ZONA. The following table shows the high and low sale prices per share of common stock, as reported by The Nasdaq National Market through July 7, 2004 and thereafter by the Nasdaq Capital Market, during the periods presented.

	<b>Price Range</b>	
	<b>High</b>	<b>Low</b>
<b>2004</b>		
First Quarter	\$ 4.35	\$ 1.83
Second Quarter	5.40	2.44
Third Quarter	5.95	2.76
Fourth Quarter	4.50	3.07
<b>2005</b>		
First Quarter	\$ 4.75	\$ 2.90
Second Quarter	3.93	2.79
Third Quarter	5.88	3.66
Fourth Quarter	5.96	4.43
<b>2006</b>		
First Quarter (January 3 through March 6)	\$ 10.21	\$ 4.50

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

On March 6, 2006, the last sale price of the common stock, as reported by the Nasdaq Capital Market, was \$10.05 per share. On March 6, 2006, there were approximately 199 holders of record and approximately 2,963 beneficial holders of the Company's common stock.

**Dividends**

The Company has never paid dividends on the common stock. The Company currently intends to retain earnings, if any, to support the development of the Company's business and does not anticipate paying dividends in the foreseeable future. Payment of future dividends, if any, will be at the discretion of the Company's Board of Directors after taking into account various factors, including the Company's financial condition, operating results, current and anticipated cash needs and plans for expansion.

On September 1, 1999, the Board of Directors of the Company adopted a stockholder rights plan, which has been subsequently amended on September 6, 2002, October 30, 2002, and June 30, 2005 (as amended, the Rights Plan), pursuant to which a dividend consisting of one preferred stock purchase right (a Right) was distributed for each share of common stock held as of the close of business on September 13, 1999, and to each share of common stock issued thereafter until the earlier of (i) the Distribution Date (as defined in the Rights Plan), (ii) the Redemption Date (as defined in the Rights Plan) or (iii) September 13, 2010. The Rights Plan is designed to deter coercive takeover tactics and to prevent an acquirer from gaining control of the Company without offering fair value to the Company's stockholders. The Rights will expire on September 13, 2010, subject to earlier redemption or exchange as provided in the Rights Plan. Each Right entitles the holder thereof to purchase from the Company one one-hundredth of a share of a new series of Series One Junior Participating Preferred Stock of the Company at a price of \$20.00 per one one-hundredth of a share, subject to adjustment. The Rights are generally exercisable only if a Person (as defined) acquires beneficial ownership of 20 percent or more of the Company's outstanding common stock.

A complete description of the Rights, the Rights Agreement between the Company and Computershare Investor Services, LLC, (as successor in interest to Harris Trust and Savings Bank), as Rights Agent, and the Series One Junior

Participating Preferred Stock is hereby incorporated by reference from the information appearing under the caption

Item 1. Description of the Registrant's Securities to be Registered contained in the Registration Statement on Form 8-A filed on September 3, 1999, and as amended by amendments to such Registration Statement on Form 8-A/A filed on September 11, 2002, October 31, 2002, and June 30, 2005.

**ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA**

The statement of operations data for the years ended December 31, 2005, 2004 and 2003, and the balance sheet data as of December 31, 2005 and 2004, have been derived from our financial statements, included elsewhere in this Annual Report on Form 10-K. The statements of operations data for the years ended December 31, 2002 and 2001, and the balance sheet data as of December 31,

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2003, 2002 and 2001 have been derived from our financial statements not included in this annual report on Form 10-K. 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 accounting principles generally accepted in the United States and should be read with our financial statements, including notes, and with Management's Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this annual report on Form 10-K.

**STATEMENTS OF OPERATIONS DATA:**

	Year Ended December 31,				
	2001	2002	2003	2004	2005
	(In thousands except per share amounts)				
Revenues and Other Income:					
Licensing fees	\$ 2,162	\$ 4,228	\$	\$	\$
Product royalties	58				
Research and development grants	115	315	595	118	4
Interest income	1,526	711	318	104	630
Gain on disposal of fixed assets			102		
Other income				35	
Total revenues	3,861	5,254	1,015	257	634
Expenses:					
Research and development	3,028	6,420	2,161	2,471	6,101
General and administrative	1,672	2,716	2,183	1,483	1,924
Total expenses	4,700	9,136	4,344	3,954	8,025
Net loss	\$ (839)	\$ (3,882)	\$ (3,329)	\$ (3,697)	\$ (7,391)
Net loss per share – basic and diluted (1)	\$ (0.07)	\$ (0.34)	\$ (0.29)	\$ (0.72)	\$ (0.77)
Shares used in loss per share calculation	11,333	11,412	11,487	5,117	9,647

**BALANCE SHEET DATA:**

Cash, cash equivalents and marketable securities	\$ 30,056	\$ 25,138	\$ 22,946	\$ 5,536	\$ 16,832
Total assets	36,914	27,370	24,028	6,606	17,682
Deficit accumulated during the development stage	(75,846)	(79,728)	(83,057)	(86,754)	(94,145)
Total stockholders' equity	30,569	26,851	23,487	5,992	16,955

(1) See Note 2, Summary of Significant Accounting Policies of Notes to Consolidated Financial Statements for a description of the computation of loss per share.

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**ITEM 7. 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 Form 10-K. 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 Form 10-K.*

**Overview**

Zonagen, Inc. (the Company, Zonagen, or we, us or our) was organized on August 28, 1987 and is a development stage company. We are a biopharmaceutical company focused on the development of new drugs to treat hormonal and reproductive system disorders. Our lead product candidate, Proellex, is an orally available small molecule compound that we are developing for the treatment of uterine fibroids and endometriosis. We recently commenced a Phase II clinical trial for Proellex in the United States for the treatment of uterine fibroids and a Phase II clinical trial in Europe for Proellex for the treatment of endometriosis in 2005. Our second product candidate is Androxal, an orally available small molecule compound being developed for the treatment of testosterone deficiency in men. We recently commenced a Phase III safety trial in the United States for Androxal for the treatment of men with testosterone deficiency. The FDA deems both Proellex and Androxal to be new clinical entities, so a two-year toxicology study will be required before an NDA may be filed. We also have recently begun investigating necessary measures to remove VASOMAX and our other phentolamine-based products from clinical hold in the United States and obtain marketing approval in non-United States jurisdictions.

We have 6 full-time employees who utilize the services of contract research organizations, contract manufacturers and various consultants to assist us in performing clinical and regulatory services for the clinical development of our products. We are substantially 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 recognize that the total costs we will incur for the clinical development of our product candidates may exceed our current estimates. 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.

We have not generated any substantial revenue from commercial sale of our current product candidates. 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. If we were to obtain regulatory approval of Proellex, we will need to develop a long-term, commercially viable source of bulk Proellex to successfully commercialize the product candidate. We cannot be certain when or if any net cash inflow from any of our current product candidates will commence.

We have experienced negative cash flows from operations since inception and have funded our activities to date primarily from equity financings and corporate collaborations. We believe that our existing capital resources under our current operating plan will be sufficient to fund our operations through at least December 31, 2006. There can be no assurance that changes in our current strategic plans or other events will not result in accelerated or unexpected expenditures.

We will need to raise additional capital through the sale of equity securities and/or through partnerships 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.

Our results of operations may vary significantly from year to year and quarter to quarter, and depend, among other factors, on our ability to be successful in our clinical trials, the regulatory approval process in the United States and other foreign jurisdictions and the ability to complete new licenses and product development agreements. The timing of our revenues may not match the timing of our associated product development expenses. To date, research and development expenses have generally exceeded revenue in any particular period and/or fiscal year.

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On February 1, 2005, we completed both a follow-on public offering of 4,400,000 shares of our common stock at \$4.00 per share and the exercise of the over allotment provision of 660,000 for a total aggregate sale of 5,060,000 shares of our common stock. All of the shares were offered by us which resulted in net proceeds to us of approximately \$18.1 million.

As of December 31, 2005, we had an accumulated deficit of \$94.1 million. Due to various tax regulations, including change in control provisions in the tax code, the value of our tax assets to us can be substantially diminished. For additional information relating to our net operating loss carryforward, see Note 6. Federal Income Taxes of the Notes to Consolidated Financial Statements. Losses have resulted principally from costs incurred in conducting clinical trials for our product candidates, in research and development activities related to efforts to develop our products and from the associated administrative costs required to support those efforts. There can be no assurance that we will be able to successfully complete the transition from a development stage company to the successful introduction of commercially viable products. Our ability to achieve profitability will depend, among other things, on successfully completing the clinical development of our products in a reasonable time frame and at a reasonable cost, obtaining regulatory approvals, establishing marketing, sales and manufacturing capabilities or collaborative arrangements with others that possess such capabilities, our and our partners' ability to realize value from our research and development programs through the commercialization of those products and raising sufficient funds to finance its activities. There can be no assurance that we will be able to achieve profitability or that profitability, if achieved, can be sustained. See Item 1. Business Risk Factors and Note 2. Organization and Operations of Notes to Consolidated Financial Statements.

### **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, Summary of Significant Accounting Policies, for a discussion of our critical accounting policies.

#### *Investments-Trading Securities*

Management determines the appropriate classification of investments in debt and equity securities at the time of purchase and re-evaluates such designation as of each subsequent balance sheet date. Securities for which the Company has the ability and intent to hold to maturity are classified as held to maturity. Securities classified as trading securities are recorded at fair value. Gains and losses on trading securities, realized and unrealized, are included in earnings and are calculated using the specific identification method. Any other securities are classified as available for sale. At December 31, 2005 all securities were classified as trading securities. The cost basis including purchased premium for these securities was \$14.7 million and \$4.8 million at December 31, 2005 and 2004, respectively.

Marketable securities as of December 31, 2005 consist of only short term investments. The Company's investments typically include corporate bonds and notes, Euro-dollar bonds, taxable auction securities and asset-backed securities. The Company's policy is to require minimum credit ratings of A2/A and A1/P1 with maturities of up to three years. The average life of the investment portfolio may not exceed 24 months.

#### *Capitalized Patent Costs*

The Company capitalizes the cost associated with building its patent library. As of December 31, 2005 other assets consist of capitalized patent costs in the amount of \$600,000. Patent costs, which include legal and application costs related to the patent portfolio, are being amortized over 20 years, or the lesser of the legal or the estimated economic life of the patent. Amortization of patent costs was zero, \$7,000 and \$9,000 in 2005, 2004 and 2003, respectively.

