

REPROS THERAPEUTICS INC.

Form 10-K

March 16, 2009

**Table of Contents**

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

**Form 10-K**

**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES  
EXCHANGE ACT OF 1934**  
For the fiscal year ended **December 31, 2008**

or

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

**Repos Therapeutics Inc.**

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

**Delaware**

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

**76-0233274**

*(IRS Employer  
Identification No.)*

**2408 Timberloch Place, Suite B-7  
The Woodlands, Texas**

*(Address of principal executive offices)*

**77380**

*(Zip Code)*

**(281) 719-3400**

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

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

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

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

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

Yes  No

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

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

Edgar Filing: REPROS THERAPEUTICS INC. - Form 10-K

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

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company   
(Do not check if a smaller reporting company)

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

The aggregate market value of the voting stock held by non-affiliates of the registrant was approximately \$94,688,000 as of June 30, 2008, 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 Global Market on such date of \$9.47 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, 2009, there were 15,174,904 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 2009 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, 2008, are incorporated by reference into Part III of this Form 10-K.

---

**REPROS THERAPEUTICS INC**  
**2008 FORM 10-K ANNUAL REPORT**  
**TABLE OF CONTENTS**

	<b>Page</b>
<b><u>PART I</u></b>	<b>2</b>
<u>Item 1. Business</u>	2
<u>Item 1A. Risk Factors</u>	13
<u>Item 1B. Unresolved Staff Comments</u>	24
<u>Item 2. Properties</u>	24
<u>Item 3. Legal Proceedings</u>	24
<u>Item 4. Submission of Matters to a Vote of Security Holders</u>	24
 <b><u>PART II</u></b>	 <b>24</b>
<u>Item 5. Market for the Registrant's Common Equity, Related Stockholder Matters &amp; Issuer Purchases of Equity Securities</u>	24
<u>Item 6. Selected Consolidated Financial Data</u>	27
<u>Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	28
<u>Item 7A. Quantitative and Qualitative Disclosures About Market Risk</u>	38
<u>Item 8. Financial Statements and Supplementary Data</u>	38
<u>Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	38
<u>Item 9A. Controls and Procedures</u>	38
<u>Item 9B. Other Information</u>	39
 <b><u>PART III</u></b>	 <b>40</b>
<u>Item 10. Directors, Executive Officers and Corporate Governance</u>	40
<u>Item 11. Executive Compensation</u>	40
<u>Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	40
<u>Item 13. Certain Relationship and Related Transactions, and Director Independence</u>	40
<u>Item 14. Principal Accountant Fees and Services</u>	40
 <b><u>PART IV</u></b>	 <b>41</b>
<u>Item 15. Exhibits and Financial Statement Schedules</u>	41
<u>EX-23.1</u>	
<u>EX-31.1</u>	
<u>EX-31.2</u>	
<u>EX-32.1</u>	
<u>EX-32.2</u>	

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.

**Table of Contents**

**PART I**

**ITEM 1. BUSINESS**

**Overview**

Repos Therapeutics Inc. ( the Company , RPRX, Repos , or we, us or our ) was organized on August 28, 1999 and is a development stage biopharmaceutical company focused on the development of oral small molecule drugs for major unmet medical needs.

Our current product pipeline (with the respective status of development) consists of the following:

**Proellex®** (female reproductive health)

Phase 3 three-month pre-surgical treatment for women with anemia due to excessive menstrual bleeding associated with uterine fibroids, or anemia associated with uterine fibroids, who may consider having a subsequent hysterectomy

Phase 3 chronic treatment of symptoms associated with uterine fibroids

Phase 2 chronic treatment of symptoms associated with endometriosis

**Androxal®** (male reproductive health)

Phase 2b proof-of-concept trial in men being treated for low testosterone levels who want to improve or maintain their fertility and/or sperm number and function

We intend to file an Investigational New Drug Application, or IND, in the first half of 2009 for Androxal as a treatment for type 2 diabetes

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

**Available Information**

Our Internet site ([www.reposrx.com](http://www.reposrx.com)) makes available free of charge to all interested parties our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to those reports, as well as all other reports and schedules filed electronically with the Securities and Exchange Commission, or SEC, as soon as reasonably practicable after such material is electronically filed with or furnished to the SEC. Interested parties may also find reports, proxy and information statements and other information on issuers that file electronically with the SEC at the SEC's Internet site (<http://www.sec.gov>).

