REPROS THERAPEUTICS INC.
Form 10-K
March 14, 2007

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**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**
**Washington, D.C. 20549**

**Form 10-K**

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
**For the fiscal year ended December 31, 2006**

**or**

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
**For the transition period from to**
**Commission File No. 001-15281**

**Repros Therapeutics Inc.**
*(Exact name of registrant as specified in its charter)*

| **Delaware** | **76-0233274** |
|---|---|
| *(State or other jurisdiction of incorporation or organization)* | *(IRS Employer Identification No.)* |
| **2408 Timberloch Place, Suite B-7 The Woodlands, Texas** | **77380** |
| *(Address of principal executive offices)* | *(Zip Code)* |

**(281) 719-3400**
**(Registrant s telephone number, including area code)**

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

| **Title of Each Class** | **Name of Each Exchange on Which Registered** |
|---|---|
| Common Stock, $.001 par value | The NASDAQ Stock Market LLC |
| Rights to purchase Series One Junior Participating Preferred Stock | The NASDAQ Stock Market LLC |

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

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

Yes o No þ

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the 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 þ No o

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer 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 o Accelerated filer þ Non-accelerated filer o

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

The aggregate market value of the voting stock held by non-affiliates of the registrant was approximately $81,475,000 as of June 30, 2006, 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 $8.14 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, 2007, there were 12,774,295 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 2007 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, 2006, are incorporated by reference into Part III of this Form 10-K.

**REPROS THERAPEUTICS INC**
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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 our 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**

Repros Therapeutics Inc., formerly known as Zonagen, Inc. ( the Company , RPRX, or we, us or our ), was organized on August 28, 1987. We are a development stage biopharmaceutical company focused on the development of new drugs to treat hormonal and reproductive system disorders. We are developing Proellex, a selective blocker of the progesterone receptor in women, for the treatment of uterine fibroids and endometriosis. We are also developing Androxal, which causes increased testosterone secretion from the testes, for the treatment of testosterone deficiency in men resulting from secondary hypogonadism. During December 2006 we conducted interim analyses of each of our three ongoing clinical trials to determine whether our calculation regarding the number of patients enrolled in each study is appropriate and to assess whether further clinical development of each product candidate, beyond completion of the current trials, is warranted. These interim analyses were conducted internally and were not audited by a third party. Upon completion of each of these trials, we will complete formal analyses of efficacy and safety data and hold discussions with the appropriate regulatory agencies about further clinical development requirements.

An interim analysis of our ongoing U.S. Phase 2 clinical trial of Proellex in uterine fibroid patients demonstrated statistically significant reductions in excessive menstrual bleeding and an improvement in quality of life scores versus placebo. Furthermore, after three months treatment, no statistically significant change in endometrial thickness was observed. An interim analysis of our ongoing European endometriosis Phase 1/2 clinical trial of Proellex demonstrated that treatment with the highest dose of Proellex, 50 mg, achieved statistically significant reduction in days of pain compared to treatment with Lupron®, the current pharmaceutical standard of care for the treatment of endometriosis.

We have completed a U.S. Phase 1/2 clinical trial and an interim analysis from an ongoing non-pivotal U.S. Phase 3 trial of Androxal for the treatment of testosterone deficiency in men resulting from secondary hypogonadism. Both trials demonstrated statistically significant increases in testosterone levels versus placebo, without suppression of luteinizing hormone, or LH. In our current U.S. Phase 3 trial, at three months, Androxal restored testosterone levels to the normal range in over 80% of patients treated.

We also continue to maintain our patent portfolio on our phentolamine-based products for the treatment of sexual dysfunction. We continue to try to create value from these assets in various ways which includes product out-licensing.

On February 5, 2007, we completed a public offering of 2,610,000 shares of our common stock at a purchase price of $13.75 per share. As a result of the offering, we received approximately $33.0 million in net proceeds which we intend to use to continue our clinical development of Proellex and Androxal.

Our product development pipeline is summarized in the table below:

| Product Candidate | Indication | Current Phase of Development | Estimate of Completion of Current Phase[(1)] |
|---|---|---|---|
| Proellex | Uterine fibroids | Phase 2 (U.S.) | Full U.S. Phase 2 data (mid-2007) One year interim extension data (4Q2007) Initiate Pivotal trials (YE2007) |
| | Endometriosis | Phase 1/2 (Europe) | Full Phase 1/2 data (3Q2007) |

| | | | |
|---|---|---|---|
| | | | Initiate U.S. Phase 2 (mid-2007) |
| Androxal | Male Secondary Hypogonadism | Non-pivotal Phase 3 (U.S.) | Full non-pivotal Phase 3 data (3Q2007)<br>Initiate first pivotal Phase 3 (YE2007) |

(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

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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. We currently have no collaborators on the development of any of our product candidates.

**Business Strategy**

Our primary business strategy is to concentrate our resources on the clinical development of Proellex and Androxal. We intend to continue 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. If necessary, we will seek to access the capital markets at appropriate times based on our clinical trial results and development needs.

**Proellex**

*Market Overviews*

Our lead product candidate, Proellex, is an orally active small molecule which we are developing for two indications: the treatment of uterine fibroids and the treatment of endometriosis. The National Uterine Fibroid Foundation estimates that as many as 80% of all women in the United States have uterine fibroids, and one in four of these women have symptoms severe enough to require treatment. According to The Endometriosis Association, endometriosis affects 5.5 million women in the United States and Canada and millions more worldwide.

The current standards of care for uterine fibroids and endometriosis include surgery and treatment with drugs. The most effective drugs on the market are gonadotropin releasing hormone agonists, or GnRH agonists, such as Lupron (leuprolide acetate). GnRH is a peptide hormone that plays an important role in the regulation of the human reproductive system. Chronic administration of GnRH agonists reduce the number of GnRH receptors and thereby block the action of GnRH and its activity in stimulating the pituitary to secrete follicle stimulating hormone and leuteinizing hormone.

GnRH agonists induce a low estrogen, menopausal-like state in women. Because estrogen is necessary for the maintenance of bone mineral density, GnRH agonists tend to promote bone loss and are not recommended to be used for more than six months at a time. When women cease treatment with GnRH agonists, fibroids generally regenerate rapidly in the case of uterine fibroids, and symptoms associated with endometriosis generally reappear quickly in the case of endometriosis.

We believe Proellex may have advantages in treating uterine fibroids and endometriosis as compared to treatment with GnRH agonists. In our previous and current human clinical trials, and consistent with our preclinical studies, women treated with Proellex maintain baseline estrogen levels. Therefore, we believe Proellex treatment may not

result in estrogen-mediated loss of bone mineral density. We believe Proellex may provide an attractive alternative to surgery because of its potential to treat these conditions in a long-term or chronic fashion, resolving the symptoms that most commonly lead to surgical treatment.

Proellex is a new chemical entity, which means that the compound will be required to undergo the full regulatory approval process. Among other requirements, this includes a two-year carcinogenicity study, which we began in mid-2006. We have also completed a nine-month primate study to evaluate the effects of Proellex on the endometrium. This study showed no significant toxicity at any dose, with the highest dose comparable to the highest dose in our human clinical trials.

All clinical trial results are subject to review by the U.S. Food and Drug Administration, or FDA, and the FDA may disagree with our conclusions about safety and efficacy. We caution that the results discussed herein are based on interim data from non-pivotal trials and that final Phase 2 and 3 data may not agree with these interim results.

*Uterine Fibroids*

Current Phase 2 Trial. We have completed enrollment of 128 patients in a randomized, double-blind, placebo-controlled U.S. Phase 2 clinical trial of Proellex. We are enrolling patients that complete the blinded portion of this trial in a 12-month open label extension to gather additional safety data. This trial is designed to assess both improvement of symptoms associated with uterine fibroids as well as effects on the fibroid itself. The three-arm trial compares two doses of Proellex, 12.5 mg and 25 mg, to placebo over a 12-week period. The primary endpoint is reduction in excessive menstrual bleeding, a common symptom of uterine fibroids. This endpoint was assessed using a visual analog scale known as the Pictorial Blood Loss Assessment Chart, also known as PBAC. Further, pain associated with fibroids was assessed using a well validated tool, the McGill pain score, and various other symptoms associated with fibroids were assessed using the validated Uterine Fibroid Symptom and Quality of Life, or UFS-QOL, questionnaire.

In December 2006, we announced an interim analysis of data from this trial. At that time of analysis, 63 patients had completed the 12-week trial and had completed analyses for their trial parameters. The data indicate that the women on Proellex in this trial experienced a dramatic reduction in PBAC from mean scores of over 100 to scores less than 10, where higher scores indicate greater

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pain. The mean scores after three months of dosing for the 25 mg and 12.5 mg dose of Proellex were 6.9 and 12.6, respectively. Women on placebo, on the other hand, exhibited a score of 91 after three months of treatment. The scores above represent a percentage reduction in PBAC scores for placebo, the 12.5 mg arm of Proellex and the 25 mg arm of Proellex of 30.7%, 92.2% and 94.7%, respectively. The 12.5 mg and 25 mg doses were statistically superior to placebo.

**Pictorial Blood Loss Assessment Baseline versus Month 3**

Women treated with 12.5 mg and 25 mg of Proellex for three months also experienced a reduction in UFS-QOL measures from an average baseline of 16 to scores of 5.3 and 5.15, respectively. UFS-QOL scores for women in the placebo arm decreased from an average baseline of 16 to 12.6 after three months. The 12.5 mg and 25 mg doses were statistically significant as compared to placebo.

Women on Proellex experienced on average a reduction of 33.6 and 33.2 in McGill pain scores for the 25 mg and 12.5 mg dose respectively. Women on placebo experienced an average reduction of 8.4 over the same three-month period. The 12.5 mg and 25 mg doses were statistically superior to placebo.

After three months on treatment, no statistically significant changes in endometrial thickness were detected among 100 women who underwent ultrasound measurements of endometrial thickness at various time points. This trial uses an endometrial thickness cut-off of 14 mm after three months of dosing to determine whether or not a woman is allowed to proceed into an ongoing open label trial. At this time 16 patients have had endometrial thicknesses greater than 14 mm. Seven of the patients were on placebo, six were on the 12.5 mg dose and three were on the 25 mg dose. Importantly, to date, of the women who have had endometrial biopsies and have been on active drug there has been no evidence of endometrial hyperplasia with atypia, a potential precursor for endometrial cancer. We did not undertake a statistical analysis of safety data in our interim assessment for this trial. In our previous clinical trial of Proellex for the treatment of uterine fibroids, none of the patients in the Proellex dose arms or placebo arms of such trial exhibited any statistically significant changes in biomarkers for bone resorption while patients on Lupron exhibited statistically significant increases in biomarkers of bone resorption. The most frequent adverse event observed in our current trial was amenorrhea, or lack of menstrual bleeding, which is expected based on our previous clinical data for Proellex as well as its mechanism of action.

We have complied with an FDA request by forming an outside safety review board. The board reviews unblinded safety data from the trial and has the ability to halt the trial at any time if it determines that the data indicates that Proellex is not safe. To date, the board has taken no action based on its ongoing review of our safety data other than to report the patient described below with elevated liver enzymes as a serious adverse event. We have had two patients in this trial exhibit serious adverse events, one of which was on placebo. The other patient, who was in the 25 mg arm of our trial, exhibited elevated liver enzymes. After review of the patient by a physician, it was determined that the liver enzymes were not seriously elevated.

Development Plan

We intend to discuss our pivotal clinical program with the FDA in mid-2007. We currently anticipate that the pivotal program will include two additional placebo-controlled clinical trials to demonstrate efficacy, which we expect to begin around year-end 2007. As with our current trial, the primary endpoint will be reduction in PBAC versus placebo. PBAC is a validated and published questionnaire designed to measure menorrhagia, or blood loss related to excessive menstrual bleeding. Pursuant to FDA requirements, we are currently validating the PBAC endpoint for Proellex for uterine fibroids. We anticipate completing this validation prior to commencing a Phase 3 clinical trial. Consistent with current regulatory policies, we will have to complete a number of additional safety-focused clinical trials and preclinical studies, including the effect of Proellex on the QT interval, a measure of the heart rate designed to provide information about potential arrhythmia. We also expect to begin a larger open-label safety trial in late 2007. We believe the earliest we can submit a New Drug Application, or NDA, for this indication would be in the fourth quarter of 2008.

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*Endometriosis*

Current Phase 1/2 Trial. We are currently conducting a six-month Phase 1/2 clinical trial of Proellex in 39 endometriosis patients in a European trial being conducted in Bulgaria. The primary objective of this trial is to assess the safety of Proellex in endometriosis patients. We consider this trial to be a pilot trial with efficacy being a secondary objective, and we designed the trial to determine whether we would commence development of Proellex for endometriosis in the United States. We completed enrollment in October 2006. This trial compares three doses of double-blinded Proellex against open label Lupron for up to six months of treatment. Proellex was administered in a double-blind manner as a daily oral dose of 12.5 mg, 25 mg or 50 mg capsules. Patients in the trial maintained daily pain diaries to record severity and frequency of pain as well as filling out an endometriosis symptom survey at each office visit that included a questionnaire that evaluated, among other related elements, distress associated with pain on a scale of 0-10 with 10 being the greatest amount of distress. Although this trial was primarily designed to assess safety, we evaluated patient responses to multiple exploratory pain-related endpoints.