Of the \$600,000 in capitalized patents, \$327,000 related to patents for Proellex, which is being developed as an oral treatment for uterine fibroids and endometriosis and \$273,000 related to Androxal, which is being developed as an oral treatment for testosterone deficiency.

#### *R&D Expense*

Research and development, or R&D expenses include salaries and related employee expenses, contracted regulatory affairs activities, insurance coverage for clinical trials and prior product sales, contracted research and consulting fees, facility costs and internal research and development supplies. The Company expenses research and



development costs in the period they are incurred. These costs consist of direct and indirect costs associated with specific projects as well as fees paid to various entities that perform research on behalf of the Company.

Actual results could differ materially from those estimates. The items in our financial statements requiring significant estimates and judgments are as follows:

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The Company has had losses since inception and, therefore, has not been subject to federal income taxes. The Company has accumulated approximately \$2.8 million of research and development tax credits. As of December 31, 2005 and 2004, the Company had approximately \$84.3 million and \$78.5 million, respectively, of net operating loss ( NOL ) carry-forwards for federal income tax purposes. Additionally, approximately \$1.3 million of NOLs, and approximately \$52,000 of research and development tax credits, expired in 2005. Under SFAS No. 109, Accounting for Income Taxes, an NOL requires the recognition of a deferred tax asset. As the Company has incurred losses since inception, and there is no certainty of future revenues, the Company's deferred tax assets have been reserved in full in the accompanying consolidated financial statements.

Marketable securities are reviewed for other-than-temporary impairment at the individual security level in each reporting period. The Company has determined that its marketable securities are not impaired as of December 31, 2005.

The Company reviews for the impairment of capitalized patent costs whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. An impairment loss exists when estimated undiscounted cash flows expected to result from the patent are less than its carrying amount.

The impairment loss recognized represents the excess of the patent cost as compared to its estimated fair value.

The Company has determined that its capitalized patent costs are not impaired as of December 31, 2005.

## **RECENT ACCOUNTING PRONOUNCEMENTS**

In December 2004, the FASB issued SFAS No. 123 (revised 2004), Share-Based Payment. SFAS No. 123(R) will require that the compensation cost relating to share-based payment transactions be recognized in financial statements. That cost will be measured based on the fair value of the equity or liability instruments issued. SFAS No. 123(R) covers a wide range of share-based compensation arrangements including share options, restricted share plans, performance-based awards, share appreciation rights, and employee share purchase plans. SFAS No. 123(R) replaces FASB Statement No. 123, Accounting for Stock-Based Compensation, and supersedes APB Opinion No. 25, Accounting for Stock Issued to Employees. SFAS No. 123, as originally issued in 1995, established as preferable a fair value-based method of accounting for share-based payment transactions with employees. However, that Statement permitted entities the option of continuing to apply the guidance in APB Opinion No. 25, as long as the footnotes to financial statements disclosed what net income would have been had the preferable fair value-based method been used. Public entities will be required to apply SFAS No. 123(R) as of the first annual reporting period that begins after June 15, 2005. The Company believes the impact of the adoption of SFAS No. 123(R) using the modified-prospective method of adoption based on share-based payments currently awarded to employees is expected to be approximately \$600,000 in additional non-cash compensation expense in 2006.

## **Results of Operations**

### *Comparison of Years Ended December 31, 2005 and 2004*

**Revenues.** Total revenue for 2005 increased 147% to \$634,000 as compared to \$257,000 for 2004. Research and development grants for 2005 were \$4,000 as compared to \$118,000 for 2004 relating to the Company's Small Business Innovative Research, or SBIR grants.

Interest income increased 506% to \$630,000 for 2005 as compared to \$104,000 for 2004. The increase is primarily due to an increase in marketable securities as a result of the completion of our follow-on public offering on February 1, 2005 in which we received approximately \$18.1 million in net proceeds, and an increase in interest rates.

Other income for 2005 was zero as compared to \$35,000 for 2004. Other income in 2004 was from the sale of some of the Company's preclinical phentolamine data that was to be used for a purpose that does not compete with the Company's sexual dysfunction technologies.

**Research and Development Expenses.** R&D expenses include contracted research, regulatory affairs activities and general research and development expenses. R&D expenses increased 144% to \$6.1 million in 2005 as compared to \$2.5 million in 2004. The increased expenses for 2005 is primarily due to an increase in the Company's clinical development programs for Proellex in the amount of \$1.9 million and Androxal in the amount of \$1.9 million, partially offset by a decrease of \$308,000 in costs associated with the 2004 write-off of our patent portfolio related to

our vaccine adjuvants, prostate cancer vaccines and hCG immuno-contraceptive vaccine.

*General and Administrative Expenses.* General and administrative ( G&A ) expenses increased 27% to \$1.9 million for 2005 as compared to \$1.5 million for 2004. The increase in expenses is primarily due to an increase in professional services in the amount of \$280,000, which includes a non-recurring \$200,000 reimbursement in 2004 of the deductible from the Company s directors and officers insurance policy relating to the Company s previous class action lawsuit, personnel costs in the amount of \$185,000, costs associated with

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strategic administrative fees in the amount of \$99,000 and investor relations expenses in the amount of \$63,000, offset by a decrease in costs associated with potential funding activities in the amount of \$117,000, and a \$60,000 decrease in non-cash stock option compensation expense.

### *Comparison of Years Ended December 31, 2004 and 2003*

**Revenues.** Total revenues for 2004 were \$257,000 as compared to \$1.0 million for 2003. Research and development grants for 2004 were \$118,000 as compared to \$595,000 for 2003 relating to the Company's Small Business Innovative Research, or SBIR grants.

Interest income decreased 67% to \$104,000 for 2004 as compared with \$318,000 for 2003 primarily due to lower cash balances due to the Company's completion of its self tender offer in January 2004.

The Company sold substantially all of its fixed assets for approximate net proceeds of \$225,000 and recognized a gain of \$102,000 over their book value for the year ended 2003.

Other income totaled \$35,000 for 2004 as compared to zero for 2003. The increase in other income was from the sale of some of the Company's preclinical phentolamine data that is to be used for a purpose that does not compete with the Company's sexual dysfunction technologies.

**Research and Development Expenses.** R&D expenses include contracted research, regulatory affairs activities and general research and development expenses. Following the April 2002 withdrawal of the Company's regulatory application for VASOMAX in the United Kingdom by Schering-Plough, the Company continued scaling back non-SBIR grant R&D spending activities through October 2003 to maintain its cash reserves for future redeployment. R&D expenses increased 14% to \$2.5 million in 2004, as compared with \$2.2 million in 2003. The increase in 2004 is primarily due to an increase of \$1.0 million related to the Company's clinical development program for Proellex, an impairment charge against the Company's patent portfolio related to its vaccine adjuvants, prostate cancer vaccines and hCG immuno-contraceptive vaccine in the amount of \$308,000 which was offset by a corresponding decrease of \$468,000 of costs associated with the Company's SBIR grant funded R&D, a decrease of \$320,000 in costs associated with Androxal clinical development, a decrease of \$122,000 which occurred in 2003 relating to prior employees severance compensation and a decrease of \$92,000 in facilities rent costs due to a decrease in facility size in 2004.

**General and Administrative Expenses.** G&A expenses decreased 32% to \$1.5 million in 2004 as compared with \$2.2 million in 2003. The decrease in expenses is primarily due to a decrease in the Company's directors' and officers' insurance premium of \$473,000 related to the Company's self tender offer which was completed in January 2004, costs associated with potential strategic alternative opportunities of \$388,000 and a reduction in professional services due to a \$200,000 reimbursement of the deductible from the Company's directors' & officers' insurance policy relating to the Company's previous class action lawsuit which was received in the quarter ended December 31, 2004, partially offset by an increase in non cash stock option compensation expenses of \$129,000.

### **Off-Balance Sheet Arrangements**

As of December 31, 2005, the Company did not have any off-balance sheet arrangements.

### **Liquidity and Capital Resources**

Since its inception, the Company has financed its operations primarily with proceeds from private placements and public offerings of equity securities and with funds received under collaborative agreements. On February 1, 2005, the Company completed a public offering of 5,060,000 shares (including the underwriters' over-allotment option) and received net proceeds of approximately \$18.1 million. The Company's 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. The Company had cash, cash equivalents and marketable securities of approximately \$16.8 million as of December 31, 2005 as compared to \$5.5 million as of December 31, 2004. The increase in cash balance as of December 31, 2005 as compared to December 31, 2004 is primarily due to the completion of the Company's public offering in February 2005 described above under Overview. Excluding maturities and purchases of marketable securities, net cash of approximately \$7.4 million, \$3.0 million, and \$3.0 million was used in operating activities during 2005, 2004, and 2003, respectively. The major uses of cash for operating activities during 2005 was to fund our clinical development programs and associated administrative costs of \$7.4 million and to prepay the majority of our insurance policies. Cash used in investing activities was \$191,000 in 2005 primarily for investments in technology rights related to our Proellex and Androxal patent portfolios. Cash provided by financing activities in 2005

was approximately \$18.7 million relating to the follow-on public offering completed in February 2005 and the exercise of 26,700 stock options.

As of December 31, 2005, the Company had future minimum lease payments under non-cancelable leases with ongoing terms in excess of one year of \$39,000, \$40,000, \$40,000, \$40,000 and \$21,000 in 2006, 2007, 2008, 2009 and 2010, respectively.

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As of December 31, 2005, the Company had non-cancelable purchase orders relating to the clinical development of both Proellex and Androxal in the amounts of \$5.8 million and \$4.9 million, respectively.

The Company has had losses since inception and, therefore, has not been subject to federal income taxes. The Company has accumulated approximately \$2.8 million of research and development tax credits. As of December 31, 2005 and 2004, the Company had approximately \$84.3 million and \$78.5 million, respectively, of net operating loss ( NOL ) carry-forwards for federal income tax purposes. Additionally, approximately \$1.3 million of NOLs, and approximately \$52,000 of research and development tax credits expired in the year 2005. Due to various tax regulations, including change in control provisions in the tax code the value of this tax asset to the Company can be substantially diminished. For additional information relating to the Company s Net Operating Loss carryforward see Note 6. Federal Income Taxes of the Notes to Consolidated Financial Statements.