**Proellex**

*Product and Clinical Development Overview*

Our lead drug, Proellex®, is a selective blocker of the progesterone receptor. We are developing Proellex for three indications: 1) anemia associated with uterine fibroids, 2) chronic treatment of symptoms associated with uterine fibroids and 3) chronic treatment of symptoms associated with 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, anemia associated with 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 FSH and LH.

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.

-2-

---

**Table of Contents**

We believe Proellex may have advantages in treating uterine fibroids, anemia associated with uterine fibroids and endometriosis compared to treatment with GnRH agonists. In our clinical trials, which are consistent with our preclinical studies, women treated with Proellex maintain physiological estrogen levels. Therefore, we believe Proellex treatment may not result in estrogen deprivation 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 is required to comply and meet full regulatory approval requirements which include pre-clinical animal safety studies; Phase 1, Phase 2 and Pivotal Phase 3 clinical trials; long-term Open Label Safety Studies; manufacturing related activities as well as other requirements requested by the FDA to receive marketing approval for each of our disease indications. In addition, the FDA may request additional previously unanticipated clinical data before approval can be obtained.

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 data from non-pivotal trials and that our pivotal Phase 3 and long-term Open Label Safety Study data may not agree with these results which will be based upon a significantly larger and more diverse patient population treated for longer periods of time.

We currently do not have reliable estimates regarding the timing of our Proellex clinical trials. The length of time required to complete Phase 1, Phase 2 and Phase 3 clinical trials and long-term open label safety studies may vary substantially according to factors relating to the particular clinical trial, such as the type and intended use of the drug candidate, the clinical trial design and the ability to enroll suitable patients. We have had difficulty recruiting patients into our Proellex clinical trials primarily due to the various test procedures that are required for a patient to be treated for these three indications, which includes multiple endometrial biopsies. In addition, the protocol for patients being treated for anemia associated with uterine fibroids who may elect to have hysterectomies post treatment have encountered both patients and doctors not wanting to be a part of those clinical trials due to this requirement. We have recently removed this requirement and will leave this procedure up to the patient and their physician. Notwithstanding the uncertainty described above, we currently estimate completion of our Proellex projects and the submission of a New Drug Application, or NDA, under the following timelines:

Pre-surgical treatment of anemia associated with uterine fibroids	2010
Treatment of symptoms associated with uterine fibroids	Late 2010-2011
Treatment of symptoms associated with endometriosis	Late 2010-2011
<i>Anemia Associated with Uterine Fibroids</i>	

We filed a new IND for Proellex as a pre-surgical short-course treatment of anemia associated with uterine fibroids which became effective in February 2008. We initiated this new clinical indication with Proellex based upon the results observed from a subset of anemic patients in our U.S. Phase 2 trial with Proellex for the treatment of uterine fibroids which was completed in 2007. In that study, women with hemoglobin levels of less than 11.5 g/dl improved by up to 2 g/dl, or the equivalent of two pints of blood, after three months of treatment with Proellex. Even though only approximately 15-17 patients per active treatment arm were able to be evaluated for anemia, the improvement of hemoglobin in Proellex-treated subjects was both clinically and statistically highly significant ( $p < 0.002$ ) compared with placebo. Oral iron supplements for correction of anemia were used by a similar number of women in the placebo and 25 mg Proellex arms of the trial. A slightly higher percentage of women in the Proellex 12.5 mg arm used oral iron supplements. This suggests that reversal of the anemia with Proellex treatment was largely due to the very effective prevention of severe blood loss experienced by these patients with symptomatic uterine fibroids.

**Current Phase 3 Trials.** In the first quarter of 2008 we contracted two clinical research organizations, or CROs, to conduct our registration Phase 3 pivotal clinical trials (ZPU-301 and ZPU-302) and began selecting the clinical sites to conduct these trials. We recently revamped this clinical program by engaging additional investigator sites as a means of completing these studies as quickly as practicable.