As of December 2006, 34 women of the 39 enrolled had completed three months of dosing. We conducted an interim analysis of data from these women. These data demonstrate that treatment with the highest dosage of Proellex, 50 mg, achieved statistically significant pain reduction compared to treatment with Lupron, the current pharmaceutical standard of care for the treatment of endometriosis. On average, women treated with 50 mg Proellex reported 85.5 pain free days during three months of treatment which amounts to 95% of the study days, compared to 61 pain free days, or 67.8% of study days, reported by patients on Lupron, a statistically significant difference ($p=0.02$). Patients treated with 25 mg and 12.5 mg Proellex exhibited a dose-dependent reduction in pain that did not reach statistical significance compared to Lupron (71.9% and 49.4% of study days pain free, respectively). On days when pain was reported, the 50 mg dose of Proellex also exhibited a statistically significant improvement in pain severity over Lupron ($p=0.02$) as well as over the 25 mg and 12.5 mg doses of Proellex.

Women treated with 50 mg Proellex also reported a significant reduction in pain-associated distress after three months with only one woman reporting mild distress (scored at 1). Average distress score for the 50 mg group was 0.125. Compared to baseline (average 50 mg group baseline distress score was 6.8 out of 10 possible), the 50 mg dose of Proellex exhibited a highly statistically significant reduction in distress score ($p <0.001$). Women treated with Lupron also reported a significant, but less robust, reduction in pain-associated distress (average score equal to 1.4 compared to average baseline score of 5.8). In this trial, we evaluated patient responses to a non-validated questionnaire that contained eight questions relating to the number of days with pain, severity, location and type of pain and distress. Overall, our data indicate a favorable treatment effect for Proellex. For example, with respect to one of the questions, women in the 50 mg arm reported a 98% reduction in days of pain compared to baseline ($p=0.009$) whereas women in the Lupron arm reported a 76% reduction in recollected days of pain compared to baseline (change not significant).

The 12.5 mg and 25 mg doses of Proellex exhibited a dose-dependent reduction in distress as measured by pain scores, but the reductions did not achieve statistical significance (3.2 compared to 6.7 baseline for 25 mg and 3.8 compared to 4.8 baseline for 12.5 mg).

On average, the women in this treatment group receiving Lupron in the trial experienced a reduction of estrogen to post-menopausal levels. Consistent with other clinical trials of Lupron, women in this treatment group also experienced a statistically significant increase in biomarkers of bone resorption and therefore an increased risk of bone loss over time. Significantly, all doses of Proellex maintained estrogen concentrations in the low normal range. Furthermore, there were no significant changes in biomarkers of bone resorption in any of the dose arms of Proellex.

The data also suggest an inverse dose dependent effect on endometrial thickness as measured by ultrasound at baseline and three months. After three months on treatment, women receiving 50 mg Proellex achieved a non-significant reduction in the thickness of the endometrium compared to baseline, whereas women receiving 12.5 mg and 25 mg Proellex experienced a non-significant thickening of the endometrium. Importantly, no women in the trial showed evidence of endometrial hyperplasia with atypia, a potential precursor for endometrial cancer.

In this clinical trial to date, side effects of Proellex were generally mild with no apparent drug-related toxicity to the liver. In two cases where non-menstrual spotting and bleeding was observed in patients with excessive endometrial thickening, a dilation and curettage procedure was administered to stop the bleeding. These cases occurred only at the

lower doses of Proellex. A similar event has not been seen at the 50 mg dose even though two of the patients have completed the 6-month trial. We are enrolling patients that complete the randomized portion of this trial into a 12-month open label extension to gather additional safety data.

Development Plan

We intend to submit a separate IND with the FDA for Proellex for the treatment of endometriosis in the second quarter of 2007. With a favorable review of this IND by the FDA, we plan to initiate a Phase 2 clinical trial of Proellex for the treatment of

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endometriosis around mid-year 2007. We expect that this trial will compare 25 mg and 50 mg of Proellex to placebo. The primary endpoint of this trial will be a clinically validated measure of dysmenorrhea, or pelvic pain.

All clinical trial results are subject to review by the FDA and the FDA may disagree with our conclusions about safety and efficacy. We caution that results obtained in early stage clinical trials may be reversed by the results of later stage clinical trials with significantly larger and more diverse patient populations treated for longer periods of time.

**Androxal**

*Market Overview*

Our second product candidate, Androxal (the *trans* isomer of clomiphene), is designed to restore normal testosterone production in males with functional testes yet 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, as compared to currently approved products that simply replace diminished testosterone either through injections, nasal spray or the application of a gel or cream containing testosterone over a large percentage of body area. The administration of replacement testosterone has been linked to numerous potential adverse effects, including shrinkage of the testes. We believe that Androxal may not cause these adverse effects to the extent that such other replacement therapies do. We will require additional clinical trials with more patients and for a longer duration.

Testosterone is an important male hormone. Testosterone deficiency in men is linked to several negative physical and mental conditions, including loss of muscle tone, reduced sexual desire, and deterioration of memory and certain other cognitive functions. Testosterone production normally decreases as men age, sometimes leading to testosterone deficiency. According to industry sources, approximately 13 million men in the United States experience testosterone deficiency. The leading therapy is Androgel, a commercially available testosterone replacement cream marketed by Solvay Pharmaceuticals for the treatment of low testosterone, with reported sales of approximately $282 million in 2005 in North America.

Based on our own screening data, we believe over 70% of men that have low testosterone suffer from secondary hypogonadism, caused by failure of the pituitary to provide appropriate hormone signaling to the testes, which we believe causes testosterone levels to drop to the point where pituitary secretions fall under the influence of estrogen. In this state, we also believe that estrogen further suppresses the testicular stimulation from the pituitary. These men are readily distinguished from those that have primary testicular failure via assessment of the levels of secretions of pituitary hormones (i.e., men with primary testicular failure experience elevated secretions of pituitary hormones). The 194 patients enrolled were determined to have secondary hypogonadism, which is caused by the pituitary deficiency described above. Secondary hypogonadism is not relegated only to older men although the condition becomes more prevalent as men age.

Androxal is being considered as a new chemical entity by the FDA which means that the compound will be required to undergo the full regulatory approval process. Among other requirements, this includes a two-year carcinogenicity study, which we began in September 2006. Although Androxal is considered a new chemical entity for purposes of requirements for approval, it is closely related chemically to the drug, Clomid, which is approved for use in women to treat certain infertility disorders. The FDA has indicated that testicular tumors, gynecomastia and adverse ophthalmologic events, which have been reported in males taking Clomid, are potential risks that should be included in informed consent forms for our Androxal clinical trials. We do not believe that Androxal will present with the same adverse events given its accelerated half-life in the human body as compared to Clomid. In our preclinical studies and our current clinical trial to date, we have observed no evidence of any of these events except for certain adverse ophthalmologic events in our preclinical study at doses significantly higher than those administered in the clinical trials.

We have had previous discussions with the FDA regarding a special protocol assessment, or SPA, for our registrational program for Androxal. When we complete our current Phase 3 trial and validate our clinical endpoint, we intend to review the data with the FDA and continue the SPA process.

*Current Non-Pivotal Phase 3 Trial*

We are currently conducting a 24-week 194 patient U.S. Phase 3 clinical trial of Androxal in men with testosterone deficiency resulting from secondary hypogonadism. We consider this trial to be non-pivotal for U.S. approval.

However, it may serve as one of two pivotal efficacy trials for approval in the European Union. We are enrolling patients that have completed the 24-week trial into a 12-month open label extension to gather additional safety data. Interim data from this trial suggest that, at this time in the trial, treatment with Androxal results in a statistically significant increase in mean testosterone. Further, Androxal demonstrates non-inferiority in all parameters measured, in all the primary endpoints of the trial, compared to Androgel.

This double-blind trial compares two doses of Androxal, 12.5 mg and 25 mg, to both placebo and open-label Androgel, which was dosed according to physician instructions (including use of higher doses where indicated). Testosterone levels as well as subjective measures of libido and distress were assessed in trial participants. Distress was assessed using an unvalidated measure. The

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primary endpoint of this trial is non-inferiority of Androxal in comparison to Androgel. During December 2006, 112 patients completed 12 weeks of treatment and have had analyses completed for their trial parameters.

In this interim analysis, men treated with 12.5 mg of Androxal experienced an increase in mean testosterone of 210 ng/dL over baseline; those treated with 25 mg of Androxal experienced an increase of 241 ng/dL over baseline; and those treated with open-label Androgel, administered at any dose, experienced an increase of 167 ng/dL over baseline. As expected, men receiving placebo experienced no statistically significant change in mean testosterone. After three months, the percentage of men with a morning testosterone level above 300 ng/dL and below 1,040 ng/dL (the range of testosterone levels in the blood generally considered normal) for placebo, Androgel, the 12.5 mg arm of Androxal and the 25 mg arm of Androxal were 26.7%, 58.6%, 81.5% and 80.8%, respectively. The changes versus baseline for the 12.5 mg and 25 mg arms were statistically significant.

Although neither men treated with Androxal nor those treated with Androgel reported a significant increase in libido as determined using the DeRogatis Interview for Sexual Functioning, also known as the DISF-SR scale, at this interim analysis, both doses of Androxal performed comparably to Androgel. Likewise, although no statistically significant differences in distress, as measured by the Male Sexual Dysfunction Survey, or MSDS scale, were recorded for men receiving Androxal or Androgel, both doses of Androxal performed in similar fashion to Androgel. Numerically, the 25 mg dose of Androxal produced the greatest reduction in distress followed by the 12.5 mg dose. Both the DISF-SR, a validated libido questionnaire, and the MSDS, a questionnaire focusing on distress associated with low testosterone, have been developed by Dr. Leonard DeRogatis, Ph.D., Director of the Center for Sexual Medicine at Sheppard Pratt, a private non-profit provider of behavioral health services based in Maryland.

Although safety data for emergent side effects has not been completed during our interim analysis, we have found no adverse events of concern in the trial. There was one reported serious adverse event reported during the trial for one patient on placebo, but we have no additional information relating to this event.

All clinical trial results are subject to review by the FDA and the FDA may disagree with our conclusions about safety and efficacy. We caution that the results discussed herein are based on interim data and that final data may not agree with these interim results.

*Development Plan*

Unlike testosterone replacement therapies in which efficacy can be shown through mere elevation of testosterone levels back to normal ranges, the FDA has noted that Androxal must demonstrate a benefit over placebo on a relevant clinical endpoint. We intend to comply with the FDA s request, develop a validated clinical test and revise our proposed Phase 3 pivotal efficacy protocol to incorporate the FDA s other suggestions. We anticipate that this trial will begin around the end of 2007, subject to available funding and timely and successful completion of our initial Phase 3 trial. Consistent with guidance for approval of new chemical entities, we believe that we will be required to study Androxal s effect on the QT interval.

**Other Products**

We are continuing our limited development assessment and out-licensing efforts for our phentolamine-based product candidates, including VASOMAX®, which had previously been approved for marketing in several countries in Latin America for the treatment of male erectile dysfunction under the brand name, Z-Max. These products have been on partial clinical hold in the United States since 2000 due to brown fat being discovered in a two-year rat carcinogenicity study. The United States is the only country where phentolamine-based products to treat sexual dysfunction are on partial clinical hold. During the first quarter 2006, we met with the Ministry of Health in Mexico regarding our second generation phentolamine-based products for the treatment of erectile dysfunction: Bimexes , an oral therapy for men with mild to moderate impotence, and ERxin , an injectable therapy for the treatment of severe erectile dysfunction. Initial assessment of the outcome from this meeting suggests that both drugs could potentially be approved in Mexico after completion of a successful single positive controlled registration trial to the satisfaction of the Mexican Ministry of Health. Approval in Mexico can potentially lead to approvals in other Latin American countries. We believe the current Latin American market for erectile dysfunction therapies exceeds $230 million annually.

**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 2006 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. We believe that these expenses will continue to be our primary R&D expenses in the near future.

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**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. 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**

Currently, we do not have the ability internally to manufacture the product candidates that we need to conduct our clinical trials. We recently entered into a development and supply contract with Gedeon Richter for the production of the active pharmaceutical ingredient, or API, for Proellex due to their extensive experience in the manufacture of similar compounds and the cost savings they offered compared to other qualified manufacturers. Pursuant to the terms of this supply contract, we are required, with certain limited exceptions, to purchase all of our future requirements of Proellex from this single supplier for a period of five years after the first sale of Proellex in the United States, to the extent that such supplier is able to satisfy our requirements. The contract may be terminated by either party for failure to remedy a default of any material provision of the contract. Should the contract be terminated for any reason, we would in all likelihood be required to obtain the API from an alternate manufacturer which may increase the costs associated with our clinical trials and result in delays to our clinical trial program for Proellex.

We have no long-term contract with suppliers of Androxal. 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. 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.

**Sales and Marketing**

We have no experience in the sales, marketing and distribution of pharmaceutical products. We anticipate that we will outsource 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.

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**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.