The Company has experienced negative cash flows from operations since inception and has funded its activities to date primarily from equity financings and corporate collaborations. The Company will require substantial funds for research and development, including preclinical studies and clinical trials of our product candidates, and to commence sales and marketing efforts if appropriate, if the FDA or other regulatory approvals are obtained. The Company believes that its existing capital resources under its current operating plan will be sufficient to fund the Company s operations through at least December 31, 2006. There can be no assurance that changes in our current strategic plans or other events will not result in accelerated or unexpected expenditures.

The Company s capital requirements will depend on many factors, including the costs and timing of seeking regulatory approvals of the Company s products; the problems, delays, expenses and complications frequently encountered by development stage companies; the progress of the Company s preclinical and clinical activities; the costs associated with any future collaborative research, manufacturing, marketing or other funding arrangements; the Company s ability to obtain regulatory approvals; the success of the Company s potential future sales and marketing programs; the cost of filing, prosecuting and defending and enforcing any patent claims and other intellectual property rights; changes in economic, regulatory or competitive conditions of the Company s planned business; and additional costs associated with being a publicly-traded company. Estimates about the adequacy of funding for the Company s activities are based on certain assumptions, including the assumption that the development and regulatory approval of the Company s products can be completed at projected costs and that product approvals and introductions will be timely and successful. There can be no assurance that changes in the Company s research and development plans, acquisitions or other events will not result in accelerated or unexpected expenditures. To satisfy its capital requirements, the Company may seek to raise additional funds in the public or private capital markets. The Company may seek additional funding through corporate collaborations and other financing vehicles. There can be no assurance that any such funding will be available to the Company on favorable terms or at all. If the Company is successful in obtaining additional financing, the terms of such financing may have the effect of diluting or adversely affecting the holdings or the rights of the holders of the Company s common stock.

### **ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Interest Rate Risk. Cash, cash equivalents and investments were approximately \$16.8 million at December 31, 2005. These assets were primarily invested in investment grade corporate bonds and commercial paper with maturities of less than 18 months, which are classified as Trading Securities. We do not invest in derivative securities. Although our portfolio is subject to fluctuations in interest rates and market conditions, no significant gain or loss on any security is expected to be recognized in earnings due to the expected short holding period.

### **ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

The financial statements required by this item are set forth in Item 15 of this Report.

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

Not applicable.

### **ITEM 9A. CONTROLS AND PROCEDURES**

The Company s chief executive officer and chief financial officer have evaluated the Company s disclosure controls and procedures as of December 31, 2005, the end of the period covered by this report. Based upon that evaluation, the Company s chief executive officer and chief financial officer concluded that the Company s disclosure controls and

procedures were effective to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Securities Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms.

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There were no changes in the Company's internal control over financial reporting during the fiscal quarter ending December 31, 2005 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

**ITEM 9B. OTHER INFORMATION**

Not applicable.

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**PART III**

**ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT**

The information required by this item as to the directors and executive officers of the Company, the Section 16(a) reporting compliance information and the information relating to the Company's Code of Ethics is hereby incorporated by reference from the information appearing under the captions "Election of Directors", "Section 16(a) Beneficial Ownership Reporting Compliance" and "Board Committees" in the Company's proxy statement (the "Proxy Statement") for its 2006 annual meeting of stockholders. Such Proxy Statement will be filed with the Securities and Exchange Commission pursuant to the Securities Exchange Act of 1934, as amended (the "Exchange Act"), within 120 days of the end of the Company's fiscal year ended December 31, 2005.

**ITEM 11. EXECUTIVE COMPENSATION**

The information required by this item as to the management of the Company is hereby incorporated by reference from the information appearing under the captions "Executive Compensation" and "Election of Directors Director Compensation" in the Company's Proxy Statement. Such Proxy Statement will be filed with the Securities and Exchange Commission pursuant to the Exchange Act within 120 days of the end of the Company's fiscal year ended December 31, 2005. Notwithstanding the foregoing, in accordance with the instructions to Item 402 of Regulation S-K, the information contained in the Company's proxy statement under the sub-heading "Report of the Compensation Committee of the Board of Directors" and "Performance Graph" shall not be deemed to be filed as part of or incorporated by reference into this Annual Report on Form 10-K.

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

The information required by this item as to the ownership by management and others of securities of the Company is hereby incorporated by reference from the information appearing under the caption "Security Ownership of Certain Beneficial Owners and Management" in the Company's Proxy Statement. Such Proxy Statement will be filed with the Securities and Exchange Commission pursuant to the Exchange Act within 120 days of the end of the Company's fiscal year ended December 31, 2005.

**ITEM 13. CERTAIN RELATIONSHIP AND RELATED TRANSACTIONS**

The information required by this item as to certain business relationships and transactions with management and other related parties of the Company is hereby incorporated by reference from the information appearing under the caption "Certain Transactions" in the Company's Proxy Statement. Such Proxy Statement will be filed with the Securities and Exchange Commission pursuant to the Exchange Act within 120 days of the end of the Company's fiscal year ended December 31, 2005.

**ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

The information required by this item as to the principal accountant fees and services and the Audit Committee's pre-approval policies and procedures is hereby incorporated by reference from the information appearing under the captions "Fees Paid to Registered Independent Public Accounting Firm" and "Audit Committee Pre-Approval Policies and Procedures" in the Company's Proxy Statement. Such Proxy Statement will be filed with the Securities and Exchange Commission pursuant to the Exchange Act within 120 days of the end of the Company's fiscal year ended December 31, 2005.

**Table of Contents****PART IV****ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

(a) Documents Filed as a Part of this Report.

**Financial Statements**

	<b>Page</b>
<u>Report of Independent Registered Public Accounting Firm</u>	F-1
<u>Consolidated Balance Sheets as of December 31, 2005 and 2004</u>	F-2
<u>Consolidated Statements of Operations for the Years Ended December 31, 2005, 2004 and 2003 and (unaudited) from Inception (August 20, 1987) through December 31, 2005</u>	F-3
<u>Consolidated Statement of Stockholders' Equity (from inception)</u>	F-4
<u>Consolidated Statements of Cash Flows for the Years Ended December 31, 2005, 2004 and 2003 and (unaudited) from Inception (August 20, 1987) through December 31, 2005</u>	F-9
Notes to Consolidated Financial Statements	F-10

All schedules are omitted because they are not applicable, not required, or because the required information is included in the financial statements or the notes thereto.

(b) Exhibits.

Exhibits to the Form 10-K have been included only with the copies of the Annual Report on Form 10-K filed with the Securities and Exchange Commission. Upon request to the Company and payment of a reasonable fee, copies of the individual exhibits will be furnished.

**Exhibit  
Number****Identification Of Exhibit**

- |        |  |
|--------|--|
| 3.1(a) | Restated Certificate of Incorporation. Exhibit 3.3 to the Company's Registration Statement on Form SB-2 (No. 33-57728-FW), as amended (Registration Statement), is incorporated herein by reference.   |
| 3.1(b) | Certificate of Designation of Series One Junior Participating Preferred Stock dated September 2, 1999. Exhibit A to Exhibit 4.1 to the Company's Registration Statement on Form 8-A as filed with the Commission on September 3, 1999 (the Rights Plan Registration Statement), is incorporated herein by reference.                         |
| 3.2    | Restated Bylaws of the Company. Exhibit 3.4 to the Registration Statement is incorporated herein by reference.   |
| 4.1    | Specimen Certificate of Common Stock, \$.001 par value, of the Company. Exhibit 4.1 to the Registration Statement is incorporated herein by reference.   |
| 4.2    | Rights Agreement dated September 1, 1999 between the Company and Computershare Investor Services LLC (as successor in interest to Harris Trust & Savings Bank), as Rights Agent. Exhibit 4.1 to the Rights Plan Registration Statement is incorporated herein by reference.  |
| 4.3    | First Amendment to Rights Agreement, dated as of September 6, 2002, between the Company, Harris Trust & Savings Bank and Computershare Investor Services LLC. Exhibit 4.3 to Amendment No. 1 to the Rights Plan Registration Statement on Form 8-A/A as filed with the Commission on September 11, 2002 is incorporated herein by reference. |
| 4.4    |  |

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Second Amendment to Rights Agreement, dated as of October 30, 2002, between the Company and Computershare Investor Services LLC. Exhibit 4.4 to Amendment No. 2 to the Rights Plan Registration Statement on Form 8-A/A as filed with the Commission on October 31, 2002 is incorporated herein by reference.

- 4.5 Third Amendment to Rights Agreement, dated as of June 30, 2005, between the Company and Computershare Trust Company, Inc. (as successor in interest to Computershare Investor Services, LLC). Exhibit 4.4 to the Company's Current Report on Form 8-K as filed with the Commission on June 30, 2005 is incorporated herein by reference.
- 4.6 Form of Rights Certificate. Exhibit B to Exhibit 4.1 to the Rights Plan Registration Statement is incorporated herein by reference.

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<b>Exhibit Number</b>	<b>Identification Of Exhibit</b>
10.1+	Amended and Restated 1993 Employee and Consultant Stock Option Plan. Exhibit 10.3 to the Registration Statement is incorporated herein by reference.
10.2+	First Amendment to the Zonagen, Inc. Amended and Restated 1993 Stock Option Plan. Exhibit 10.22 to the Company's Annual Report on Form 10-K for the year ended December 31, 1999 (the 1999 Form 10-K) is incorporated herein by reference.
10.3+	1996 Non-Employee Directors' Stock Option Plan. Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 1997 is incorporated herein by reference.
10.4+	2000 Non-Employee Directors' Stock Option Plan. Appendix B to the Company's Definitive Proxy Statement filed on April 26, 2000 is incorporated herein by reference.
10.5+	First Amendment to the Zonagen, Inc. 2000 Non-Employee Directors' Stock Option Plan. Exhibit 10.21 to the 2000 Form 10-K is incorporated herein by reference.
10.6+	Second Amendment to 2000 Non-Employee Directors' Stock Option Plan. Exhibit 10.6 to the Company's Annual Report on Form 10-K for the year ended December 31, 2002 (the 2002 Form 10-K) is incorporated herein by reference.
10.7+	Zonagen, Inc. 2004 Stock Option Plan. Exhibit 10.17 to the Company's Registration Statement on Form S-1 (No. 333-119861), as amended, is incorporated herein by reference.
10.8+	Employment Agreement between the Company and Joseph S. Podolski. Exhibit 10.5 to the Registration Statement is incorporated herein by reference.
10.9+	First Amendment to Employment Agreement between the Company and Joseph S. Podolski. Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2001 is incorporated herein by reference.
10.10+	Second Amendment to Employment Agreement between the Company and Joseph S. Podolski. Exhibit 10.17 to the 2002 Form 10-K is incorporated herein by reference.
10.11+	Amended and Restated Employment Agreement between the Company and Louis Ploth, Jr. dated December 23, 2005. Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Commission on December 23, 2005 is incorporated herein by reference.
10.12	Lease Agreement dated May 11, 2004 between the Company and Sealy Woodlands, L.P. Exhibit 10.14 to the Company's Annual Report on Form 10-K for

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the year ended December 31, 2004 is incorporated herein by reference.