We are currently conducting these Phase 3 Pivotal clinical trials in both the U.S. and Latin America. These trials consist of three parallel arms each consisting of placebo, 25 and 50 mg Proellex. Each trial will enroll 65 patients unevenly distributed between placebo (15 patients) and 25 and 50 mg Proellex (25 patients each). Patients are being

treated with Proellex or placebo for three months. The primary endpoint of both of these clinical trials is improvement in hemoglobin concentration. All patients will receive a fixed dose of daily iron supplementation as well. All patients that complete these two Pivotal Phase 3 clinical trials are now eligible to enroll in a 12-month Open Label Safety study (ZPU-307).

Development Plan. In addition to our Phase 3 pivotal trials listed above, the FDA will require data from 100 patients that have been exposed to Proellex for a six-month period. Our goal is to file a NDA for Proellex for the treatment of anemia associated with uterine fibroids in 2010. Such filing depends on a variety of factors, including the timing of enrollment of patients in our two clinical



## **Table of Contents**

trials as well as the outcome and results of such clinical trials. We will also have to provide the FDA with data from additional Phase 1 studies, other safety and efficacy data as requested, preclinical safety data and meet all manufacturing requirements. No assurance can be given that such filing will be made at such time or at all.

### *Symptomatic Uterine Fibroids Chronic Management*

We completed a Phase 2 clinical trial (ZPU-003) with Proellex for the treatment of uterine fibroids during 2007. This study consisted of 128 patients in a randomized, double-blind, placebo-controlled trial. The analysis of the clinical trial data demonstrated statistically significant reductions in excessive menstrual bleeding and an improvement in quality of life scores versus placebo. Furthermore, after three months of treatment, no statistically significant change in endometrial thickness was observed and 48 women consenting to endometrial biopsy had no evidence of hyperplasia with atypia the diagnosis in all being benign endometrium by WHO criteria. This trial was designed to assess both improvement of symptoms associated with uterine fibroids as well as effects on the actual fibroids. The three-arm trial compared two doses of Proellex, 12.5 mg and 25 mg, to placebo over a 3-month period. The primary endpoint was a 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, or PBAC. Various other symptoms associated with fibroids were assessed using the validated Uterine Fibroid Symptom and Quality of Life, or UFS-QOL, questionnaire. Patients that completed the blinded portion of this clinical trial were enrolled into a 12-month Open Label Safety extension study (ZPU-003ext).

Current Phase 3 Trials. As a result of a Type B meeting with the FDA at the end of November 2007, two registration Phase 3 (ZPU-303 and ZPU-304) pivotal four-month double blind placebo controlled clinical trials with Proellex for the treatment of uterine fibroids were initiated in the first quarter of 2008. At that time we contracted two CROs to conduct these registration Phase 3 Pivotal clinical trials and began selecting the clinical sites that will conduct these trials. We recently revamped this clinical program to increase the number of investigator sites as a means of completing these studies as quickly as practicable.

We are currently conducting these Phase 3 Pivotal clinical trials in both the U.S. and Latin America. These trials consist of three parallel arms each consisting of placebo, 25 and 50 mg Proellex. Each trial is scheduled to enroll 75 patients evenly distributed between placebo, 25 and 50 mg Proellex. Patients are being treated with Proellex or placebo for four months.

Current and Upcoming Open Label Safety Studies. We are currently conducting a second small 12-month Open Label Safety extension study (ZPU-003ext 2) with patients from our previously completed U.S. Phase 2 (ZPU-003) clinical trial.

We also initiated two 400-patient long-term Open Label Safety Studies during the first quarter of 2008. We contracted one CRO to conduct both studies that will enroll patient in the U.S. as well as Latin America.

The first long-term 400-patient Open Label Safety Study (ZPU-305) is a twelve-month on drug study which will incorporate two off-drug intervals between three four-month drug treatment periods. After patients complete a four-month course of treatment, they will be taken off the drug until they menstruate normally before commencing further treatment. Then they will begin the next four-month drug treatment until three drug treatments have been completed. We began randomizing patients into this study during 2008 and we continue to randomize patients into this clinical trial.

The second long-term 400-patient Open Label Safety Study (ZPU-306) will enroll patients after the initial 400-patient Open Label Safety Study (ZPU-305) has been fully recruited. This study will consist of two four-month drug treatment periods, separated by one off-drug interval. After patients complete a four-month course of treatment they will be taken off the drug until their symptoms return and then they will begin the final four-month drug treatment period. We anticipate patient randomization to begin during the second half of 2009 for this clinical trial.