Under a license agreement with the National Institutes of Health, we have exclusive rights to three issued U.S. patents, which expire in 2017, and a foreign filing made by the NIH regarding Proellex. We also have five provisional U.S. patent applications and two non-provisional patent applications pending in the United States and one foreign PCT application that cover various formulations of Proellex and methods for using Proellex.

Our Androxal product candidate and its uses are covered in the United States by three pending patent applications and one issued U.S. patent. Foreign coverage of our Androxal product candidate includes two issued foreign patents and 25 foreign pending patent applications and three PCT applications. The issued patents and pending applications relate to methods and compositions for treating certain conditions including the treatment of testosterone deficiency in men. Androxal (the *trans* isomer of clomiphene) is purified from clomiphene citrate. A third party individual holds two issued patents related to the use of an anti-estrogen such as clomiphene citrate and others 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 one of these patents based on prior art. The third party amended the claims in the reexamination proceedings, which has since led the PTO to determine that the amended claims are patentable in view of those publications under consideration and a reexamination certificate was issued. However, we believe that the amended claims are invalid based on additional prior art publications, and our request for reexamination by the PTO in light of a number of these additional publications and other publications cited by the PTO, has been granted. We also believe that the second of these two patents is invalid in view of published prior art not considered by the PTO. A request for reexamination of this patent is pending. Nevertheless, there is no assurance that either patent will ultimately be found invalid over the prior art. If such patents are not invalidated, we may be required to obtain a license from the holder of such patents in order to develop Androxal further. If such licenses were not available on acceptable terms or at all, we may not be able to successfully 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.

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

The standard process required by the FDA before a pharmaceutical agent may be marketed in the United States includes: (1) preclinical tests; (2) submission to the FDA of an 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 a new drug application, or NDA, to the FDA; and (5) FDA approval of the NDA prior to any commercial sale or shipment of the drug.

Clinical trials typically are conducted in three sequential phases, but the phases may overlap. Phase 1 typically involves the initial introduction of the drug into human subjects. In phase 1, the drug is tested for safety and, as appropriate, for absorption, metabolism, distribution, excretion, pharmacodynamics and pharmacokinetics. Phase 2 usually involves studies in a limited patient population to evaluate preliminarily the efficacy of the drug for specific targeted indications, determine dosage tolerance and optimal dosage and identify possible adverse effects and safety risks.

Phase 3 clinical trials are undertaken to further evaluate clinical efficacy and to test further for safety within an expanded patient population at geographically dispersed clinical study sites. Phase 1, Phase 2 or Phase 3 testing may not be completed successfully within any specific time period, if at all, with respect to any products being tested by a sponsor. Furthermore, the FDA or the Investigational Review Board, or IRB may suspend clinical trials at any time on various grounds, including a finding that the healthy volunteers or patients are being exposed to an unacceptable health risk.

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 drug-manufacturing establishment supplying the United States must be registered with the FDA. Manufacturing establishments are subject to periodic inspections by the FDA and must comply with the FDA s requirements regarding current Good Manufacturing Practices, or GMP. In complying with current GMP, 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

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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 approval of an abbreviated new drug application, or ANDA, for a generic version of the drug during the five-year exclusivity 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 time of active FDA review 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 and within 60 days of the approval of the NDA. 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**

On August 21, 2006 we transferred the listing of our common stock from the NASDAQ Capital Market to the NASDAQ Global Market under our ticker symbol, RPRX. Effective January 8, 2007, we voluntarily withdrew the

listing of our common stock from NYSE Arca, Inc., formerly the Pacific Exchange, in order to streamline administrative requirements and reduce expenses.

**Employees and Consultants**

*Employees*

At March 11, 2007, we had 8 full-time employees. We also utilize part-time consultants as well as

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contract research organizations and other outside specialty firms for various services such as clinical trial support, manufacturing and regulatory approval advice. We may hire up to five employees over the next two years. 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, if appropriate, 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

*You should carefully consider the risks described below before making an investment decision. You should also refer to the other information in this report, including our financial statements and the related notes incorporated by reference. The risks and uncertainties described below are not the only risks and uncertainties we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. If any of the following risks actually occur, our business, results of operations and financial condition could suffer. In that event the trading price of our common stock could decline, and you may lose all or part of your investment in our common stock. The risks discussed below also include forward-looking statements and our actual results may differ substantially from those discussed in these forward-looking statements.*

### *Risks Relating to Our Business*

*Our product candidates are at an early clinical 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. Androxal is in a 194 patient non-pivotal Phase 3 safety trial in the United States for the treatment of men with testosterone deficiency, and Proellex is presently in a 128 patient Phase 2 trial in the United States for the treatment of uterine fibroids and in a 39 patient Phase 1/2 trial in Europe for the treatment of endometriosis. Based on our current interim data from the Phase 1/2 trial for Proellex for the treatment of endometriosis, we intend to submit a U.S. investigational new drug application, or IND, to the U.S. Food and Drug Administration, or FDA. We have expended significant time, money and effort in the development of Proellex and Androxal, 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 our 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 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. In addition, these studies have not been subjected to the exacting design requirements typically required by FDA for pivotal trials. Thus the limited data we have obtained may not predict results from studies in larger numbers of patients drawn from more diverse populations, and may not predict the ability of Proellex to treat uterine fibroids and endometriosis or Androxal to treat testosterone deficiency. We will be required to

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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 together with the $33.0 million from our 2007 offering are expected to be sufficient to fund our operations into 2008, depending on the timing and success of our clinical trials. Thereafter 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 candidate 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 cost involved in obtaining regulatory approvals;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims; and
- competing technological and market developments.

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

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

We have experienced significant operating losses in each fiscal year since our inception. As of December 31, 2006, we had an accumulated deficit of approximately $108.3 million. We expect to continue incurring net losses and we may not achieve or maintain profitability for some time if at all. As we increase expenditures for the 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 and Androxal, obtaining regulatory approvals, establishing marketing, sales and manufacturing capabilities or collaborative arrangements with others that possess such capabilities, and raising sufficient funds to finance our activities. There can be no assurance that we will be able to achieve profitability or that profitability, if achieved, can be sustained.

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

We may raise additional funds through public or private equity offerings, debt financings or corporate collaborations and licensing arrangements. We cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that we raise additional capital by issuing equity securities, our stockholders ownership will be diluted. Any debt financing we enter into

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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.

*Our stock price could decline significantly based on the results and timing of clinical trials of, and decisions affecting, our product candidates.*

Results of clinical trials and preclinical studies of our current and potential product candidates may not be viewed favorably by us or third parties, including the FDA or other regulatory authorities, investors, analysts and potential collaborators. The same may be true of how we design the clinical trials of our product candidates and regulatory decisions affecting those clinical trials. Biopharmaceutical company stock prices have declined significantly when such results and decisions were unfavorable or perceived negatively or when a product candidate did not otherwise meet expectations.

We recently commenced our non-pivotal Phase 3 clinical trial for Androxal in the United States for the treatment of men with testosterone deficiency and our Phase 2 clinical trial for Proellex in the United States for the treatment of symptoms associated with uterine fibroids. We also recently commenced a Phase 1/2 clinical trial in Europe for the treatment of women suffering from endometriosis. While interim results are encouraging, the final results from these programs may be negative, may not meet expectations or may be perceived negatively. The design of these clinical trials (which may change significantly and be more expensive than currently anticipated depending on our clinical results and regulatory decisions) may also be viewed negatively by third parties. We may not be successful in completing these clinical trials on our projected timetable, if at all.

Failure to initiate additional clinical trials or delays in existing clinical trials of Androxal and Proellex or any of our other current or future product candidates, or unfavorable results or decisions or negative perceptions regarding any of such clinical trials, could cause our stock price to decline significantly.

*Delays in the commencement of preclinical studies and clinical trials 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 studies and extensive clinical trials prior to the submission of a regulatory application for commercial sales. We recently commenced our non-pivotal Phase 3 clinical trial for Androxal in the United States for the treatment of men with testosterone deficiency and our Phase 2 clinical trial for Proellex in the United States for the treatment of symptoms associated with uterine fibroids. We also recently commenced a Phase 1/2 clinical trial for Proellex 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 preclinical studies and clinical trials 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:

- demonstrating sufficient safety and efficacy in past clinical trials to obtain regulatory approval to commence a further clinical trial;
- reaching agreements 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.*

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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:

- lack of effectiveness of any product candidate during clinical trials;
- side effects experienced by trial participants or other safety issues;
- slower than expected rates of patient recruitment and enrollment or lower than expected patient retention rates;
- delays or inability to manufacture or obtain sufficient quantities of materials for use in clinical trials;
- Inadequacy of or changes in our manufacturing process or compound formulation;
- delays in obtaining regulatory approvals to commence a trial, or clinical holds or delays requiring suspension or termination of a trial by a regulatory agency, such as the FDA, after a trial is commenced;
- changes in applicable regulatory policies and regulations;
- delays in identifying and reaching agreement on acceptable terms with prospective clinical trial sites;
- uncertainty regarding proper dosing;
- unfavorable results from on-going clinical trials and preclinical studies;
- failure of our clinical research organizations to comply with all regulatory and contractual requirements or otherwise fail to perform their services in a timely or acceptable manner;
- scheduling conflicts with participating clinicians and clinical institutions;
- failure to construct appropriate clinical trial protocols;
- insufficient data to support regulatory approval;
- inability or unwillingness of medical investigators to follow our clinical protocols;
- difficulty in maintaining contact with subjects during or after treatment, which may result in incomplete data;
- ongoing discussions with the FDA or other regulatory authorities regarding the scope or design of our clinical trials;
- acceptability to the FDA of data obtained from clinical studies conducted in Europe or other non-United States jurisdictions; and
- lack of adequate funding to continue clinical trials.

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.

If we experience delays in the completion of, or termination of, clinical testing of any product candidates in the future, our financial results and the commercial prospects for our product candidates will be harmed, and our ability to

generate product revenues will be delayed.

*Even if we successfully complete clinical trials for 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 studies and clinical trial data relevant to the safety and effectiveness of the product at the suggested dose and duration of use for the proposed indication, 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

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does reject NDAs and requires additional clinical trials, even when drug candidates achieve favorable results in large-scale Phase 3 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.

*The results of preclinical studies and completed clinical trials are not necessarily predictive of future results, and our current drug candidates may not have favorable results in later studies or trials.*

Preclinical studies and Phase 1 and Phase 2 clinical trials are not primarily designed to test the efficacy of a drug candidate, but rather to test safety, to study pharmacokinetics and pharmacodynamics, and to understand the drug candidate s side effects at various doses and schedules. To date, long-term safety and efficacy have not yet been demonstrated in clinical trials for any of our product candidates. Favorable results in our early studies or trials may not be repeated in later studies or trials, including continuing preclinical studies and large-scale clinical trials analyzed with more rigorous statistical methods, and our drug candidates in later-stage trials may fail to show desired safety and efficacy despite having progressed through earlier-stage trials. For example, clinical results that we have obtained for Androxal may not predict results from studies in larger numbers of subjects drawn from more diverse populations treated for longer periods of time. They also may not predict the ability of Androxal to achieve or sustain the desired effects in the intended population or to do so safely. Unfavorable results from ongoing preclinical studies or clinical trials could result in delays, modifications or abandonment of ongoing or future clinical trials. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Negative or inconclusive results or adverse medical events during a clinical trial could cause a clinical trial to be delayed, repeated or terminated. In addition, we may report top-line data from time to time, which is based on a preliminary analysis of key efficacy and safety data; such data may be subject to change following a more comprehensive review of the data related to the applicable clinical trial.

*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 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. 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:

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

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

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

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

Currently, we do not have the ability internally to manufacture the product candidates that we need to conduct our clinical trials. We recently entered into a long-term supply contract with Gedeon Richter for the production of the active pharmaceutical ingredient, or API, for Proellex due to their extensive experience in the manufacture of similar compounds and the cost savings they offered compared to other qualified manufacturers. Pursuant to the terms of this long-term supply contract, we are required, with certain limited exceptions, to purchase all of our future requirements of Proellex from this single supplier for a period of five years after the first sale of Proellex in the United States, to the extent that such supplier is able to satisfy our requirements. The contract may be terminated by either party for failure to remedy a default of any material provision of the contract. Should the contract be terminated for any reason, we would in all likelihood be required to obtain the API from an alternate manufacturer which may increase the costs associated with our clinical trials and result in delays to our clinical trial program for Proellex.

We have no long-term contract with suppliers of Androxal. 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. 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.

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

We cannot assure that we will be able to successfully increase the manufacturing capacity or scale-up manufacturing volume per batch, whether on our own or in reliance on third-party manufacturers, for any of our product candidates in a timely or economical manner, or at all. To date our product candidates have been manufactured exclusively by third parties in small quantities for preclinical studies and clinical trials. We have arranged for the production of significantly larger quantities of Proellex, and we will need to arrange for the production of significantly larger quantities of Androxal, for future clinical trials and for future commercial sale in the event that such product candidates are approved by the FDA or foreign regulatory bodies. Significant scale-up of manufacturing requires certain additional developmental work, which the FDA must review and approve to assure product comparability. 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 their 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

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result in patient injury or death, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could seriously hurt our business.