10.13++	Letter Agreement dated July 15, 2002 between the Company, Schering Plough Ltd. and Schering-Plough Corporation. Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2002 is incorporated herein by reference.
10.14++	PHS Patent License Agreement dated April 16, 1999 between the Company and certain agencies of the United States Public Health Service within the Department of Health and Human Services, with amendments. Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2003 is incorporated herein by reference.
23.1*	Consent of PricewaterhouseCoopers LLP
31.1*	Certification Pursuant to Rule 13(a)-14(a) or 15(d)-14(a) of the Exchange Act, As Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (Chief Executive Officer)
31.2*	Certification Pursuant to Rule 13(a)-14(a) or 15(d)-14(a) of the Exchange Act, As Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (Chief Financial Officer)
32.1*	Certification Furnished Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Chief Executive Officer)
32.2*	Certification Furnished Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Chief Financial Officer)

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\* Filed herewith.

+ Management contract or compensatory plan.

++ Portions of this exhibit have been omitted based on a request for confidential treatment pursuant to Rule 24b-2 of the Exchange Act. Such omitted portions have been filed separately with the Commission.

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**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**ZONAGEN, INC.**

By: /s/ Joseph S. Podolski  
Joseph S. Podolski  
President and Chief Executive Officer

Dated: March 13, 2006

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ Joseph S. Podolski  Joseph S. Podolski	President, Chief Executive Officer and Director (Principal Executive Officer)	March 13, 2006
/s/ Louis Ploth, Jr.  Louis Ploth, Jr.	Chief Financial Officer, VP Business Development, Director and Secretary (Principal Financial Officer and Principal Accounting Officer)	March 13, 2006
/s/ Daniel F. Cain  Daniel F. Cain	Chairman of the Board	March 13, 2006
/s/ Jean L. Fourcroy, M.D., Ph.D., M.P.H.  Jean L. Fourcroy, M.D., Ph.D., M.P.H.	Director	March 13, 2006
/s/ Jeffrey R. Harder  Jeffrey R. Harder	Director	March 13, 2006
/s/ Nola Masterson  Nola Masterson.	Director	March 13, 2006
/s/ David Poorvin, Ph.D.  David Poorvin, Ph. D.	Director	March 13, 2006

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**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, 2005 and 2004 and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2005 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). 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, 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.

/s/ PricewaterhouseCoopers LLP

Houston, Texas

March 7, 2006

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**ZONAGEN, INC. AND SUBSIDIARY**  
 (A development stage company)  
**CONSOLIDATED BALANCE SHEETS**  
 (in thousands except share amounts)

	<b>December 31, 2005</b>	<b>December 31, 2004</b>
<b>ASSETS</b>		
<b>Current Assets</b>		
Cash and cash equivalents	\$ 2,165	\$ 736
Marketable securities	14,667	4,800
Prepaid expenses and other current assets	231	34
Total current assets	17,063	5,570
<b>Fixed asset, net</b>	19	18
<b>Other assets, net</b>	600	1,018
Total assets	\$ 17,682	\$ 6,606
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
<b>Current Liabilities</b>		
Accounts payable	\$ 338	\$ 144
Accrued expenses	389	470
Total current liabilities	727	614
<b>Commitments &amp; Contingencies</b>		
<b>Stockholders Equity</b>		
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, 12,016,636 and 11,989,936 shares issued, respectively; 10,079,601 and 4,992,901 shares outstanding, respectively	12	12
Additional paid-in capital	117,166	114,455
Deferred compensation	(130)	(234)
Cost of treasury stock, 1,937,035 and 6,997,035 shares, respectively	(5,948)	(21,487)
Deficit accumulated during the development stage	(94,145)	(86,754)
Total stockholders equity	16,955	5,992
Total liabilities and stockholders equity	\$ 17,682	\$ 6,606

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

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**ZONAGEN, INC. AND SUBSIDIARY**  
(A development stage company)  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
(in thousands except per share amounts)

	<b>For the Year Ended December 31,</b>			<b>From Inception (August 20, 1987) through December 31, 2005 (unaudited)</b>
	<b>2005</b>	<b>2004</b>	<b>2003</b>	
<b>Revenues and other income</b>				
Licensing fees	\$	\$	\$	\$ 28,755
Product royalties				627
Research and development grants	4	118	595	1,219
Interest income	630	104	318	13,756
Gain on disposal of fixed assets			102	102
Other income		35		35
Total revenues and other income	634	257	1,015	44,494
<b>Expenses</b>				
Research and development	6,101	2,471	2,161	100,361
General and administrative	1,924	1,483	2,183	28,547
Interest expense and amortization of intangibles				388
Total expenses	8,025	3,954	4,344	129,296
Loss from continuing operations	(7,391)	(3,697)	(3,329)	(84,802)
Income (loss) from discontinued operations				(1,828)
Gain on disposal of discontinued operations				939
Net loss before cumulative effect of change in accounting principle	(7,391)	(3,697)	(3,329)	(85,691)
Cumulative effect of change in accounting principle				(8,454)
<b>Net loss</b>	<b>\$ (7,391)</b>	<b>\$ (3,697)</b>	<b>\$ (3,329)</b>	<b>\$ (94,145)</b>
<b>Loss per share basic and diluted</b>	<b>\$ (0.77)</b>	<b>\$ (0.72)</b>	<b>\$ (0.29)</b>	
Shares used in loss per share calculation:				
Basic	9,647	5,117	11,487	
Diluted	9,647	5,117	11,487	

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



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**ZONAGEN, INC. AND SUBSIDIARY**  
(A development stage company)  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**  
(in thousands except share amounts)

	<b>Preferred Stock</b>		<b>Common Stock</b>		<b>Additional Paid-in Capital</b>		<b>Deferred Compensation</b>		<b>Treasury Stock</b>		<b>Deficit Accumulated During the</b>	<b>Total Stockholders' Equity</b>
	<b>Shares</b>	<b>Amount</b>	<b>Shares</b>	<b>Amount</b>	<b>Capital</b>	<b>Compensation</b>	<b>Shares</b>	<b>Amount</b>	<b>Shares</b>	<b>Amount</b>	<b>Stage</b>	<b>Equity</b>
Exchange of common stock (\$0.004 per share) for technology rights and services from founding stockholders		\$	245,367	\$	\$	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)
			311,265			4					(4,568)	(4,564)

BALANCE AT DECEMBER 31, 1991 (unaudited)					
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
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
	280,248		599		600

Conversion of Series D preferred stock to common stock				
Conversion of bridge loan to common stock	64,000	256		256
Net Loss			(2,532)	(2,532)

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**ZONAGEN, INC. AND SUBSIDIARY**  
(A development stage company)  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**  
(in thousands except share amounts)

	Preferred Stock		Common Stock		Additional Paid-in Capital		Deferred Compensation	Treasury Stock	Development Stage	Deficit Accumulated During the	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				Shares	Amount		
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 (\$1.0 to \$6.13 per share)			4,546		14						14
			16,000		76						76

Issuance of common stock for cash and a financing charge, March 9, 1995								
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	598,850	1			5,336			5,337
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
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	(507,563)	(1)	1,396,826	2	(1)			



common stock, January through November 1996 Issuance of options for services, January 12, 1996			99		99
Exercise of options to purchase common stock for cash, February through November 1996 (\$0.01 to \$5.50 per share)		23,100	75		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)

(continued)

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**ZONAGEN, INC. AND SUBSIDIARY**  
(A development stage company)  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**  
(in thousands except share amounts)

					Additional				Deficit Accumulated During the	Total
	Preferred Stock		Common Stock		Paid-in Capital	Deferred Compensation	Treasury Shares	Stock Amount	Development Stage	Stockholders' Equity
	Shares	Amount	Shares	Amount						
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
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			81,294							

September 1997						
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	(1,514,906)	(2)	2,295,263	2	(1)	(1)
Series B						
preferred stock						
into common						
stock, January						

through 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)

(continued)

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**ZONAGEN, INC. AND SUBSIDIARY**  
(A development stage company)  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**  
(in thousands except share amounts)

			Additional				Deficit Accumulated During the	Total
	Preferred Stock Shares	Common Stock Shares	Amount	Paid-in Capital	Deferred Compensation	Treasury Stock Shares	Development Stage	Stockholders' Equity
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
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,						353,800	(6,197)	(6,197)

January through  
September 1998  
(\$13.00 to \$20.65  
per share)  
Net loss

(12,316) (12,316)

BALANCE AT  
DECEMBER 31,  
1998

11,621,140 12 113,717 (958) 415,300 (7,484) (51,900) 53,387

Deferred  
compensation  
resulting from  
grant of options  
Amortization of  
deferred  
compensation  
Exercise of  
options to  
purchase  
common stock  
for cash,

(229) 229

239 239

February through  
September 1999  
(\$0.04 to \$8.375  
per share)

31,866 72 72

Issuance of  
common stock  
for a cashless  
exercise of  
common stock  
warrants,  
February 1999  
Issuance of  
common stock  
for a cashless  
exercise of  
Series A  
preferred stock  
warrants,  
April 1999  
Issuance of  
common stock  
for a cashless  
exercise of  
Series B  
preferred stock  
warrants, March  
through  
April 1999

4,775

22,131

876

Exercise of  
Series B

536

4

4

preferred stock warrants to purchase common stock for cash, January 1999 (\$11.00 per share) Net loss							(11,952)	(11,952)
BALANCE AT DECEMBER 31, 1999	11,681,324	12	113,564	(490)	415,300	(7,484)	(63,852)	41,750
Deferred compensation resulting from grant of options			77	(34)				43
Amortization of deferred compensation				283				283
Exercise of options to purchase common stock for cash, March through September 2000 (\$0.43 to \$8.375 per share)	49,416		112					112
Issuance of common stock through employee stock purchase plan for cash, December 2000	9,379		21					21
Issuance of common stock to Board of Director members for services, May through December 2000	2,034		6					6
Net loss							(11,155)	(11,155)