Development Plan. In addition to our ongoing two Pivotal Phase 3 clinical trials, the FDA will require data from 200 patients that have been exposed to Proellex for one year with the final duration of drug exposure to be determined as data from ongoing trials continues to evolve. We will also need to provide the FDA with data from approximately 300 to 600 patients that have been on Proellex for six months. The FDA has suggested a total safety data base of 1,500 patients which may be derived from all of our trials and studies of Proellex for all indications, doses and durations of exposure.

We anticipate that a NDA for this indication will be filed in late 2010 or 2011. Such filing depends on a variety of factors, including the timing of enrollment of patients in the two pivotal clinical and open label safety trials described above, as well as the outcome and results of the trials. We will also incorporate any data submitted in the NDA for the anemia associated with uterine fibroids indication into this NDA submission as well as any other additional data that the FDA may require. No assurance can be given that such filing will be made at such time or at all.

*Endometriosis*

Recent Phase 2 Trial. During February 2009, we reported data from our recently completed U.S. Phase 2 clinical trial (ZPE-201) with Proellex for the treatment of endometriosis. This trial was conducted in the United States and was designed to assess the

**Table of Contents**

improvement of symptoms associated with endometriosis. The trial tested two doses of Proellex, 25mg and 50mg, as a once-a-day oral therapy versus placebo in a double-blind design and was four-months in duration. The trial utilized a daily diary into which patients recorded their endometriosis symptom scores as a primary endpoint. Per a request from the FDA, the diary was derived from the symptom section of the previously validated Biberoglu and Behrman Symptom Score, or BBSS.

The endometrium, or lining of the uterus, was monitored monthly using ultrasound and endometrial biopsies which was done at baseline and the end of four-month treatment exposure. The four-month duration of the trial is similar to the duration of treatment in previously conducted trials with Proellex. After the double-blind treatment period, patients will roll over to an Open Label Safety Extension Study (ZPE-201 ext) on Proellex 25 mg with the option to up-titrate to 50 mg if symptoms are not adequately controlled. This extension study will allow these completed patients to be treated for two additional four-month cycles with an intervening menstruation between each cycle if symptoms recur.

Doses used in this trial were previously tested in a 24-week clinical trial (ZPE-002) with Proellex for the treatment of endometriosis in 40 patients which was conducted in Bulgaria. The trial compared Proellex to Lucrin<sup>®</sup>, also known as Lupron<sup>®</sup>, an approved GnRH agonist, commonly used to treat the symptoms associated with endometriosis. The 50mg dose of Proellex achieved statistical significance (p=0.0012) when compared to Lucrin in reducing the number of days of pelvic abdominal pain over the course of the trial. In addition, a statistically significant greater percentage of patients had a reduction in pain in the 50 mg treatment arm compared with the other treatments. There was no statistical difference between the 25 mg dose of Proellex and Lucrin. There was a clear dose response in the Proellex treatment groups, and Proellex was well tolerated over the course of the trial.

**Development Plan.** We are preparing to request an end of Phase 2 meeting with the FDA that we anticipate could occur mid-year 2009. Pending positive FDA outcome from that meeting and acceptance of clinical protocols, we plan to initiate registration Phase 3 pivotal trials as soon as practicable. We estimate the filing of a NDA for endometriosis in late 2010-2011. Such filings depend on a variety of factors, including the timing of enrollment of patients in the trials as well as the outcome and results of the trials. No assurance can be given that such filings will be made at such time or at all.