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

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

The FDA also requires that we demonstrate structural and functional comparability between the same drug product produced by different third-party manufacturers. Because we may use multiple sources to manufacture 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 and our clinical trial in Europe for Proellex for endometriosis. 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 neither provide adequate coverage nor may it always be available on favorable terms or at all.*

Neither Proellex nor Androxal has been approved for commercial sale. However, the current and future use of our product candidates by us and potential corporate collaborators in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims might be made directly by consumers or healthcare providers or indirectly by pharmaceutical companies, potential corporate collaborators or others selling such products. We may experience financial losses in the future due to product liability claims. We have obtained limited general commercial liability insurance coverage for our clinical trials. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for any of our product candidates. However, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or for liabilities in excess of our insurance limits, our assets may not be sufficient to cover such claims and our business operations could be impaired.

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

We are engaged in biopharmaceutical product development, an industry that is characterized by extensive research efforts and rapid technological progress. The biopharmaceutical industry is also highly competitive. Our success will depend on our ability to acquire, develop and commercialize products and our ability to establish and maintain markets for 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.

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Many of our competitors have substantially greater research and development and regulatory capabilities and experience, and substantially greater management, manufacturing, distribution, marketing and financial resources, than we do. Accordingly, our competitors may:

- develop or license products or other novel technologies that are more effective, safer or less costly than the product candidates that we are developing;
- obtain regulatory approval for products before we do; or
- commit more resources than we can to developing, marketing and selling competing products.

The main therapeutic products competitive with 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 3 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 would compete with Proellex, if approved, 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.

*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 eight full-time employees at the present time, including our President and CEO, Joseph S. Podolski, our Vice President, Business Development and CFO, Louis Ploth, Jr. and our Senior Vice President and Chief Medical Officer, Dr. Andre van As. We are highly dependent on Messrs. Podolski and Ploth and Dr. van As for the management of our company and the development of our technologies. Messrs. Podolski and Ploth and Dr. van As have employment agreements with us. There can be no assurance that Mr. Podolski, Mr. Ploth or Dr. van As 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, Mr. Ploth or Dr. van As 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. We may hire up to five 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 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 may incur increased costs as a result of laws and regulations relating to corporate governance matters.*

Laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002, or Sarbanes-Oxley, and rules adopted or proposed by the Securities and Exchange Commission, or SEC, and by NASDAQ, will result in increased costs to us as we evaluate the implications of any new rules and respond to their requirements. We are currently an accelerated filer and, as a result, are subject to additional regulatory requirements, including Section 404 of Sarbanes-Oxley which requires us to include in our annual report for the period ending December 31, 2006 a report by management on our internal control over financial reporting and an accompanying auditor s report. Additionally, new rules could make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. We cannot predict or estimate the amount of the additional costs we may incur or the timing of such costs to comply with such new rules and regulations.

***Risks Relating to Our Intellectual Property***

*We licensed our rights to Proellex from 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 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. We periodically update the commercial development plan as such plans evolve. There can be no assurance that we will be able to meet any or all of the performance objectives in the future on a timely basis or at all, or that, if we fail to meet any of such objectives, NIH will agree to revised objectives. NIH has the ability to terminate the agreement for an uncured material breach of the agreement, if we made a false statement or willful omission in our license application, if we do not keep Proellex reasonably available to the public after commercial launch, if we cannot reasonably satisfy unmet health and safety needs, or if we cannot reasonably justify a failure to comply with the domestic production requirement unless such requirement has been waived. As previously described, we recently entered into a supply agreement with Gedeon Richter, a non-U.S. based company, to manufacture the API for Proellex, for final packaging in the United States.

We are in the process of obtaining clarification with respect to the domestic production requirement from NIH or, if necessary, a waiver and acknowledgement of the current commercial development plan. If NIH does not grant the acknowledgement and either clarify, or grant us a waiver with respect to this domestic production requirement, we may be required to either engage another manufacturer to make the API for Proellex or risk being in breach of the license agreement. Should NIH terminate the license agreement, we would lose all rights to commercialize Proellex, which would harm our business. We also have five patent applications pending in the United States and one foreign PCT application that cover various formulations of Proellex and methods of using Proellex.

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

A third party individual holds two issued patents related to the use of an anti-estrogen such as clomiphene citrate and others 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 one of

these patents based on prior art. The third party amended the claims in the reexamination proceedings, which has since led the PTO to determine that the amended claims are patentable in view of those publications that were under consideration and a reexamination certificate was issued. However, we believe that the amended claims are invalid based on additional prior art publications, and our request for reexamination by the PTO in light of a number of these additional publications and other publications cited by the PTO, has been granted. We also believe that the

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second of these two patents is invalid in view of published prior art not yet considered by the PTO. A request for reexamination of this patent is pending. Nevertheless, there is no assurance that either patent will ultimately be found invalid over the prior art. If such patents are not invalidated, we may be required to obtain a license from the holder of such patents in order to develop Androxal further. If such licenses were not available on acceptable terms or at all, we may not be able to successfully 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 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.

*A dispute regarding the infringement or misappropriation of our proprietary rights or the proprietary rights of others could be costly and result in delays in our research and development activities.*

Our commercial success also depends upon our ability to develop and manufacture our product candidates and market and sell drugs, if any, and conduct our research and development activities without infringing or misappropriating the proprietary rights of others. We may be exposed to future litigation by others based on claims that our product candidates, technologies or activities infringe the intellectual property rights of others. Numerous United States and foreign issued patents and pending patent applications owned by others also exist in the therapeutic areas in, and for the therapeutic targets for, which we are developing drugs. These could materially affect our ability to develop our product candidates or sell drugs, and our activities, or those of our licensor or future collaborators, could be determined to infringe these patents. Because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that our drug candidates or technologies may infringe. There also may be existing patents, of which we are not aware, that our product candidates or technologies may infringe. Further, there may be issued patents and pending patent applications in fields relevant to our business, of which we are or may become aware, that we believe we do not infringe or that we believe are invalid or relate to immaterial portions of our overall drug discovery and development efforts. We cannot assure you that others holding any of these patents or patent applications will not assert infringement claims against us for damages or seeking to enjoin our activities. We also cannot assure you that, in the event of litigation, we will be able to successfully assert any belief we may have as to non-infringement, invalidity or immateriality, or that any infringement claims will be resolved in our favor.

In addition, others may infringe or misappropriate our proprietary rights, and we may have to institute costly legal action to protect our intellectual property rights. We may not be able to afford the costs of enforcing or defending our intellectual property rights against others. There could also be significant litigation and other administrative proceedings in our industry that affect us regarding patent and other intellectual property rights. Any legal action or administrative action against us, or our collaborators, claiming damages or seeking to enjoin commercial activities relating to our drug discovery and development programs could:

- require us, or potential collaborators, to obtain a license to continue to use, manufacture or market the affected drugs, methods or processes, which may not be available on commercially reasonable terms, if at all;

- prevent us from importing, making, using, selling or offering to sell the subject matter claimed in patents held by others and subject to potential liability for damages; or

consume a substantial portion of our managerial, scientific and financial resources; or be costly, regardless of the outcome.

Furthermore, because of the substantial amount of pre-trial documents and witness discovery required in connection with intellectual property litigation, there is risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the trading price of our common stock.

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*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 licensor s 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 and relating to our products, Proellex and 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 applications relating to Proellex or Androxal, or any patents that have been or may be issued to our licensor, such as the patent(s) and application(s) underlying our Proellex compound, when issued, will be valid and 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 licensor s inventions and products, as well as about the enforceability, validity or scope of protection afforded by the patents. Any adverse decisions about the patentability of our product candidates could cause us to either lose rights to develop and commercialize our product candidates or to license such rights at substantial cost to us. In addition, even if we were successful in such proceedings, the cost and delay of such proceedings would most likely have a material adverse effect on our business.

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

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

*We cannot protect our intellectual property rights throughout the world.*

Filing, prosecuting, and defending patents on all of our drug discovery technologies and all of our potential drug candidates throughout the world would be prohibitively expensive. Competitors may use our technologies to develop their own drugs in jurisdictions where we have not obtained patent protection. These drugs may compete with our

drugs, if any, and may not be covered by any of our patent claims or other intellectual property rights. The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. Many countries, including certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties (for example, the patent owner has failed to work the invention in that country or the third party has patented improvements). In addition, many countries limit the enforceability

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of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of the patent. Compulsory licensing of life-saving drugs is also becoming increasingly popular in developing countries either through direct legislation or international initiatives. Such compulsory licenses could be extended to include some of our drug candidates, which could limit our potential revenue opportunities. Moreover, the legal systems of certain countries, particularly certain developing countries, do not favor the aggressive enforcement of patents and other intellectual property protection, particularly those relating to biotechnology and/or pharmaceuticals, which makes it difficult for us to stop the infringement of our patents. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

***Risks Relating to our Securities***

*Our stock price will likely be volatile, and your investment in our stock could decline in value.*

Our stock price has fluctuated historically. From January 1, 2005 to March 6, 2007, the market price of our stock was as low as $2.79 per share and as high as $14.67 per share.

Very few biotechnology drug candidates being tested will ultimately receive FDA approval, and a biotechnology company may experience a significant drop in its stock price based on a clinical trial result or regulatory action. Our stock price may fluctuate significantly, depending on a variety of factors, including:

- the success or failure of, or other results or decisions affecting, our clinical trials;
- the timing of the discovery of drug leads and the development of our drug candidates;
- the entrance into a new collaboration or the modification or termination of an existing collaboration;
- changes in our research and development budget or the research and development budgets of our existing or potential collaborators;
- the introduction of new drug discovery techniques or the introduction or withdrawal of drugs by others that target the same diseases and conditions that we or our collaborators target;
- regulatory actions; and
- expenses related to, and the results of, litigation and other proceedings relating to intellectual property rights or other matters.

We are not able to control all of these factors. Period-to-period comparisons of our financial results are not necessarily indicative of our future performance. In addition, if our revenues or results of operations in a particular period do not meet stockholders or analysts expectations, our stock price may decline and such decline could be significant.

*Any future equity or debt issuances by us may have dilutive or adverse effects on our existing stockholders.*

We have financed our operations, and we expect to continue to finance our operations, primarily by issuing and selling our common stock or securities convertible into or exercisable for shares of our common stock. In light of our need for additional financing, we may issue additional shares of common stock or convertible securities that could dilute your ownership in our company and may include terms that give new investors rights that are superior to yours. For example, we completed a public offering in February 2007 of 2,610,000 shares of our common stock at a purchase price of $13.75 per share. This public offering represented 52% of our current shelf registration of 5,000,000 shares. Moreover, any issuances by us of equity securities may be at or below the prevailing market price of our common stock and in any event may have a dilutive impact on your ownership interest, which could cause the market price of our common stock to decline.

We may also raise additional funds through the incurrence of debt, and the holders of any debt we may issue would have rights superior to your rights in the event we are not successful and are forced to seek the protection of bankruptcy laws.

*Our rights agreement and certain provisions in our charter documents and Delaware law could delay or prevent a change in management or a takeover attempt that you may consider to be in your best interest.*

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We have adopted certain anti-takeover provisions, including a Rights Agreement, dated as of September 1, 1999, between us and Computershare Trust Company, Inc. (as successor in interest to Harris Trust & Savings Bank), as Rights Agent. The Rights Agreement will cause substantial dilution to any person who attempts to acquire us in a manner or on terms not approved by our board of directors.

The Rights Agreement and Certificate of Designations for the Series One Junior Participating Preferred Stock dated September 2, 1999, as well as other provisions in our certificate of incorporation and bylaws and under Delaware law, could delay or prevent the removal of directors and other management and could make more difficult a merger, tender offer or proxy contest involving us that you may consider to be in your best interest. For example, these provisions:

- allow our board of directors to issue preferred stock without stockholder approval;
- limit who can call a special meeting of stockholders; and
- establish advance notice requirements for nomination for election to the board of directors or for proposing matters to be acted upon at stockholder meetings.

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

**ITEM 2. PROPERTIES**

We lease our current property under a lease agreement that expires in June 2010. This lease is for approximately 7,100 square feet of our laboratory and office space located in The Woodlands, Texas. We do not own or lease any other property and believe that our current facilities are sufficient for our needs for the foreseeable future.

**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 our security holders in the fourth quarter of 2006.

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## PART II

## ITEM 5. MARKET FOR THE REGISTRANT S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our common stock is quoted on The NASDAQ Global Market under the symbol RPRX. The following table shows the high and low sale prices per share of common stock, as reported by The NASDAQ Capital Market through August 18, 2006 and thereafter by the Nasdaq Global Market, during the periods presented.

| | Price Range | |
|---|---|---|
| | **High** | **Low** |
| **2005** | | |
| First Quarter | $ 4.75 | $2.90 |
| Second Quarter | 3.93 | 2.79 |
| Third Quarter | 5.88 | 3.66 |
| Fourth Quarter | 5.96 | 4.43 |
| **2006** | | |
| First Quarter | $10.35 | $4.50 |
| Second Quarter | 14.27 | 7.95 |
| Third Quarter | 8.88 | 7.26 |
| Fourth Quarter | 13.23 | 5.50 |
| **2007** | | |
| First Quarter (January 3 through March 6) | $14.67 | $9.33 |

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, 2007, the last sale price of our common stock, as reported by the Nasdaq Global Market, was $10.01 per share. On March 6, 2007, there were approximately 195 holders of record and approximately 3,052 beneficial holders of our common stock.