(continued)  
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**ZONAGEN, INC. AND SUBSIDIARY**  
(A development stage company)  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**  
(in thousands except share amounts)

			Additional				Deficit Accumulated During the	Total	
	Preferred Stock Amount	Common Stock Shares	Common Stock Amount	Paid-in Capital	Deferred Compensation	Treasury Stock Shares	Treasury Stock Amount	Development Stage	Stockholders' Equity
BALANCE AT DECEMBER 31, 2000	\$	11,742,153	\$ 12	\$ 113,780	\$ (241)	415,300	\$ (7,484)	\$ (75,007)	\$ 31,060
Compensation resulting from grant of options				36					36
Compensation resulting from extension of warrants				23					23
Amortization of deferred compensation					230				230
Exercise of options to purchase common stock for cash, February through December 2001 (\$0.64 to \$4.00 per share)		12,242		25					25
Issuance of common stock through employee stock purchase plan for cash, June and December 2001		8,431		25					25
Issuance of common stock to Board of Director members for services, February		2,690		9					9



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through December 2001 Net loss							(839)	(839)
BALANCE AT DECEMBER 31, 2001	\$	11,765,516	\$ 12	\$ 113,898	\$ (11)	415,300	\$ (7,484)	\$ (75,846) \$ 30,569
Amortization of deferred compensation					11			11
Exercise of options to purchase common stock for cash, January and February 2002 (\$0.64 to \$2.94 per share)		31,265		21				21
Issuance of common stock through employee stock purchase plan for cash, June 2002		4,824		6				6
Issuance of common stock to Employees		105,000		111				111
Issuance of common stock to Board of Director members for services, March through December 2002		11,572		15				15
Net loss							(3,882)	(3,882)
BALANCE AT DECEMBER 31, 2002	\$	11,918,177	\$ 12	\$ 114,051	\$	415,300	\$ (7,484)	\$ (79,728) \$ 26,851
Issuance of common stock to Board of Director members for services, February through May 2003		10,871		14		34,100	(49)	14 (49)
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Purchase of treasury stock April (\$1.37 to \$1.50 per share)									
Net loss							(3,329)		(3,329)

BALANCE AT DECEMBER 31,

2003	\$	11,929,048	\$	12	\$	114,065	\$	449,400	\$	(7,533)	\$	(83,057)	\$	23,487
Self Tender Offer of 6,547,635 shares at \$2.10 including 60,888 exercised options		60,888						6,547,635		(13,665)				(13,665)
Costs associated with self tender offer										(289)				(289)
Noncash stock compensation related to stock option bonus program						78								78
Issuance of 354,474 stock options to employees on March 29, 2004 and approved on September 29, 2004 (issue price of \$2.72, fmV when approved \$3.60)						312		(312)						
Amortization of deferred compensation								78						78
Net loss												(3,697)		(3,697)

BALANCE AT DECEMBER 31,

2004	\$	11,989,936	\$	12	\$	114,455	\$	(234)		6,997,035	\$	(21,487)	\$	(86,754)	\$	5,992
Issuance of 5,060,000 shares of treasury stock at \$4.00 per share																
February 1, 2005						2,641				(5,060,000)		15,539				18,180
Exercise of options to		26,700				85										85

purchase common stock for cash, January and February 2005 (\$2.94 to \$3.47 per share)									
Noncash stock compensation related to stock option bonus program			(15)						(15)
Amortization of deferred compensation				104					104
Net loss							(7,391)		(7,391)

BALANCE AT  
DECEMBER 31,  
2005

\$	12,016,636	\$	12	\$	117,166	\$	(130)		1,937,035	\$	(5,948)	\$	(94,145)	\$	16,955
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The accompanying notes are an integral part of these consolidated financial statements.  
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**ZONAGEN, INC. AND SUBSIDIARY**  
(A development stage company)  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(in thousands)

	<b>For the Year Ended December 31,</b>			<b>From Inception (August 20, 1987) through December 31, 2005 (unaudited)</b>
	<b>2005</b>	<b>2004</b>	<b>2003</b>	
<b>Cash Flows from Operating Activities</b>				
Net loss	\$ (7,391)	\$ (3,697)	\$ (3,329)	\$ (94,145)
Gain on disposal of discontinued operations				(939)
Gain on disposal of assets			(102)	(102)
Adjustments to reconcile net loss to net cash used in operating activities:				
Noncash financing costs				316
Noncash inventory impairment				4,417
Noncash patent impairment		308		1,339
Noncash decrease in accounts payable				(1,308)
Depreciation and amortization	7	9	78	3,780
Noncash expenses related to stock-based transactions	89	156	14	2,817
Common stock issued for agreement not to compete				200
Series B Preferred Stock issued for consulting services				18
Maturities of marketable securities	24,825	9,850	51,758	24,825
Purchases of marketable securities	(34,692)	(12,650)	(37,303)	(10,957)
Changes in operating assets and liabilities (net effects of purchase of businesses in 1988 and 1994):				
Decrease (increase) in receivables				(199)
Decrease (increase) in inventory				(4,447)
Decrease (increase) in prepaid expenses and other current assets	(197)	201	297	68
(Decrease) increase in accounts payable and accrued expenses	114	73	22	1,923
Net cash (used in) provided by operating activities	(17,245)	(5,750)	11,435	(72,394)
<b>Cash Flows from Investing Activities</b>				
Maturities (purchases) of marketable securities				(28,723)
Capital expenditures	(8)	(21)		(2,297)
Purchase of technology rights and other assets	(183)	(169)	(64)	(2,621)

Decrease (increase) in note receivable			1,000	
Proceeds from sale of PP&E			225	225
Cash acquired in purchase of FTI				3
Proceeds from sale of subsidiary, less \$12,345 for operating losses during 1990 phase-out period				138
Proceeds from sale of the assets of FTI				2,250
Increase in net assets held for disposal				(213)
Net cash provided by (used in) investing activities	(191)	(190)	1,161	(31,238)
<b>Cash Flows from Financing Activities</b>				
Proceeds from issuance of common stock, net of offering costs	18,180			102,404
(Increase) decrease in prepaid offering costs	600	(316)	(284)	
Exercise of stock options	85			85
Proceeds from issuance of preferred stock				23,688
Purchase of treasury stock		(13,954)	(49)	(21,487)
Proceeds from issuance of notes payable				2,839
Principal payments on notes payable				(1,732)
Net cash provided by (used in) financing activities	18,865	(14,270)	(333)	105,797
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>1,429</b>	<b>(20,210)</b>	<b>12,263</b>	<b>2,165</b>
<b>Cash and cash equivalents at beginning of period</b>	<b>736</b>	<b>20,946</b>	<b>8,683</b>	
<b>Cash and cash equivalents at end of period</b>	<b>\$ 2,165</b>	<b>\$ 736</b>	<b>\$ 20,946</b>	<b>\$ 2,165</b>

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

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### **1. ORGANIZATION AND OPERATIONS:**

Zonagen, Inc. ( the Company , Zonagen, or we, us or our ) was organized on August 28, 1987 and is a development stage company. We are a biopharmaceutical company focused on the development of new drugs to treat hormonal and reproductive system disorders. Our lead product candidate, Proellex, is an orally available small molecule compound that we are developing for the treatment of uterine fibroids and endometriosis. Our second product candidate is Androxal, an orally available small molecule compound being developed for the treatment of testosterone deficiency in men.

On February 1, 2005 the Company completed its follow-on public offering of 5,060,000 shares of its common stock at \$4.00 per share (which included the underwriters' exercise of its over allotment option for 660,000 shares). The shares offered by the Company were issued out of its existing treasury stock, and the offering resulted in net proceeds to the Company of approximately \$18.1 million.

Prior to 2004, we focused our resources on the development of VASOMAX<sup>®</sup>, and related phentolamine-based products for the treatment of male erectile dysfunction. Beginning in 1999, the U.S. Food and Drug Administration ( 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 2002 and 2000 to aggressively locate strategic alternatives, including the use of two investment banks to assist in this search. All of these efforts culminated in a definitive merger agreement being signed 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.

In January 2004, the Company accepted for purchase 6,547,635 shares (approximately 57% of its outstanding common stock, at that time) at a purchase price of \$2.10 per share in accordance with the terms of the self tender offer, which included 60,888 shares issuable upon exercise of options tendered by directors, for a total aggregate cost of approximately \$14.0 million, inclusive of costs associated with the offer.

Nasdaq has established rules and policies with respect to the continued listing of securities on Nasdaq. Due to the Company's self tender offer which was completed in January 2004, the Company had fallen below the Nasdaq National Market requirement that a listed company have at least \$10 million in stockholders' equity. Due to this shortfall in equity, the Company applied for a Nasdaq SmallCap Market listing which was approved by Nasdaq and the Company's stock began trading on the Nasdaq SmallCap Market on July 8, 2004. The Nasdaq SmallCap Market has since been renamed the Nasdaq Capital Market.

The Company has experienced negative cash flows from operations since inception and has funded its activities to date primarily from equity financings and corporate collaborations. The Company will continue to require substantial funds for research and development, including preclinical studies and clinical trials of our product candidates, and to commence sales and marketing efforts if appropriate, if the FDA or other regulatory approvals are obtained. The Company believes that its existing capital resources under its current operating plan will be sufficient to fund the Company's operations through at least December 31, 2006. There can be no assurance that changes in our current strategic plans or other events will not result in accelerated or unexpected expenditures.

Zonagen's results of operations may vary significantly from year to year and quarter to quarter, and depend, among other factors, on the Company's ability to be successful in our clinical trials, the regulatory approval process in the United States and other foreign jurisdictions and the ability to complete new licenses and product development agreements. The timing of our revenues may not match the timing of our associated product development expenses. To date, research and development expenses have generally exceeded revenue in any particular period and/or fiscal year.

As of December 31, 2005, the Company had an accumulated deficit of \$94.1 million. Losses have resulted principally from costs incurred in conducting clinical trials of its phentolamine-based products which include VASOMAX<sup>®</sup> and the related female sexual dysfunction product and more recently for the clinical development of Androxal and Proellex; in research and development activities related to efforts to develop our products and from the associated administrative costs required to support those efforts. Due to various tax regulations, including change in control provisions in the tax code the value of this tax asset to the Company can be substantially diminished. For

additional information relating to the Company's net operating loss carryforward see Note 6. Federal Income Taxes of the Notes to Consolidated Financial Statements.

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### **2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:**

#### **USE OF ESTIMATES**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

#### **CERTAIN RISKS AND UNCERTAINTIES**

Our product candidates under development require approval from the FDA or other international regulatory agencies prior to commercial sales. There can be no assurance our product candidates will receive the necessary clearance. If we are denied clearance or clearance is delayed, it may have a material adverse impact on us.

Our product candidates are concentrated in rapidly changing, highly competitive markets, which are characterized by rapid technological advances, evolving regulatory requirements and industry standards. Any failure by us to anticipate or to respond adequately to technological developments in our industry, changes in regulatory requirements or industry standards, or any significant delays in the development or introduction of products or services, could have a material adverse effect on our business, operating results and future cash flows.

#### **CASH AND CASH EQUIVALENTS**

For purposes of the consolidated statements of cash flows, the Company considers all cash accounts and highly liquid investments having original maturities of three months or less to be cash and cash equivalents.

#### **MARKETABLE SECURITIES**

Management determines the appropriate classification of investments in debt and equity securities at the time of purchase and re-evaluates such designation as of each subsequent balance sheet date. Securities for which the Company has the ability and intent to hold to maturity are classified as held to maturity. Securities classified as trading securities are recorded at fair value. Gains and losses on trading securities, realized and unrealized, are included in earnings and are calculated using the specific identification method. Any other securities are classified as available for sale. At December 31, 2005 all securities were classified as trading securities. The cost basis including purchased premium for these securities was \$14.7 million and \$4.8 million at December 31, 2005 and 2004, respectively.

Marketable securities as of December 31, 2005 consist of only short term investments. The Company's investments typically include corporate bonds and notes, Euro-dollar bonds, taxable auction securities and asset-backed securities. The Company's policy is to require minimum credit ratings of A2/A and A1/P1 with maturities of up to three years. The average life of the investment portfolio may not exceed 24 months.

Marketable securities are reviewed for other-than-temporary impairment at the individual security level in each reporting period. The Company has determined that its marketable securities are not impaired as of December 31, 2005 or 2004.

#### **PREPAID EXPENSES AND OTHER CURRENT ASSETS**

Prepaid expenses and other current assets primarily consist of prepaid insurance, prepaid operating expenses and other miscellaneous assets, interest and other receivables.

#### **FIXED ASSETS**

Fixed assets include lab equipment, furniture and leasehold improvements and are recorded at cost, less accumulated depreciation and amortization. Depreciation is computed on the straight-line method over an estimated useful life of three to five years or, in the case of leasehold improvements, amortized over the remaining term of the lease. Maintenance and repairs that do not improve or extend the life of assets are expensed as incurred. When assets are sold or retired, the cost and accumulated depreciation are removed from the accounts and the resulting gain or loss is included in income during the period in which the transaction occurred.



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Since the Company was operating primarily as a virtual company utilizing outside consultants to perform limited research and development and clinical development activities and previously intended to redeploy its existing assets, the Company held an auction in June 2003 and sold substantially all of its fixed assets for approximate net proceeds of \$225,000, which was \$102,000 over their book value.

### **OTHER ASSETS**

The Company capitalizes the cost associated with building its patent library. As of December 31, 2005 other assets consist of capitalized patent costs in the amount of \$600,000. Patent costs, which include legal and application costs related to the patent portfolio, are being amortized over 20 years, or the lesser of the legal or the estimated economic life of the patent. Amortization of patent costs was zero, \$7,000 and \$9,000 in 2005, 2004 and 2003, respectively.

Of the \$600,000 in capitalized patents, \$327,000 related to patents for Proellex, which is being developed as an oral treatment for uterine fibroids and endometriosis and \$273,000 related to Androxal, which is being developed as an oral treatment for testosterone deficiency.

The Company reviews for the impairment of capitalized patent costs whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. An impairment loss exists when estimated undiscounted cash flows expected to result from the patent are less than its carrying amount. The impairment loss recognized represents the excess of the patent cost as compared to its estimated fair value. The Company has determined that its capitalized patent costs are not impaired as of December 31, 2005.

The Company no longer maintains its previous patent portfolio for its vaccine adjuvants, prostate cancer vaccines, hCG and zona pellucida immuno-contraceptive vaccines. This decision resulted in an impairment charge of approximately \$308,000 during 2004 against capitalized patent costs.

### **REVENUE RECOGNITION**

#### **Research and Development Grants**

The Company applies for research and development grants from the federal government usually in the form of Small Business Innovation Research, or SBIR grants. When the Company is awarded one of these research and development grants it is obligated to spend grant dollars on research activities based on a budget that was submitted with the grant application. The Company typically bills the federal government on a monthly basis after it has expended its funds for the grant activities. At that time the Company recognizes research and development grant revenues. During 2002 the Company was awarded three SBIR grants totaling in excess of \$1 million. The last SBIR grant was essentially depleted during 2004.

### **RESEARCH AND DEVELOPMENT COSTS**

Research and development, or R&D expenses include salaries and related employee expenses, contracted regulatory affairs activities, insurance coverage for clinical trials and prior product sales, contracted research and consulting fees, facility costs and internal research and development supplies. The Company expenses research and development costs in the period they are incurred. These costs consist of direct and indirect costs associated with specific projects as well as fees paid to various entities that perform research on behalf of the Company.

### **LOSS PER SHARE**

Basic EPS is computed by dividing net loss by the weighted average number of shares of common stock outstanding during the year. Diluted EPS is computed in the same manner as fully diluted EPS, except that, among other changes, the average share price for the period is used in all cases when applying the treasury stock method to potentially dilutive outstanding options. In all applicable years all potential common stock equivalents were antidilutive and accordingly were not included in the computation.

### **STOCK-BASED COMPENSATION**

The Company has two stock-based compensation plans at December 31, 2005, which are described more fully in note 8.

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The Company accounts for its stock option plans under APB No. 25 Accounting for Stock Issued to Employees. Accordingly, deferred compensation is recorded for stock options based on the excess of the market value of the common stock on the measurement date over the exercise price of the options. This deferred compensation is amortized over the vesting period of each option.

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The Company has adopted the disclosure requirements of SFAS No. 123 Accounting for Stock-Based Compensation, as amended, for employee stock-based compensation and has elected not to record related compensation expense in accordance with this statement. Had compensation expense for its stock option plans been determined consistent with SFAS No. 123, the Company's net loss and loss per share would have been increased to the following pro forma amounts (in thousands, except for per share amounts):

	<b>December 31,</b>		
	<b>2005</b>	<b>2004</b>	<b>2003</b>
Net loss, as reported	\$ (7,391)	\$ (3,697)	\$ (3,329)
Add: Stock-based employee compensation expense included in reported net income, net of related tax effects	89	156	14
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	(746)	(457)	(1,374)
Pro forma net loss	\$ (8,048)	\$ (3,998)	\$ (4,689)
Loss per share			
Basic and diluted as reported	\$ (0.77)	\$ (0.72)	\$ (0.29)
Basic and diluted pro forma	(0.83)	(0.78)	(0.41)

Under SFAS No. 123, the fair value of each option grant was estimated on the date of grant using the Black-Scholes option-pricing model. The following weighted average assumptions were used for grants in 2005, 2004, and 2003, respectively: risk-free interest rates of 4.0%, 3.5%, and 3.8%; with no expected dividends; expected lives of 5.8, 6.4, and 4.2 years; expected volatility of 86%, 88%, and 90%. The weighted average fair value of options, all of which were granted at market for 2005, 2004 and 2003 was \$2.88, \$1.99 and \$0.39, respectively.

The Black-Scholes option valuation model and other existing models were developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of and are highly sensitive to subjective assumptions including the expected stock price volatility. The Company's employee stock options have characteristics significantly different from those of traded options and changes in the subjective input assumptions can materially affect the fair value estimate.

**RECENT ACCOUNTING PRONOUNCEMENTS**

In December 2004, the FASB issued SFAS No. 123 (revised 2004), Share-Based Payment. SFAS No. 123(R) will require that the compensation cost relating to share-based payment transactions be recognized in financial statements. That cost will be measured based on the fair value of the equity or liability instruments issued. SFAS No. 123(R) covers a wide range of share-based compensation arrangements including share options, restricted share plans, performance-based awards, share appreciation rights, and employee share purchase plans. SFAS No. 123(R) replaces FASB Statement No. 123, Accounting for Stock-Based Compensation, and supersedes APB Opinion No. 25, Accounting for Stock Issued to Employees. SFAS No. 123, as originally issued in 1995, established as preferable a fair value-based method of accounting for share-based payment transactions with employees. However, that Statement permitted entities the option of continuing to apply the guidance in APB Opinion No. 25, as long as the footnotes to financial statements disclosed what net income would have been had the preferable fair value-based method been used. Public entities will be required to apply SFAS No. 123(R) as of the first annual reporting period that begins after June 15, 2005. The Company believes the impact of the adoption of SFAS No. 123(R) using the modified-prospective method of adoption based on share-based payments currently awarded to employees is expected to be approximately \$600,000 in additional non-cash compensation expense in 2006.

**3. FIXED ASSETS:**

Fixed assets are classified as follows (in thousands):

**December 31,**  
**2005                      2004**

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Laboratory equipment	\$	4	\$	4
Office equipment		18		10
Leasehold improvements		7		7
		29		21
Less Accumulated depreciation and amortization		10		3
Total	\$	19	\$	18

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The Company held an auction in June 2003 and sold substantially all of its fixed assets for approximate net proceeds of \$225,000, which was \$102,000 over their book value. In addition to purchases in 2004, the Company currently possesses some lab equipment and furniture whose value had previously been fully depreciated.

**4. OPERATING LEASES:**

The Company leases laboratory and office space, and equipment pursuant to leases accounted for as operating leases. The lease for the Company's laboratory and office space expires in June 2010. Rental expense for the years ended December 31, 2005, 2004 and 2003, was approximately \$39,000, \$37,000 and \$145,000, respectively. Future minimum lease payments under non-cancelable leases with original terms in excess of one year as of December 31, 2005, are as follows (in thousands):

2006	39
2007	40
2008	40
2009	40
2010 & later	21
Total	\$ 180

**5. ACCRUED EXPENSES:**

Accrued expenses consist of the following (in thousands):

	<b>December 31,</b>	
	<b>2005</b>	<b>2004</b>
Research and development costs	\$ 7	\$ 7
Payroll	159	
Legal	45	48
Offering costs		250
Patent costs	97	90
Other	81	75
Total	\$ 389	\$ 470

**6. FEDERAL INCOME TAXES:**

The Company has had losses since inception and, therefore, has not been subject to federal income taxes. The Company has accumulated approximately \$2.8 million of research and development tax credits. As of December 31, 2005 and 2004, the Company had approximately \$84.3 million and \$78.5 million, respectively, of net operating loss ( NOL ) carry-forwards for federal income tax purposes. Additionally, approximately \$1.8 million of NOLs, and approximately \$72,000 of research and development tax credits will expire in 2006.