**Dividends**

We have never paid dividends on our common stock. We currently intend to retain earnings, if any, to support the development of our business and do not anticipate paying dividends in the foreseeable future. Payment of future dividends, if any, will be at the discretion of our board of directors after taking into account various factors, including our financial condition, operating results, current and anticipated cash needs and plans for expansion.

*Rights Plan*

On September 1, 1999, our board of directors adopted a stockholder rights plan, which has been subsequently amended on September 6, 2002, October 30, 2002, and June 30, 2005, pursuant to which a dividend consisting of one preferred stock purchase right was distributed for each share of our 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 which is defined in the rights plan, (ii) the redemption date which is 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 us without offering fair value to our stockholders. The rights will expire on September 13, 2010, subject to earlier redemption or exchange as provided in the rights plan. Each right entitles its holder to purchase from us one one-hundredth of a share of a new series of Series One Junior Participating Preferred Stock 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 acquires beneficial ownership of 20 percent or more of our outstanding common stock.

A complete description of the rights, the rights plan with Computershare Trust Company, N.A., 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.

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*Performance Graph*

This information is required by Item 201(e) of Regulation S-K. Such information shall not be deemed to be filed or incorporated by reference in future filings with the SEC, or subject to the liabilities of Section 18 of the Securities Exchange Act of 1934, except to the extent that we specifically incorporate it by reference into a document filed under the Securities Act of 1933 or the Securities Exchange Act of 1934.

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**ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA**

The statement of operations data for the years ended December 31, 2004, 2005 and 2006, and the balance sheet data as of December 31, 2005 and 2006, 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 2003, and the balance sheet data as of December 31, 2002, 2003 and 2004 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, | | | | |
|---|---|---|---|---|---|
| | **2002** | **2003** | **2004** | **2005** | **2006** |
| | **(In thousands except per share amounts)** | | | | |
| Revenues and Other Income: | | | | | |
| Licensing fees | $ 4,228 | $ | $ | $ | $ |
| Research and development grants | 315 | 595 | 118 | 4 | |
| Interest income | 711 | 318 | 104 | 630 | 596 |
| Gain on disposal of fixed assets | | 102 | | | |
| Other income | | | 35 | | |
| Total revenues | 5,254 | 1,015 | 257 | 634 | 596 |
| Expenses: | | | | | |
| Research and development | 6,420 | 2,161 | 2,471 | 6,101 | 11,912 |
| General and administrative | 2,716 | 2,183 | 1,483 | 1,924 | 2,879 |
| Total expenses | 9,136 | 4,344 | 3,954 | 8,025 | 14,791 |
| Net loss | $ (3,882) | $ (3,329) | $ (3,697) | $ (7,391) | $ (14,195) |
| Net loss per share basic and diluted (1) | $ (0.34) | $ (0.29) | $ (0.72) | $ (0.77) | $ (1.40) |
| Shares used in loss per share calculation | 11,412 | 11,487 | 5,117 | 9,647 | 10,147 |
| **BALANCE SHEET DATA:** | | | | | |
| Cash, cash equivalents and marketable securities | $ 25,138 | $ 22,946 | $ 5,536 | $ 16,832 | $ 6,736 |
| Total assets | 27,370 | 24,028 | 6,606 | 17,682 | 7,849 |
| Deficit accumulated during the development stage | (79,728) | (83,057) | (86,754) | (94,145) | (108,340) |
| Total stockholders equity | 26,851 | 23,487 | 5,992 | 16,955 | 3,790 |

(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**

Repros Therapeutics Inc. ( the Company , RPRX , 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 are also developing Androxal, which causes increased testosterone secretion from the testes, for the treatment of testosterone deficiency in men resulting from secondary hypogonadism.

We are currently conducting a U.S. Phase 2 clinical trial with Proellex for the treatment of uterine fibroids and are also conducting a European Phase 2 clinical trial with Proellex for the treatment of endometriosis. During December 2006 we provided an internally generated interim analysis of our ongoing Phase 2 clinical trial of Proellex in uterine fibroid patients which demonstrated statistically significant reductions in excessive menstrual bleeding and an improvement in quality of life versus placebo. Furthermore, after three months of treatment, no statistically significant change in endometrial thickness was observed. Also during December 2006 we provided an internally generated interim analysis of our ongoing European endometriosis Phase 1/2 clinical trial of Proellex which demonstrated that treatment with the highest dose of Proellex, 50 mg, achieved statistically significant reduction in days of pain compared to treatment with Lupron, the current pharmaceutical standard of care for the treatment of endometriosis.

We have completed a Phase 1/2 clinical trial and during December 2006 we provided an internally generated interim analysis from an ongoing non-pivotal Phase 3 trial of Androxal for the treatment of testosterone deficiency in men resulting from secondary hypogonadism. Both trials demonstrated statistically significant increases in testosterone levels versus placebo. In our current Phase 3 trial, at three months, Androxal restored testosterone levels to the normal range in over 80% of patients treated.

On February 5, 2007, we completed a public offering of 2,610,000 shares of our common stock at a purchase price of $13.75 per share. As a result of the offering, we received approximately $33.0 million in net proceeds which we intend to use to continue our clinical development of Proellex and Androxal.

Effective January 8, 2007, we voluntarily withdrew the listing of our common stock from NYSE Arca, Inc., formerly the Pacific Exchange, in order to streamline administrative requirements and reduce expenses.

On December 16, 2006, we hired Dr. Andre van As, M.D., Ph.D., to serve as our Chief Medical Officer and Senior Vice President of Clinical and Regulatory Affairs. Dr. van As has extensive experience in drug development and regulatory approvals, including as Executive Director of the Novartis team responsible for gaining regulatory approval of Xolair, the first monoclonal antibody for the management of severe asthma.

On August 21, 2006 we transferred the listing of our common stock from the NASDAQ Capital Market to the NASDAQ Global Market under our ticker symbol, RPRX.

On May 2, 2006, we changed our legal name from Zonagen, Inc. to Repros Therapeutics Inc. to better reflect our focus on the reproductive and hormonal health market.

We are now an accelerated filer and are subject to additional financial regulatory requirements, including Section 404 of Sarbanes-Oxley, which requires us to include in this annual report a report by management on our internal control over financial reporting and an accompanying auditor s report. These additional activities have resulted in increased costs to us and will result in future increased costs as we maintain compliance with these requirements.

We have 8 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

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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 March 31, 2008. There can be no assurance that changes in our current strategic plans or other events will not result in accelerated or unexpected expenditures.

We may 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.

As of December 31, 2006, we had an accumulated deficit of $108.3 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 1. 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 detailed discussion of our critical accounting policies. A brief summary of our accounting policies is provided below.

*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 we have 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, 2006 all securities were classified as trading securities. The fair value and cost basis including purchased premium for these securities was $5.6 million and $14.7 million at December 31, 2006 and 2005, respectively.

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Our investments typically include corporate bonds and notes, Euro-dollar bonds, taxable auction securities and asset-backed securities. Our 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*

We capitalize the cost associated with building our patent library. As of December 31, 2006 other assets consist of capitalized patent costs in the amount of $823,000. 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 $71, zero and $7,000 in 2006, 2005 and 2004, respectively.

Of the $823,000 in capitalized patents, $391,000 related to patents for Proellex, which is being developed as an oral treatment for uterine fibroids and endometriosis and $432,000 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. We expense 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 our behalf.

*Stock-Based Compensation*

We have two stock-based compensation plans at December 31, 2006, the 2000 Non-Employee Directors Stock Option Plan, or 2000 Director Plan and the 2004 Stock Option Plan, or 2004 Plan. We account for our stock-based compensation plans under FASB Statement No. 123(R), Share-Based Payments ( SFAS 123(R) ). SFAS 123(R) generally requires the recognition of the cost of employee services for share-based compensation based on the grant date fair value of the equity or liability instruments issued. Under SFAS 123(R), we used the Black-Scholes option pricing model to estimate the fair value of our stock options. We follow the expanded guidance in SFAS 123(R) for the development of our assumptions used as inputs to the Black-Scholes model. Expected volatility is determined using historical volatilities based on historical stock prices for a period equal to the expected term. The expected volatility assumption is adjusted if future volatility is expected to vary from historical experience. The expected term of options represents the period of time that options granted are expected to be outstanding and falls between the options vesting and contractual expiration dates. The risk-free interest rate is based on the yield at the date of grant of a zero-coupon U.S. Treasury bond whose maturity period equals the option s expected term.

*Use of Estimates*

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

We have had losses since inception and, therefore, have not been subject to federal income taxes. We have accumulated approximately $2.7 million of research and development tax credits. As of December 31, 2006 and 2005, we had approximately $96.0 million and $84.3 million, respectively, of net operating loss, or 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, expired in 2006. Under SFAS No. 109, Accounting for Income Taxes, an NOL requires the recognition of a deferred tax asset. However, a valuation allowance must be recorded for deferred tax assets whose recovery is deemed unlikely. As we have incurred losses since inception, and there is no certainty of future revenues, our deferred tax assets have been reserved in full in the accompanying consolidated financial statements.

We review 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. We have determined that our capitalized patent costs are not impaired as of December 31, 2006.

The amount of compensation cost recognized in each period is based on our estimate of fair value of stock options granted on their grant date. Our estimate of fair value is derived from the Black-Scholes option pricing model and that

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fair value is significantly influenced by the assumptions we have made regarding volatility and expected term, which are somewhat subjective. While we believe our assumptions are reasonable and based on the best available information, changes in those assumptions could have a material impact on our financial statements.

**RECENT ACCOUNTING PRONOUNCEMENTS**

In June 2006, the FASB issued Interpretation No. 48, Accounting for Uncertainty in Income Taxes (FIN 48), which clarifies the accounting for uncertainty in income taxes recognized in an enterprise s financial statements in accordance with SFAS No. 109, Accounting for Income Taxes. FIN 48 establishes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. This interpretation also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006. We are currently evaluating the impact the adoption of this interpretation will have on our consolidated financial statements.

In September 2006, FASB issued SFAS No. 157, Fair Value Measurements which defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair value measurements. This Statement is effective for financial statements issued for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. Earlier application is encouraged provided that the reporting entity has not yet issued financial statements for that fiscal year including financial statements for an interim period within that fiscal year. We are assessing SFAS No. 157 and have not determined yet the impact that the adoption of SFAS No. 157 will have on our results of operations or financial position.

In September 2006, the SEC released Staff Accounting Bulletin No. 108 Considering the Effects of Prior Year Misstatements When Quantifying Misstatements in Current Year Financial Statements (SAB 108). SAB 108 provides interpretative guidance on how public companies quantify financial statement misstatements. There have been two common approaches used to quantify such errors. Under an income statement approach, the roll-over method, the error is quantified as the amount by which the current year income statement is misstated. Alternatively, under a balance sheet approach, the iron curtain method, the error is quantified as the cumulative amount by which the current year balance sheet is misstated. In SAB 108, the SEC established an approach that requires quantification of financial statement misstatements based on the effects of the misstatements on each of the company s financial statements and the related financial statement disclosures. This model is commonly referred to as a dual approach because it requires quantification of errors under both the roll-over and iron curtain methods. SAB 108 is effective for us as of January 1, 2007. The adoption of SAB 108 did not impact our consolidated financial statements.

In February 2007, the FASB issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115. This pronouncement permits entities to use the fair value method to measure certain financial assets and liabilities by electing an irrevocable option to use the fair value method at specified election dates. After election of the option, subsequent changes in fair value would result in the recognition of unrealized gains or losses as period costs during the period the change occurred. SFAS No. 159 becomes effective as of the beginning of the first fiscal year that begins after November 15, 2007, with early adoption permitted. However, entities may not retroactively apply the provisions of SFAS No. 159 to fiscal years preceding the date of adoption. We are currently evaluating the impact that SFAS No. 159 may have on our financial position, results of operations and cash flows.

**Results of Operations**

*Comparison of Years Ended December 31, 2006 and 2005*

*Revenues*. Total revenues for 2006 decreased 6% to $596,000 as compared to $634,000 for 2005. Research and development grants for 2006 were zero as compared to $4,000 for 2005 which was the remaining amount under our Small Business Innovative Research, or SBIR, grants.

Interest income decreased 5% to $596,000 for 2006 as compared to $630,000 for 2005. The decrease in interest income is primarily due to lower cash balances.

*Research and Development Expenses.* R&D expenses include contracted research, regulatory affairs activities and general research and development expenses. R&D expenses increased 95% to $11.9 million in 2006 as compared to

$6.1 million in 2005. The increased expenses for 2006 are primarily due to increased spending in our clinical development programs ($3.5 million for Proellex and $2.1 million for Androxal), an increase of $142,000 in personnel costs, an increase in non-cash stock option compensation expense of $107,000 and a $71,000 increase in consulting fees.

*General and Administrative Expenses*. G&A expenses increased 50% to $2.9 million for 2006 as compared to $1.9 million for 2005. The increase in expenses is primarily due to an increase of $593,000 in non-cash stock option compensation expense, an increase of $184,000 in investor relations expenses and an increase of $66,000 in costs associated with meeting the requirements of Section 404 of the Sarbanes-Oxley Act.

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

*Revenues*. Total revenues 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 which amounts all related to our 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 our preclinical phentolamine data that was to be used for a purpose that does not compete with our sexual dysfunction technologies.

*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 increased spending in our clinical development programs ($1.9 million for Proellex and $1.9 million for Androxal), 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*. 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 our directors and officers insurance policy relating to our previous class action lawsuit, personnel costs in the amount of $185,000, costs associated with 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.

**Off-Balance Sheet Arrangements**

As of December 31, 2006, we did not have any off-balance sheet arrangements.

**Liquidity and Capital Resources**

Since our inception, we have financed our operations primarily with proceeds from private placements and public offerings of equity securities and with funds received under collaborative agreements. We recently completed, on February 5, 2007, a public offering of 2,610,000 shares of our common stock at a purchase price of $13.75 per share resulting in net proceeds to us of approximately $33.0 million. In February 2005, we completed a public offering of 5,060,000 shares of our common stock for net proceeds of approximately $18.1 million.

Our primary use of cash to date has been in operating activities to fund research and development, including preclinical studies and clinical trials, and general and administrative expenses. We had cash, cash equivalents and marketable securities of approximately $6.7 million as of December 31, 2006 as compared to $16.8 million as of December 31, 2005. The decrease in cash balance as of December 31, 2006 as compared to December 31, 2005 is primarily due to an increase in costs related to our clinical development programs for Androxal and Proellex and associated administrative costs.

Excluding maturities and purchases of marketable securities, net cash of approximately $10.1 million, $7.4 million, and $3.0 million was used in operating activities during 2006, 2005, and 2004, respectively. The major uses of cash for operating activities during 2006 was to fund our clinical development programs and associated administrative costs of $14.2 million, partially offset by a $3.3 million increase in accounts payable and accrued expenses. Cash used in investing activities was $287,000 in 2006 primarily for investments in technology rights related to our Proellex and Androxal patent portfolios. Cash provided by financing activities in 2006 was approximately $241,000 relating to the exercise of 71,361 stock options.

As of December 31, 2006, we had future minimum lease payments under non-cancelable leases with ongoing terms in excess of one year of $59,000, $60,000, $60,000 and $30,000 in 2007, 2008, 2009 and 2010 and later, respectively.

| | | Payments Due By Period | | | |
|---|---|---|---|---|---|
| Contractual Obligations | Total | 2007 | 2008 | 2009 | 2010 |
| Operating Lease Obligations | $209,000 | $59,000 | $120,000 | | $30,000 |

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We have had losses since inception and, therefore, have not been subject to federal income taxes. We have accumulated approximately $2.7 million of research and development tax credits. As of December 31, 2006 and 2005, we had approximately $96.0 million and $84.3 million, respectively, of NOLs for federal income tax purposes. Additionally, approximately $1.8 million of NOLs, and approximately $72,000 of research and development tax credits expired in the year 2006. Due to various tax regulations, including change in control provisions in the tax code the value of this tax asset to us can be substantially diminished. For additional information relating to our NOLs, see Note 6. Federal Income Taxes of the Notes to Consolidated Financial Statements.

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 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. We believe that our existing capital resources under our current operating plan will be sufficient to fund our operations through at least March 31, 2008. There can be no assurance that changes in our current strategic plans or other events will not result in accelerated or unexpected expenditures.

Our capital requirements will depend on many factors, including the costs and timing of seeking regulatory approvals of our products; the problems, delays, expenses and complications frequently encountered by development stage companies; the progress of our preclinical and clinical activities; the costs associated with any future collaborative research, manufacturing, marketing or other funding arrangements; our ability to obtain regulatory approvals; the success of our 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 our planned business; and additional costs associated with being a publicly-traded company. Estimates about the adequacy of funding for our activities are based on certain assumptions, including the assumption that the development and regulatory approval of our 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 our research and development plans, acquisitions or other events will not result in accelerated or unexpected expenditures. To satisfy our capital requirements, we may seek to raise additional funds in the public or private capital markets. We may seek additional funding through corporate collaborations and other financing vehicles. There can be no assurance that any such funding will be available to us on favorable terms or at all. If we are 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 holders of our common stock.

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

Interest Rate Risk. Cash, cash equivalents and investments were approximately $6.7 million at December 31, 2006. 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

### Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports filed with the Securities and Exchange Commission, or SEC, pursuant to the Securities Exchange Act of 1934, or the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the Commission and that such information is accumulated and communicated to our management, including our Chief Executive Officer (CEO) and Chief Financial Officer (CFO), as appropriate, to allow timely decisions regarding required disclosures.

Management, with the participation of our CEO and CFO, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act) as of the end of the period covered by this report. Based on such evaluation, our CEO and CFO have each concluded that as of the end of such period, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms and that

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such information is accumulated and communicated to our management, including the CEO and CFO, as appropriate, to allow timely decisions regarding required disclosures.

**Management s Report on Internal Control Over Financial Reporting**

Management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) under the Exchange Act. Our internal control over financial reporting was designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

Management evaluated the effectiveness of internal control over financial reporting based on the criteria in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Due to its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Based on management s evaluation, management has concluded that internal control over financial reporting was effective as of December 31, 2006.

PricewaterhouseCoopers LLP, an independent registered public accounting firm, has audited and issued their report on management s assessment of the effectiveness of our internal control over financial reporting as of December 31, 2006, which appears herein.

**ITEM 9B. OTHER INFORMATION**

Not applicable.

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## PART III

### ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item is hereby incorporated by reference from the information in our proxy statement for our 2007 annual meeting of stockholders. Such proxy statement will be filed with the SEC pursuant to the Exchange Act within 120 days of the end of our fiscal year ended December 31, 2006.

### ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is hereby incorporated by reference from the information in our proxy statement for our 2007 annual meeting of stockholders. Such proxy statement will be filed with the SEC pursuant to the Exchange Act within 120 days of the end of our fiscal year ended December 31, 2006.

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

The information required by this item is hereby incorporated by reference from the information in our proxy statement for our 2007 annual meeting of stockholders. Such proxy statement will be filed with the SEC pursuant to the Exchange Act within 120 days of the end of our fiscal year ended December 31, 2006.

### ITEM 13. CERTAIN RELATIONSHIP AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item is hereby incorporated by reference from the information in our proxy statement for our 2007 annual meeting of stockholders. Such proxy statement will be filed with the SEC pursuant to the Exchange Act within 120 days of the end of our fiscal year ended December 31, 2006.

### ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item is hereby incorporated by reference from the information in our proxy statement for our 2007 annual meeting of stockholders. Such proxy statement will be filed with the SEC pursuant to the Exchange Act within 120 days of the end of our fiscal year ended December 31, 2006.

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## PART IV

## ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

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



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 Amendment to the Company s Restated Certificate of Incorporation, dated as of May 2, 2006. Exhibit 3.1 to the Company s Current Report on Form 8-K as filed with the Commission on May 2, 2006 is incorporated herein by reference. |
| 3.1(c) | 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. |

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| Exhibit Number | Identification Of Exhibit |
|---|---|
| 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+ | 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+ | 1994 Employee and Consultant Stock Option Plan. Exhibit 4.2 to the Company s Registration Statement on Form S-8 (File No. 033-83406) as filed with the Commission on August 29, 1994 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+ | Employment Agreement between the Company and Andre van As dated March 7, 2007. Exhibit 10.1 to the Company s Current Report on Form 8-K as filed with the Commission on March 8, 2007 is incorporated herein by reference. |
| 10.13 | 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. |
| 10.14 | Amendment to Lease Agreement between the Company and Sealy Woodlands, L.P., dated May 17, 2006. Exhibit 10.1 to the Company s Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2006 is incorporated herein by reference. |
| 10.15++ | 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. |
| 10.16++ | 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 |

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| Exhibit Number | Identification Of Exhibit |
|---|---|
| 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) |

* 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.

**REPROS THERAPEUTICS INC.**

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

Dated: March 14, 2007

| Signature | Title | Date |
|---|---|---|
| /s/ Joseph S. Podolski<br>Joseph S. Podolski | President, Chief Executive Officer and Director (Principal Executive Officer) | March 14, 2007 |
| /s/ Louis Ploth, Jr.<br>Louis Ploth, Jr. | Chief Financial Officer, VP Business Development, Director and Secretary (Principal Financial Officer and Principal Accounting Officer) | March 14, 2007 |
| /s/ Daniel F. Cain<br>Daniel F. Cain | Chairman of the Board | March 14, 2007 |
| /s/ Jean L. Fourcroy, M.D., Ph.D., M.P.H.<br>Jean L. Fourcroy, M.D., Ph.D., M.P.H. | Director | March 14, 2007 |
| /s/ Jeffrey R. Harder<br>Jeffrey R. Harder | Director | March 14, 2007 |
| /s/ Nola Masterson<br>Nola Masterson. | Director | March 14, 2007 |
| /s/ David Poorvin, Ph.D.<br>David Poorvin, Ph. D. | Director | March 14, 2007 |

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**Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Stockholders of Repros Therapeutics Inc.:

We have completed an integrated audit of Repros Therapeutics Inc. s 2006 consolidated financial statements and of its internal control over financial reporting as of December 31, 2006 and audits of its 2005 and 2004 consolidated financial statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Our opinions, based on our audits, are presented below.

Consolidated financial statements

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 Repros Therapeutics Inc. and its subsidiary (a development stage company) at December 31, 2006 and December 31, 2005, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2006 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 of financial statements 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.

As discussed in Note 2 to the consolidated financial statements, the Company changed its method of accounting for share based payments effective January 1, 2006.

Internal control over financial reporting

Also, in our opinion, management s assessment, included in Management s Report on Internal Control Over Financial Reporting appearing under Item 9A, that the Company maintained effective internal control over financial reporting as of December 31, 2006 based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), is fairly stated, in all material respects, based on those criteria. Furthermore, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2006, based on criteria established in *Internal Control Integrated Framework* issued by the COSO. The Company s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express opinions on management s assessment and on the effectiveness of the Company s internal control over financial reporting based on our audit. We conducted

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our audit of internal control over financial reporting in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. An audit of internal control over financial reporting includes obtaining an understanding of internal control over financial reporting, evaluating management s assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we consider necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinions.

A company s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ PricewaterhouseCoopers LLP

Houston, Texas

March 14, 2007

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

| | December 31, 2006 | December 31, 2005 |
|---|---|---|
| **ASSETS** | | |
| **Current Assets** | | |
| Cash and cash equivalents | $ 1,136 | $ 2,165 |
| Marketable securities | 5,600 | 14,667 |
| Prepaid expenses and other current assets | 225 | 231 |
| Total current assets | 6,961 | 17,063 |
| **Fixed assets,** net | 65 | 19 |
| **Other assets,** net | 823 | 600 |
| Total assets | $ 7,849 | $ 17,682 |
| **LIABILITIES AND STOCKHOLDERS EQUITY** | | |
| **Current Liabilities** | | |
| Accounts payable | $ 1,973 | $ 338 |
| Accrued expenses | 2,086 | 389 |
| Total current liabilities | 4,059 | 727 |
| **Commitments & Contingencies** | | |
| **Stockholders Equity** | | |
| Undesignated Preferred Stock, $.001 par value, 5,000,000 shares authorized, none issued and outstanding | | |
| Common Stock, $.001 par value, 20,000,000 shares authorized, 12,087,997 and 12,016,636 shares issued, respectively; 10,150,962 and 10,079,601 shares outstanding, respectively | 12 | 12 |
| Additional paid-in capital | 118,066 | 117,166 |
| Deferred compensation | | (130) |
| Cost of treasury stock, 1,937,035 and 1,937,035 shares, respectively | (5,948) | (5,948) |
| Deficit accumulated during the development stage | (108,340) | (94,145) |
| Total stockholders equity | 3,790 | 16,955 |
| Total liabilities and stockholders equity | $ 7,849 | $ 17,682 |

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

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

| | For the Year Ended December 31, | | | From Inception (August 20, 1987) through December 31, |
|---|---|---|---|---|
| | 2006 | 2005 | 2004 | 2006 (unaudited) |
| **Revenues and other income** | | | | |
| Licensing fees | $ | $ | $ | $ 28,755 |
| Product royalties | | | | 627 |
| Research and development grants | | 4 | 118 | 1,219 |
| Interest income | 596 | 630 | 104 | 14,352 |
| Gain on disposal of fixed assets | | | | 102 |
| Other income | | | 35 | 35 |
| Total revenues and other income | 596 | 634 | 257 | 45,090 |
| **Expenses** | | | | |
| Research and development | 11,912 | 6,101 | 2,471 | 112,273 |
| General and administrative | 2,879 | 1,924 | 1,483 | 31,426 |
| Interest expense and amortization of intangibles | | | | 388 |
| Total expenses | 14,791 | 8,025 | 3,954 | 144,087 |
| Loss from continuing operations | (14,195) | (7,391) | (3,697) | (98,997) |
| Loss from discontinued operations | | | | (1,828) |
| Gain on disposal of discontinued operations | | | | 939 |
| Net loss before cumulative effect of change in accounting principle | (14,195) | (7,391) | (3,697) | (99,886) |
| Cumulative effect of change in accounting principle | | | | (8,454) |
| **Net loss** | $ (14,195) | $ (7,391) | $ (3,697) | $ (108,340) |
| **Loss per share basic and diluted** | $ (1.40) | $ (0.77) | $ (0.72) | |
| Shares used in loss per share calculation: | | | | |
| Basic | 10,147 | 9,647 | 5,117 | |
| Diluted | 10,147 | 9,647 | 5,117 | |