The Tax Reform Act of 1986 provided for a limitation on the use of NOL and tax credit carryforwards following certain ownership changes that could limit the Company's ability to utilize these NOLs and tax credits. The sale of preferred stock in 1996, together with previous changes in stock ownership, resulted in an ownership change in 1996 for federal income tax purposes. The Company estimates that the amount of pre-1997 NOL carryforwards and the credits available to offset taxable income is limited to approximately \$5.4 million per year on a cumulative basis. Accordingly, if the Company generates taxable income in any year in excess of its then cumulative limitation, the Company may be required to pay federal income taxes even though it has unexpired NOL carryforwards. Additionally, because U.S. tax laws limit the time during which NOLs and tax credit carryforwards may be applied against future taxable income and tax liabilities, the Company may not be able to take full advantage of its NOLs and tax credit carryforwards for federal income tax purposes.

The redemption of shares under the Company's tender offer in January 2004 (Note 1) and the Company's follow-on public offering completed on February 1, 2005 may have created a change of ownership for Federal Income tax purposes. The Company has not undertaken a study to determine if this has occurred. A change in ownership for Federal income tax purposes may result in a limitation in the use of net operating loss carryforwards in future periods.

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Under SFAS No. 109, Accounting for Income Taxes, an NOL requires the recognition of a deferred tax asset. As the Company has incurred losses since inception, and there is no certainty of future revenues, a valuation allowance has been provided in full in the accompanying consolidated financial statements.

The tax effects of temporary differences that give rise to significant portions of the deferred tax assets are as follows (in thousands):

	<b>December 31,</b>	
	<b>2005</b>	<b>2004</b>
Net operating loss carryforwards	\$ 28,672	\$ 26,693
Research and development tax credits	2,819	2,871
Accruals/expenses not currently deductible	1,510	1,510
Total deferred tax assets	33,001	31,074
Less Valuation allowance	(33,001)	(31,074)
Net deferred tax assets	\$	\$

**7. STOCKHOLDERS' EQUITY:****TREASURY STOCK**

On January 13, 2004 the Company announced the final results of its self tender offer, which expired on January 7, 2004. Zonagen accepted for purchase 6,547,635 shares at a purchase price of \$2.10 per share in accordance with the terms of the offer, which included 60,888 shares issuable upon exercise of options tendered by directors, for a total aggregate cost of approximately \$14.0 million, which is inclusive of costs associated with the offer.

In April 2003, the Company bought back an additional 34,100 treasury shares at an aggregate purchase price of \$49,000 for an average price of \$1.44 per share.

As of December 31, 2004, the Company had 6,997,035 shares of treasury stock. The Company sold 5,060,000 of these shares in its public offering which was completed on February 1, 2005.

**EARNINGS PER SHARE**

The following table presents information necessary to calculate earnings per share for the three years ended December 31, 2005, 2004 and 2003 (in thousands, except per share amounts):

	<b>2005</b>	<b>2004</b>	<b>2003</b>
Net loss	\$ (7,391)	\$ (3,697)	\$ (3,329)
Weighted average common shares outstanding	9,647	5,117	11,487
Basic earnings per share	\$ (0.77)	\$ (0.72)	\$ (0.29)
Weighted average common and dilutive potential common shares outstanding:			
Weighted average common shares outstanding	9,647	5,117	11,487
Assumed exercise of stock options	9,647	5,117	11,487
Diluted earnings per share	\$ (0.77)	\$ (0.72)	\$ (0.29)

**8. STOCK OPTIONS AND EMPLOYEE STOCK PURCHASE PLAN:**

During 2004 the Company had three stock option plans available which were the 1994 Employee and Consultant Stock Option Plan, or 1994 Plan which expired in June 2004; the 2000 Non-Employee Directors' Stock Option Plan, or 2000 Director Plan; and the 2004 Stock Option Plan, or 2004 Plan. Due to the expiration of the Company's Amended and Restated 1993 Employee and Consultant Stock Option Plan, or 1993 Plan, in May 2003, the Company's Board of

Directors approved the 2004 Plan on February 24, 2004. The 2004 Plan was approved by shareholders at the 2004 Annual Shareholders Meeting which was held on September 29, 2004.

As of December 31, 2005, there were 292,935 options available under the 2004 Plan and 500,000 available under the 2000 Plan. The 2000 Plan has an evergreen provision pursuant to which the number of shares available under such plan are automatically increased each year on the day after the Company's Annual Shareholders Meeting by the number of shares granted during the prior year under such plan (or by one-half percent of the Company's then outstanding common stock, if greater). There are no significant differences between the provisions of the two remaining plans. Typically, options are granted with an exercise price per share which is equal to the fair market

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value per share of common stock on the date of grant. Vesting provisions for each grant are determined by the board of directors and typically vest quarterly over a three year period. All options expire no later than the tenth anniversary of the grant date.

During the 2003 Annual Shareholders Meeting which was concluded on January 14, 2004, four prior Board Members did not stand for re-election and four new Board Members were elected which consisted of 3 outside directors and the Company's Chief Financial Officer. Pursuant to the terms of the Company's 2000 Director Plan, each of the three new non-employee directors were automatically granted options to purchase 40,000 shares of the Company's common stock at an exercise price of \$2.40, which was the closing price on the date of grant. On February 24, 2004, the Board of Directors approved an amendment to these options to provide that such options vest in quarterly installments over a three year period.

Under the general terms of the 2000 Director Plan the four prior Board Members who did not stand for re-election at the Company's 2003 Annual Shareholders Meeting were automatically granted a 2 year extension to January 14, 2006 to exercise their fully vested options. These options consisted of 140,715 shares with exercise prices ranging from \$1.70 to \$5.65. In addition, these same Directors also received an extension to January 14, 2006 for any fully vested options granted under other option plans. These options consisted of 112,500 shares with exercise prices ranging from \$4.00 to \$22.25. In January 2006, we received \$203,600 from former Board Members for the exercise of their soon to be expired options to purchase 66,361 shares of common stock with exercise prices ranging from \$1.70 to \$3.47. The remaining 176,854 stock options held by prior Board Members were canceled on January 14, 2006.

On March 29, 2004, the Compensation Committee approved grants to the Company's executive officers of incentive options to purchase 358,763 shares of its common stock that vest quarterly over three years and to non-executive employees of (i) incentive options to purchase 123,350 shares that vest quarterly over three years and (ii) incentive options to purchase 22,361 shares (granted in lieu of additional increases in cash compensation) that vested in equal increments through December 31, 2004. All of the options were granted at an exercise price of \$2.72, the fair market value of the Company's common stock on the date of grant.

In addition, the Compensation Committee approved grants to the Company's executive officers for incentive options to purchase 79,486 shares of its common stock and also granted incentive options to purchase 17,504 shares to non-executive employees. Vesting of these options was tied to attaining certain milestones and all options were granted at an exercise price of \$2.72, the fair market value of the Company's common stock on the date of grant. The Company recorded compensation expense as performance milestones were achieved for these incentive options. Five of the ten milestones were met resulting in non-cash compensation expense for the year ended December 31, 2004 of \$55,000 under these incentive option grants. Three additional milestones were met resulting in additional compensation expense of \$8,000 during the three-month period ended June 30, 2005. The two remaining performance milestones expired without being met.

Of all of the options granted to both executive officers and employees, options to purchase 150,000 shares were granted under the Company's 1994 Plan and the remaining options were granted under the new 2004 Employee and Consultant Stock Option Plan. All of the options granted under the 1994 Plan are immediately valid and all of the options granted under the new 2004 Plan were subject to shareholder approval. The 2004 Plan was approved by shareholders at the September 29, 2004 Annual Shareholders Meeting. Due to the approval of these options, the Company recorded non-cash compensation expense of \$78,000 for the year ended December 31, 2004 and will record additional non-cash compensation expense of \$26,000 per quarter through the quarter ended March 31, 2007. This expense represents the difference between the grant price of \$2.72, which was the closing price of the Company's common stock on the date of grant on March 29, 2004, and \$3.60, the closing price of the Company's common stock on September 29, 2004, the date under which these options were approved by stockholders at the Company's 2004 Annual Meeting of Stockholders.

During 2000, the Company amended the 2000 Director Plan to allow for issuance of stock awards and options in lieu of cash for fees owed to directors and consultants. In connection with this amendment, no shares of common stock or options to purchase common stock were issued to directors and consultants in 2005 or 2004. In connection with this amendment, during 2003, the Company granted options to a director, totaling 12,972 shares of common stock at exercise prices ranging from \$0.93 to \$1.58, which was the fair market value at the time of issue. In addition,

during 2003, the Company issued stock awards to directors, totaling 10,871 shares of common stock in connection with the same amendment at the closing price on the date of grant.

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A summary of the status of the Company's option plans at December 31, 2005, 2004, and 2003 and changes during the years then ended is presented in the tables below:

	<b>2005 Weighted Average Exercise</b>		<b>2004 Weighted Average Exercise</b>		<b>2003 Weighted Average Exercise</b>	
	<b>Shares</b>	<b>Price</b>	<b>Shares</b>	<b>Price</b>	<b>Shares</b>	<b>Price</b>
Outstanding at beginning of year	1,786,846	\$ 4.77	1,225,470	\$ 5.98	1,531,710	\$ 6.76
Granted	85,000	3.81	816,464	2.78	12,972	1.23
Exercised	(26,700)	3.18	(60,888)	1.39		
Forfeited	(129,783)	5.92	(194,200)	5.24	(319,212)	9.52
Outstanding at end of year	1,715,363	4.66	1,786,846	4.77	1,225,470	5.98
Exercisable at end of year	1,098,141	5.29	858,930	6.44	810,370	6.97

The following table summarizes information about stock options outstanding at December 31, 2005:

<b>Range Of Exercise Prices</b>		<b>Number Outstanding</b>	<b>Weighted Average Remaining Life</b>	<b>Weighted Average Exercise Price</b>	<b>Number Exercisable</b>	<b>Weighted Average Exercise Price</b>
\$ .00						
to	\$ 5.00	1,443,259	6.7	\$ 3.21	826,037	\$ 2.96
5.01 to	10.00	206,354	0.7	8.36	206,354	8.36
10.01 to	15.00	7,500	0.1	13.44	7,500	13.44
15.01 to	20.00	3,250	3.0	18.61	3,250	18.61
20.01 to	25.00	20,000	0.6	21.08	20,000	21.08
25.01 to	30.00	30,000	2.3	29.67	30,000	29.67
30.01 to	35.00	5,000	4.4	33.25	5,000	33.25
		1,715,363			1,098,141	

On May 23, 2000, the shareholders also approved the Company's 2000 Employee Stock Purchase Plan (the Purchase Plan). The Purchase Plan provides all eligible full-time employees with an opportunity to purchase common stock through accumulated payroll deductions. Purchases of common stock are made at the lower of 85% of the fair market value at the beginning or end of each six-month offering period. A total of 150,000 shares of common stock have been reserved for issuance under the Purchase Plan through December 2000. In addition, the Purchase Plan provides for annual increases in the number of shares available for issuance under the Purchase Plan on the first day of each year, beginning January 1, 2001, in an amount equal to 50,000 shares. In 2005, the Company did not issue any common stock and there was no participation under the Purchase Plan in 2005.

#### 9. LICENSE, RESEARCH AND DEVELOPMENT AGREEMENTS: NATIONAL INSTITUTES OF HEALTH (NIH)

In 1999, we licensed rights to Proellex 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 Proellex for the treatment of uterine fibroids in 2008. We provide annual updates to the NIH on the progress of our development of Proellex. Based on our interaction with the NIH to date, we believe our license and relationship with NIH 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 Proellex 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

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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 Proellex and severely harm our business prospects.

**10. COMMITMENTS AND CONTINGENCIES:**

We are not currently a party to any material legal proceedings.

See footnote 4 for a discussion of our operating lease.

As of December 31, 2005, the Company also had non-cancelable purchase orders relating to the clinical development of both Proellex and Androxal in the amounts of \$5.8 million and \$4.9 million, respectively. As of December 31, 2004, the Company had non-cancelable purchase orders relating to the clinical development of both Proellex and Androxal in the amount of \$739,700 and \$185,300, respectively.

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	<b>First Quarter Ended March 31, 2005</b>	<b>Second Quarter Ended June 30, 2005</b>	<b>Third Quarter Ended September 30, 2005</b>	<b>Fourth Quarter Ended December 31, 2005</b>
<b>(In thousands except per share amounts)</b>				
Revenues and other income:				
Licensing fees	\$	\$	\$	\$
Research and development grants	4			
Interest income	108	173	175	174
Total revenues	112	173	175	174
Expenses:				
Research and development	1,236	1,355	1,641	1,869
General and administrative	431	465	461	567
Total expenses	1,667	1,820	2,102	2,436
Net loss	\$ (1,555)	\$ (1,647)	\$ (1,927)	\$ (2,262)
Net loss per share basic and diluted	\$ (0.19)	\$ (0.16)	\$ (0.19)	\$ (0.22)
Shares used in loss per share calculation	8,326	10,080	10,080	10,080
	<b>First Quarter Ended March 31, 2004</b>	<b>Second Quarter Ended June 30, 2004</b>	<b>Third Quarter Ended September 30, 2004</b>	<b>Fourth Quarter Ended December 31, 2004</b>
<b>(In thousands except per share amounts)</b>				
Revenues and other income:				
Licensing fees	\$	\$	\$	\$
Research and development grants	64	53	2	
Interest income	26	22	27	28
Gain on disposal of fixed assets				
Other Income	35			
Total revenues	125	75	29	28
Expenses:				
Research and development	477	508	929	557
General and administrative	434	294	540	215

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Total expenses	911	802	1,469	772
Net loss	\$ (786)	\$ (727)	\$ (1,440)	\$ (744)
Net loss per share basic and diluted	\$ (0.14)	\$ (0.15)	\$ (0.29)	\$ (0.15)
Shares used in loss per share calculation	5,492	4,993	4,993	4,993

## 12. SUBSEQUENT EVENT

In January 2006, we received \$203,600 from the exercise of 66,361 stock options that were exercised by former Board Members. These options were scheduled to expire on January 14, 2006 and had an exercise price range of \$1.70 to \$3.47. The remaining 176,854 stock options held by the former Board Members expired unexercised on January 14, 2006.

The Company has amended its current lease effective April 1, 2006 for its current office space in The Woodlands, Texas. The amendment will increase the space to approximately 7,100 square feet to provide additional space needed for the increase in headcount expected in 2006. This will increase the Company's obligations under its current lease by approximately \$20,000 per year for the remainder of the lease term. The lease term is not being affected as a result of the amendment.

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**INDEX TO EXHIBITS**

<b>Exhibit Number</b>	<b>Identification Of Exhibit</b>
3.1(a)	Restated Certificate of Incorporation. Exhibit 3.3 to the Company's Registration Statement on Form SB-2 (No. 33-57728-FW), as amended (Registration Statement), is incorporated herein by reference.
3.1(b)	Certificate of Designation of Series One Junior Participating Preferred Stock dated September 2, 1999. Exhibit A to Exhibit 4.1 to the Company's Registration Statement on Form 8-A as filed with the Commission on September 3, 1999 (the Rights Plan Registration Statement), is incorporated herein by reference.
3.2	Restated Bylaws of the Company. Exhibit 3.4 to the Registration Statement is incorporated herein by reference.
4.1	Specimen Certificate of Common Stock, \$.001 par value, of the Company. Exhibit 4.1 to the Registration Statement is incorporated herein by reference.
4.2	Rights Agreement dated September 1, 1999 between the Company and Computershare Investor Services LLC (as successor in interest to Harris Trust & Savings Bank), as Rights Agent. Exhibit 4.1 to the Rights Plan Registration Statement is incorporated herein by reference.
4.3	First Amendment to Rights Agreement, dated as of September 6, 2002, between the Company, Harris Trust & Savings Bank and Computershare Investor Services LLC. Exhibit 4.3 to Amendment No. 1 to the Rights Plan Registration Statement on Form 8-A/A as filed with the Commission on September 11, 2002 is incorporated herein by reference.
4.4	Second Amendment to Rights Agreement, dated as of October 30, 2002, between the Company and Computershare Investor Services LLC. Exhibit 4.4 to Amendment No. 2 to the Rights Plan Registration Statement on Form 8-A/A as filed with the Commission on October 31, 2002 is incorporated herein by reference.
4.5	Third Amendment to Rights Agreement, dated as of June 30, 2005, between the Company and Computershare Trust Company, Inc. (as successor in interest to Computershare Investor Services, LLC). Exhibit 4.4 to the Company's Current Report on Form 8-K as filed with the Commission on June 30, 2005 is incorporated herein by reference.
4.6	Form of Rights Certificate. Exhibit B to Exhibit 4.1 to the Rights Plan Registration Statement is incorporated herein by reference.
10.1+	Amended and Restated 1993 Employee and Consultant Stock Option Plan. Exhibit 10.3 to the Registration Statement is incorporated herein by reference.
10.2+	



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First Amendment to the Zonagen, Inc. Amended and Restated 1993 Stock Option Plan. Exhibit 10.22 to the Company's Annual Report on Form 10-K for the year ended December 31, 1999 (the 1999 Form 10-K) is incorporated herein by reference.

- 10.3+ 1996 Non-Employee Directors' Stock Option Plan. Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 1997 is incorporated herein by reference.
- 10.4+ 2000 Non-Employee Directors' Stock Option Plan. Appendix B to the Company's Definitive Proxy Statement filed on April 26, 2000 is incorporated herein by reference.
- 10.5+ First Amendment to the Zonagen, Inc. 2000 Non-Employee Directors' Stock Option Plan. Exhibit 10.21 to the 2000 Form 10-K is incorporated herein by reference.

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<b>Exhibit Number</b>	<b>Identification Of Exhibit</b>
10.6+	Second Amendment to 2000 Non-Employee Directors' Stock Option Plan. Exhibit 10.6 to the Company's Annual Report on Form 10-K for the year ended December 31, 2002 (the 2002 Form 10-K) is incorporated herein by reference.
10.7+	Zonagen, Inc. 2004 Stock Option Plan. Exhibit 10.17 to the Company's Registration Statement on Form S-1 (No. 333-119861), as amended, is incorporated herein by reference.
10.8+	Employment Agreement between the Company and Joseph S. Podolski. Exhibit 10.5 to the Registration Statement is incorporated herein by reference.
10.9+	First Amendment to Employment Agreement between the Company and Joseph S. Podolski. Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2001 is incorporated herein by reference.
10.10+	Second Amendment to Employment Agreement between the Company and Joseph S. Podolski. Exhibit 10.17 to the 2002 Form 10-K is incorporated herein by reference.
10.11+	Amended and Restated Employment Agreement between the Company and Louis Ploth, Jr. dated December 23, 2005. Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Commission on December 23, 2005 is incorporated herein by reference.
10.12	Lease Agreement dated May 11, 2004 between the Company and Sealy Woodlands, L.P. Exhibit 10.14 to the Company's Annual Report on Form 10-K for the year ended December 31, 2004 is incorporated herein by reference.
10.13++	Letter Agreement dated July 15, 2002 between the Company, Schering Plough Ltd. and Schering-Plough Corporation. Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2002 is incorporated herein by reference.
10.14++	PHS Patent License Agreement dated April 16, 1999 between the Company and certain agencies of the United States Public Health Service within the Department of Health and Human Services, with amendments. Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2003 is incorporated herein by reference.
23.1*	Consent of PricewaterhouseCoopers LLP
31.1*	Certification Pursuant to Rule 13(a)-14(a) or 15(d)-14(a) of the Exchange Act, As Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (Chief Executive Officer)
31.2*	

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Certification Pursuant to Rule 13(a)-14(a) or 15(d)-14(a) of the Exchange Act, As Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (Chief Financial Officer)

32.1\* Certification Furnished Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Chief Executive Officer)

32.2\* Certification Furnished Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Chief Financial Officer)

\* Filed herewith.

+ Management contract or compensatory plan.

++ Portions of this exhibit have been omitted based on a request for confidential treatment pursuant to Rule 24b-2 of the Exchange Act. Such omitted portions have been filed separately with the Commission.

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