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

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**REPROS THERAPEUTICS INC.**
(A development stage company)
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY**
(in thousands except share amounts)

| | Preferred Stock Shares | Preferred Stock Amount | Common Stock Shares | Common Stock Amount | Additional Paid-in Capital | Deferred Compensation | Treasury Stock Shares | Treasury Stock Amount | Deficit Accumulated During the Development Stage | Total Stockholders Equity |
|---|---|---|---|---|---|---|---|---|---|---|
| Exchange of common stock ($.004 per share) for technology rights and services from founding stockholders | | $ | 245,367 | $ | $ 1 | $ | | $ | $ | $ 1 |
| Net Loss | | | | | | | | | (28) | (28) |
| BALANCE AT DECEMBER 31, 1987 (unaudited) | | | 245,367 | | 1 | | | | (28) | (27) |
| Net Loss | | | | | | | | | (327) | (327) |
| BALANCE AT DECEMBER 31, 1988 (unaudited) | | | 245,367 | | 1 | | | | (355) | (354) |
| Proceeds from issuance of common stock | | | 65,431 | | 3 | | | | | 3 |
| Net Loss | | | | | | | | | (967) | (967) |
| BALANCE AT DECEMBER 31, 1989 (unaudited) | | | 310,798 | | 4 | | | | (1,322) | (1,318) |
| Proceeds from issuance of common stock | | | 467 | | | | | | | |
| Net Loss | | | | | | | | | (1,426) | (1,426) |
| BALANCE AT DECEMBER 31, 1990 (unaudited) | | | 311,265 | | 4 | | | | (2,748) | (2,744) |
| Net Loss | | | | | | | | | (1,820) | (1,820) |
| | | | 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) |

(continued)

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**REPROS THERAPEUTICS INC.**
(A development stage company)
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY**
(in thousands except share amounts)

| | Preferred Stock Shares | Preferred Stock Amount | Common Stock Shares | Common Stock Amount | Additional Paid-in Capital | Deferred Compensation | Treasury Stock Shares | Treasury Stock Amount | Deficit Accumulated During the Development Stage | Total Stockholders Equity |
|---|---|---|---|---|---|---|---|---|---|---|
| BALANCE AT DECEMBER 31, 1993 (unaudited) | | $ | 3,667,536 | $ 4 | $ 15,136 | $ | | $ | $ (8,683) | $ 6,457 |
| Deferred compensation resulting from grant of options | | | | | 188 | (188) | | | | |
| Amortization of deferred compensation | | | | | | 38 | | | | 38 |
| Exercise of warrants to purchase common stock for cash, June 30, 1994 ($3.94 per share) | | | 39,623 | | 156 | | | | | 156 |
| Issuance of common stock for purchase of FTI, October 13, 1994 | | | 111,111 | | 1,567 | | | | | 1,567 |
| Net loss | | | | | | | | | (3,970) | (3,970) |
| BALANCE AT DECEMBER 31, 1994 | | | 3,818,270 | 4 | 17,047 | (150) | | | (12,653) | 4,248 |
| Amortization of deferred compensation | | | | | | 37 | | | | 37 |
| Exercise of options to purchase common stock for cash, January and April 1995 ($.10 to $6.13 per share) | | | 4,546 | | 14 | | | | | 14 |
| | | | 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 ($.001 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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**REPROS THERAPEUTICS INC.**
(A development stage company)
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY**
(in thousands except share amounts)

| | Preferred Stock Shares | Preferred Stock Amount | Common Stock Shares | Common Stock Amount | Additional Paid-in Capital | Deferred Compensation | Treasury Stock Shares | Treasury Stock Amount | Deficit Accumulated During the Development Stage | Total Stockholders Equity |
|---|---|---|---|---|---|---|---|---|---|---|
| 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 Series B preferred stock into common stock, January | (1,514,906) | (2) | 2,295,263 | 2 | (1) | | (1) |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 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) | (13,174) |

(continued)

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**REPROS THERAPEUTICS INC.**
(A development stage company)
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY**
(in thousands except share amounts)

| | Preferred Stock Shares | Preferred Stock Amount | Common Stock Shares | Common Stock Amount | Additional Paid-in Capital | Deferred Compensation | Treasury Stock Shares | Treasury Stock Amount | Deficit Accumulated During the Development Stage | Total 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 | | | (229) | 229 | | | | |
| Amortization of deferred compensation | | | | 239 | | | | 239 |
| Exercise of options to purchase common stock for cash, 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 | 4,775 | | | | | | | |
| Issuance of common stock for a cashless exercise of Series A preferred stock warrants, April 1999 | 22,131 | | | | | | | |
| Issuance of common stock for a cashless exercise of Series B preferred stock warrants, March through April 1999 | 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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**REPROS THERAPEUTICS INC.**
(A development stage company)
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY**
(in thousands except share amounts)

| | Preferred Stock Shares | Amount | Common Stock Shares | Amount | Additional Paid-in Capital | Deferred Compensation | Treasury Stock Shares | Amount | Deficit Accumulated During the Development Stage | Total 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, | | | 2,690 | | 9 | | | | | 9 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| February 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 | 10,871 | | 14 | | | | | 14 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| May 2003 Purchase of treasury stock April ($1.37 to $1.50 per share) | | | | | 34,100 | (49) | | (49) |
| 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 | 26,700 | | 2,641 85 | | (5,060,000) | 15,539 | | 18,180 85 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Exercise of options to 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 |
| Exercise of options to purchase common stock for cash, January and July 2006 ($1.70 to $7.50 per share) | 71,361 | | 241 | | | | | 241 |
| Reclassification of previous deferred compensation due to the adoption of FAS 123(R) | | | (130) | 130 | | | | |
| FAS 123(R) stock option compensation | | | 789 | | | | | 789 |
| Net loss | | | | | | | (14,195) | (14,195) |
| Balance at December 31, 2006 | $ 12,087,997 | $ 12 | $ 118,066 | $ | 1,937,035 | $ (5,948) | $ (108,340) | $ 3,790 |

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

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**REPROS THERAPEUTICS INC. AND SUBSIDIARY**
(A development stage company)
**CONSOLIDATED STATEMENTS OF CASH FLOWS**
(in thousands)

| | For the Year Ended December 31, | | | From Inception (August 20, 1987) through December 31, |
|---|---|---|---|---|
| | 2006 | 2005 | 2004 | 2006 (unaudited) |
| **Cash Flows from Operating Activities** | | | | |
| Net loss | $ (14,195) | $ (7,391) | $ (3,697) | $ (108,340) |
| Gain on disposal of discontinued operations | | | | (939) |
| Gain on disposal of assets | | | | (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 | 18 | 7 | 9 | 3,798 |
| Noncash expenses related to stock-based transactions | 789 | 89 | 156 | 3,606 |
| Common stock issued for agreement not to compete | | | | 200 |
| Series B Preferred Stock issued for consulting services | | | | 18 |
| Sales and maturities of marketable securities | 33,157 | 24,825 | 9,850 | 57,982 |
| Purchases of marketable securities | (24,090) | (34,692) | (12,650) | (35,047) |
| 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 | 6 | (197) | 201 | 74 |
| (Decrease) increase in accounts payable and accrued expenses | 3,332 | 114 | 73 | 5,255 |
| Net cash (used in) provided by operating activities | (983) | (17,245) | (5,750) | (73,377) |
| **Cash Flows from Investing Activities** | | | | |
| Maturities (purchases) of marketable securities | | | | (28,723) |
| Capital expenditures | (64) | (8) | (21) | (2,361) |

| | | | | |
|---|---|---|---|---|
| Purchase of technology rights and other assets | (223) | (183) | (169) | (2,844) |
| Decrease (increase) in note receivable | | | | |
| Proceeds from sale of PP&E | | | | 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 | (287) | (191) | (190) | (31,525) |
| **Cash Flows from Financing Activities** | | | | |
| Proceeds from issuance of common stock, net of offering costs | | 18,180 | | 102,404 |
| (Increase) decrease in prepaid offering costs | | 600 | (316) | |
| Exercise of stock options | 241 | 85 | | 326 |
| Proceeds from issuance of preferred stock | | | | 23,688 |
| Purchase of treasury stock | | | (13,954) | (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 | 241 | 18,865 | (14,270) | 106,038 |
| **Net increase (decrease) in cash and cash equivalents** | (1,029) | 1,429 | (20,210) | 1,136 |
| **Cash and cash equivalents at beginning of period** | 2,165 | 736 | 20,946 | |
| **Cash and cash equivalents at end of period** | $ 1,136 | $ 2,165 | $ 736 | $ 1,136 |

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

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1. ORGANIZATION AND OPERATIONS:

Repros Therapeutics Inc. ( the Company , RPRX , 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 are also developing Androxal, which causes increased testosterone secretion from the testes, for the treatment of testosterone deficiency in men resulting from secondary hypogonadism.

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 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. We believe that our existing capital resources under our current operating plan will be sufficient to fund our operations through at least the first quarter of 2008. There can be no assurance that changes in our current strategic plans or other events will not result in accelerated or unexpected expenditures.

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.

As of December 31, 2006, we had an accumulated deficit of $108.3 million. Losses have resulted principally from costs incurred in conducting clinical trials of our phentolamine-based products which include VASOMAX® 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 the tax asset created by these accumulated losses 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.

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.

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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, 2006 and 2005 all securities were classified as trading securities. The fair value and cost basis including purchased premium for these securities was $5.6 million and $14.7 million at December 31, 2006 and 2005, respectively.

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, which are held to maturity, 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, 2006 or 2005 due to the high credit quality of the issuers of the securities.

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.

OTHER ASSETS

The Company capitalizes the cost associated with building its patent library. As of December 31, 2006 other assets consist of capitalized patent costs in the amount of $823,000. 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 $71, zero and $7,000 in 2006, 2005 and 2004, respectively.

Of the $823,000 in capitalized patents, $391,000 related to patents for Proellex, which is being developed as an oral treatment for uterine fibroids and endometriosis and $432,000 related to Androxal, which is being developed as an oral treatment for testosterone deficiency.

The Company reviews capitalized patent costs for impairment 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, 2006.

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.

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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 loss per share is computed by dividing net loss by the weighted average number of shares of common stock outstanding during the year. Diluted loss per share is computed using the average share price for the period and 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, 2006, which are described more fully in note 8.

On January 1, 2006, we adopted Statement of Financial Accounting Standards No. 123(R), Share-Based Payments ( SFAS 123(R) ) and are using the modified prospective method of adoption, which does not require restatement of prior periods. SFAS 123(R) eliminated the intrinsic value method of accounting for share-based employee compensation under APB Opinion No. 25, Accounting for Stock-Based Compensation, which we previously used (see pro-forma disclosure of prior period included herein). SFAS 123(R) generally requires the recognition of the cost of employee services for share-based compensation based on the grant date fair value of the equity or liability instruments issued. The effect of adoption of the new standard related to stock option plans was an additional expense of $219,000 ($0.02 per share, basic and diluted) for the three-months ended December 31, 2006, of which $37,000 was recorded to Research and Development expense and $182,000 was recorded to General and Administrative expense and $789,000 ($0.08 per share, basic and diluted) for the year ended December 31, 2006, of which $127,000 was recorded to Research and Development expense and $662,000 was recorded to General and Administrative expense. At December 31, 2006, there was $764,000 of total unrecognized compensation cost related to non-vested stock options. This compensation cost is expected to be recognized over a weighted-average period of approximately 1 year.

Under SFAS 123(R), we continue to use the Black-Scholes option pricing model to estimate the fair value of our stock options. However, we will apply the expanded guidance under SFAS 123(R) for the development of our assumptions used as inputs for the Black-Scholes option pricing model for grants issued after January 1, 2006. Expected volatility is determined using historical volatilities based on historical stock prices for a period equal to the expected term. The expected volatility assumption is adjusted if future volatility is expected to vary from historical experience. The expected term of options represents the period of time that options granted are expected to be outstanding and falls between the options vesting and contractual expiration dates. The risk-free interest rate is based on the yield at the date of grant of a zero-coupon U.S. Treasury bond whose maturity period equals the option s expected term. Options to purchase an aggregate of 25,000 shares of common stock at an exercise

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price of $12.70 per share were granted to non-employee members of the Company s Board of Directors for their re-election to the Board at the Company s Annual Meeting held on May 2, 2006. Additionally, options to purchase 20,000, 20,000, and 50,000 shares of common stock were granted to three employees on June 14, August 16 and December 16, 2006 at exercise prices of $8.41, $8.00 and $6.17 per share, respectively. All stock options were granted at the closing price of the Company s common stock on the date of grant. The following assumptions were used for stock option grants: risk-free interest rate of 3.5% to 5.0%; no expected dividends; expected lives of 4.2 to 7 years; and expected volatility of 81% to 90%.

Due to our net operating loss position there are no anticipated windfall tax benefits upon exercise of options.

Prior to the adoption of SFAS 123(R) we recorded deferred compensation in equity for options issued in the money under APB Opinion No. 25. Due to the adoption of SFAS 123(R) on January 1, 2006, we reclassified $130,000 from deferred compensation to additional paid in capital.

Under the modified prospective application method, results for prior periods have not been restated to reflect the effects of implementing SFAS 123(R). The following pro forma information, as required by SFAS No. 148 Accounting for Stock-Based Compensation-an Amendment to FAS 123 , is presented for comparative purposes and illustrates the effect on our net loss and loss per share if we had applied the provisions of SFAS 123 (R) during the years ended 2005 and 2004 (in thousands, except for per share amounts):

| | December 31, | |
|---|---|---|
| | **2005** | **2004** |
| Net loss, as reported | $ (7,391) | $ (3,697) |
| Add: Stock-based employee compensation expense included in reported net income, net of related tax effects | 89 | 156 |
| Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects | (746) | (457) |
| Pro forma net loss | $ (8,048) | $ (3,998) |
| Loss per share | | |
| Basic and diluted as reported | $ (0.77) | $ (0.72) |
| Basic and diluted pro forma | (0.83) | (0.78) |

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 2006, 2005, and 2004, respectively: risk-free interest rates of 4.8%, 4.0%, and 3.5%; with no expected dividends; expected lives of 7.0, 5.8, and 6.4 years; expected volatility of 85%, 86%, and 88%. The weighted average fair value of options, all of which were granted at market for 2006, 2005 and 2004 was $6.49, $2.88 and $1.99, 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.

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RECENT ACCOUNTING PRONOUNCEMENTS

In June 2006, the FASB issued Interpretation No. 48, Accounting for Uncertainty in Income Taxes (FIN 48), which clarifies the accounting for uncertain income tax positions recognized in an enterprise s financial statements in accordance with SFAS No. 109, Accounting for Income Taxes. FIN 48 establishes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. This interpretation also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006. The Company is currently evaluating the impact the adoption of this interpretation will have on its consolidated financial statements.

In September 2006, FASB issued SFAS No. 157, Fair Value Measurements which defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair value measurements. This Statement is effective for financial statements issued for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. Earlier application is encouraged provided that the reporting entity has not yet issued financial statements for that fiscal year including financial statements for an interim period within that fiscal year. The company is assessing SFAS No. 157 and has not determined yet the impact that the adoption of SFAS No. 157 will have on its result of operations or financial position.

In September 2006, the SEC released Staff Accounting Bulletin No. 108 Considering the Effects of Prior Year Misstatements When Quantifying Misstatements in Current Year Financial Statements ( SAB 108 ). SAB 108 provides interpretative guidance on how public companies quantify financial statement misstatements. There have been two common approaches used to quantify such errors. Under an income statement approach, the roll-over method, the error is quantified as the amount by which the current year income statement is misstated. Alternatively, under a balance sheet approach, the iron curtain method, the error is quantified as the cumulative amount by which the current year balance sheet is misstated. In SAB 108, the SEC established an approach that requires quantification of financial statement misstatements based on the effects of the misstatements on each of the company s financial statements and the related financial statement disclosures. This model is commonly referred to as a dual approach because it requires quantification of errors under both the roll-over and iron curtain methods. SAB 108 is effective for the Company as of January 1, 2007. The adoption of SAB 108 did not have an impact on the Company s consolidated financial statements.

In February 2007, the FASB issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115. This pronouncement permits entities to use the fair value method to measure certain financial assets and liabilities by electing an irrevocable option to use the fair value method at specified election dates. After election of the option, subsequent changes in fair value would result in the recognition of unrealized gains or losses as period costs during the period the change occurred. SFAS No. 159 becomes effective as of the beginning of the first fiscal year that begins after November 15, 2007, with early adoption permitted. However, entities may not retroactively apply the provisions of SFAS No. 159 to fiscal years preceding the date of adoption. We are currently evaluating the impact that SFAS No. 159 may have on our financial position, results of operations and cash flows.

3. FIXED ASSETS:

Fixed assets are classified as follows (in thousands):

| | December 31, | |
|---|---|---|
| | **2006** | **2005** |
| Laboratory equipment | $ 19 | $ 4 |
| Office equipment | 35 | 18 |
| Leasehold improvements | 38 | 7 |
| Total fixed assets | 92 | 29 |
| Less Accumulated depreciation and amortization | 27 | 10 |

| | | |
|---|---|---|
| Net Fixed Assets | $ 65 | $ 19 |

4. OPERATING LEASES:

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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, 2006, 2005 and 2004, was approximately $53,000, $39,000 and $37,000, respectively. Future minimum lease payments under non-cancelable leases with original terms in excess of one year as of December 31, 2006, are as follows (in thousands):

| | |
|---|---|
| 2007 | $ 59 |
| 2008 | 60 |
| 2009 | 60 |
| 2010 and later | 30 |
| Total | $ 209 |

5. ACCRUED EXPENSES:

Accrued expenses consist of the following (in thousands):

| | December 31, | |
|---|---|---|
| | 2006 | 2005 |
| Research and development costs | $ 1,686 | $ 7 |
| Payroll | 123 | 159 |
| Legal | | 45 |
| Patent costs | 127 | 97 |
| Other | 150 | 81 |
| Total | $ 2,086 | $ 389 |

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 $2.7 million of research and development tax credits. As of December 31, 2006 and 2005, the Company had approximately $96.0 million and $84.3 million, respectively, of net operating loss ( NOL ) carry-forwards for federal income tax purposes. Additionally, approximately $1.5 million of NOLs, and approximately $64,000 of research and development tax credits will expire in 2007.

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 on the use of net operating loss and tax credit carryforwards in future periods.

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.

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

| | December 31, | |
|---|---|---|
| | 2006 | 2005 |
| Net operating loss carryforwards | $ 32,650 | $ 28,672 |
| Research and development tax credits | 2,748 | 2,819 |
| Accruals/expenses not currently deductible | 1,510 | 1,510 |
| Total deferred tax assets | 36,908 | 33,001 |
| Less Valuation allowance | (36,908) | (33,001) |
| 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. As of December 31, 2006 and 2005 the Company had 1,937,035 shares of treasury stock.

LOSS PER SHARE

The following table presents information necessary to calculate loss per share for the three years ended December 31, 2006, 2005 and 2004 (in thousands, except per share amounts):

| | 2006 | 2005 | 2004 |
|---|---|---|---|
| Net loss | $ (14,195) | $ (7,391) | $ (3,697) |
| Weighted average common shares outstanding | 10,147 | 9,647 | 5,117 |
| Basic loss per share | $ (1.40) | $ (0.77) | $ (0.72) |
| Weighted average common and dilutive potential common shares outstanding: | | | |
| Weighted average common shares outstanding | 10,147 | 9,647 | 5,117 |
| Assumed exercise of stock options | | | |
| | 10,147 | 9,647 | 5,117 |
| Diluted earnings per share | $ (1.40) | $ (0.77) | $ (0.72) |

Other potential common stock of 1,469,148, 1,715,363 and 1,786,846 for the periods ended December 31, 2006, 2005 and 2004, respectively, were excluded from the above calculation of diluted loss per share since they were antidilutive.

8. STOCK OPTIONS AND EMPLOYEE STOCK PURCHASE PLAN:

During 2006 the Company had two stock option plans available which were 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, 2006, there were 202,935 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 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.

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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 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 2006, 2005 or 2004.

A summary of the status of the Company s option plans at December 31, 2006, 2005, and 2004 and changes during the years then ended is presented in the tables below:

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| | Stock Options | Weighted Average Exercise Price | Remaining Weighted Average Contractual Term (Years) | Aggregate Intrinsic Value (In Thousands) |
|---|---|---|---|---|
| Outstanding at December 31, 2003 | 1,225,470 | $ 5.98 | | |
| Granted | 816,464 | 2.78 | | |
| Exercised | (60,888) | 1.39 | | |
| Forfeited | (194,200) | 5.24 | | |
| Outstanding at December 31, 2004 | 1,786,846 | 4.77 | | |
| Granted | 85,000 | 3.81 | | |
| Exercised | (26,700) | 3.18 | | |
| Forfeited | (129,783) | 5.92 | | |
| Outstanding at December 31, 2005 | 1,715,363 | 4.66 | | |
| Granted | 115,000 | 8.30 | | |
| Exercised | (71,361) | 3.38 | | |
| Forfeited | (289,854) | 7.85 | | |
| Outstanding at December 31, 2006 | 1,469,148 | 4.38 | 6.49 | $ 12,091 |
| Exercisable at December 31, 2006 | 1,026,035 | 4.07 | 6.29 | $ 8,762 |

The following table summarizes information about stock options outstanding at December 31, 2006:

| Range Of Exercise Prices | Number Outstanding | Weighted Average Remaining Life | Weighted Average Exercise Price | Number Exercisable | Weighted Average Exercise Price |
|---|---|---|---|---|---|
| $2.40 to $5.00 | 1,302,898 | 6.4 | $ 3.22 | 969,785 | $ 2.95 |
| 5.01 to 10.00 | 98,000 | 9.3 | 7.20 | 13,000 | 8.45 |
| 10.01 to 15.00 | 25,000 | 9.3 | 12.70 | 0 | .00 |
| 15.01 to 20.00 | 3,250 | 2.0 | 18.61 | 3,250 | 18.61 |
| 20.01 to 25.00 | 5,000 | 1.5 | 20.38 | 5,000 | 20.38 |
| 25.01 to 30.00 | 30,000 | 1.3 | 29.67 | 30,000 | 29.67 |
| 30.01 to 35.00 | 5,000 | 3.4 | 33.25 | 5,000 | 33.25 |
| | 1,469,148 | | | 1,026,035 | |

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 2006, the Company did not issue any common stock and there was no participation under the Purchase Plan in 2006. The Board of Directors terminated the Purchase Plan on March 9, 2007.

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 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

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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.

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11. QUARTERLY FINANCIAL INFORMATION (UNAUDITED):

| | First Quarter Ended March 31, 2006 | Second Quarter Ended June 30, 2006 | Third Quarter Ended September 30, 2006 | Fourth Quarter Ended December 31, 2006 |
|---|---|---|---|---|
| | (In thousands except per share amounts) | | | |
| Revenues and other income: | | | | |
| Interest income | $ 174 | $ 166 | $ 146 | $ 110 |
| Total revenues and other income | 174 | 166 | 146 | 110 |
| Expenses: | | | | |
| Research and development | 1,808 | 2,363 | 3,073 | 4,668 |
| General and administrative | 610 | 666 | 713 | 890 |
| Total expenses | 2,418 | 3,029 | 3,786 | 5,558 |
| Net loss | $ (2,244) | $ (2,863) | $ (3,640) | $ (5,448) |
| Net loss per share basic and diluted | $ (0.22) | $ (0.28) | $ (0.36) | $ (0.54) |
| Shares used in loss per share calculation | 10,140 | 10,146 | 10,150 | 10,151 |

| | First Quarter Ended March 31, 2005 | Second Quarter Ended June 30, 2005 | Third Quarter Ended September 30, 2005 | Fourth Quarter Ended December 31, 2005 |
|---|---|---|---|---|
| | (In thousands except per share amounts) | | | |
| Revenues and other income: | | | | |
| Research and development grants | $ 4 | $ | $ | $ |
| Interest income | 108 | 173 | 175 | 174 |
| Total revenues and other income | 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 |

12. SUBSEQUENT EVENTS

In January 2007, we received approximately $32,000 from the exercise of 13,333 stock options that were exercised by a former Board Member. These options were scheduled to expire on March 23, 2007 and had an exercise price of $2.40.

On February 5, 2007 the Company completed a follow-on public offering of 2,610,000 shares of common stock at $13.75 per share. The net proceeds from the sale of shares of common stock in this offering were approximately $33.0 million.

On March 9, 2007 the Company s Board of Directors voted to terminate its current 2000 Employee Stock Purchase Plan.

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## INDEX TO EXHIBITS

| 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 Amendment to the Company s Restated Certificate of Incorporation, dated as of May 2, 2006. Exhibit 3.1 to the Company s Current Report on Form 8-K as filed with the Commission on May 2, 2006 is incorporated herein by reference. |
| 3.1(c) | 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+ | 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+ | 1994 Employee and Consultant Stock Option Plan. Exhibit 4.2 to the Company s Registration Statement on Form S-8 (File No. 033-83406) as filed with the Commission on August 29, 1994 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. |

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| Exhibit Number | Identification Of Exhibit |
|---|---|
| 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+ | Employment Agreement between the Company and Andre van As dated March 7, 2007. Exhibit 10.1 to the Company s Current Report on Form 8-K as filed with the Commission on March 8, 2007 is incorporated herein by reference. |
| 10.13 | 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. |
| 10.14 | Amendment to Lease Agreement between the Company and Sealy Woodlands, L.P., dated May 17, 2006. Exhibit 10.1 to the Company s Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2006 is incorporated herein by reference. |
| 10.15++ | 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. |
| 10.16++ | 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.