***Management of Increasing Endometrial Thickening and Uterine Bleeding***

During the six-month study of endometriosis in Bulgaria (ZPE-002) it was observed that the development of endometrial thickening was dependent on duration of exposure and the dose that was used. In summary, the lower the dose and the longer the exposure beyond 4 months, the greater the risk became for endometrial thickening and severe uterine bleeding. Four instances of severe bleeding, all managed successfully by intervention with Dilatation and Curettage, occurred after 5 months. In addition there was a very strong tendency for endometrial thickening to occur in the 12.5 mg dose by month three of exposure. These results were corroborated by the fact that none of the 127 women in the U.S. Phase 2 (ZPU-003) uterine fibroid study, who were exposed to treatment for 3 months, had similar events. The increase in endometrial thickening correlates well with the development of cystic dilatation of the glands in the endometrium which has been observed histologically on endometrial biopsy. These observations have led Repros to develop a proactive strategy to manage these events. A dosing regimen consisting of sequential four-month treatment cycles, each followed by an off drug interval, in order to refresh the endometrium after a withdrawal bleed has occurred, has been developed and we believe this treatment regimen will allow Proellex<sup>®</sup> to be used in a safe and practical manner for longer term treatment exposures and subsequently avoid the development of endometrial thickening with the attendant risk of severe bleeding.

**Androxal*****Product Overview***

Our second product candidate, Androxal<sup>®</sup> (the *trans* isomer of clomiphene) is a single isomer of clomiphene citrate and is an orally active proprietary small molecule compound. We were previously developing Androxal in the United States to treat testosterone deficiency due to secondary hypogonadism by restoring normal testosterone production in males with functional testes and diminished pituitary function, a common condition in the aging male. Based on a Type C meeting held with the FDA, on October 15, 2007 we believe that we do not have a clear clinical path to develop Androxal for this indication in the U.S. at this time. Although we believe Androxal could be developed outside of the U.S., due to the limited European market for this indication and our limited internal resources we do not

intend to pursue approval outside of the U.S. at this time.

We intend to development Androxal for men of reproductive age with low testosterone levels who want to improve or maintain their fertility and/or sperm function while being treated for low testosterone. In addition, we received guidance from the FDA in November 2008 suggesting submission of a new IND to the Division of Metabolic and Endocrine Products, or DMEP, for the investigation of Androxal as a potential treatment for type 2 diabetes. We plan to submit a new IND for this indication to the DMEP as soon as practicable. This new indication replaces our previously announced plan to develop Androxal in men with adult-onset idiopathic hypogonadotropic hypogonadism, or AIHH, with concomitant plasma glucose and lipid elevations, all of which are components of Metabolic Syndrome.

-5-

---

**Table of Contents**

Data relating to the findings of Androxal's beneficial effect on fertility and as a treatment for AIHH associated with glucose and lipid dysregulation was discovered after a retrospective review of our clinical data from our 200 patient non-pivotal U.S. Phase 3 clinical trial. Our findings showed that Androxal therapy resulted in a significant reduction in mean glucose levels in men with a body mass index, or BMI, >26 and glucose levels >104 mg/dL, an outcome not seen in the placebo or AndroGel® arms of this study. AndroGel is the current leading therapy for testosterone replacement. Men with AIHH are characterized as having both low testosterone and LH, often accompanied by obesity and elevated blood glucose, among other signs. Our clinical trial data suggests that Androxal modifies the endocrinologic profile in terms of both hormones and glucose. There can be no assurance that clinical trials performed for these two new indications will be successful.

We believe Androxal may have advantages over current therapies for the treatment of low testosterone due to secondary hypogonadism because it is 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 believe Androxal will be superior to the existing administration of exogenous testosterone products used to normalize testosterone as only Androxal has the property of restoring both LH and FSH levels. LH and FSH are the pituitary hormones that stimulate testicular testosterone and sperm production, respectively.

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 the Urology Channel, recent estimates show that 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, which had reported sales of approximately \$282 million in 2005 in North America.

Based on our own clinical trial 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). Secondary hypogonadism is not relegated only to older men although the condition becomes more prevalent as men age.

Androxal is considered a new chemical entity by the FDA which means that the compound will be required to undergo the full regulatory approval process. We must still meet additional clinical requirements including pre-clinical, Phase 1, Phase 2b trials, pivotal Phase 3 trials, long-term Open Label Safety Studies as well as other requirements. 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 clinical trials to date, we have observed no evidence of any of these events except for certain ophthalmologic events in our preclinical dog study at doses significantly higher than those administered in the clinical trials.

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 data from non-pivotal trials and that our Phase 2b trials, pivotal Phase 3 and long-term Open Label Safety Trial data may not agree with these results which will be based upon significantly larger and more diverse patient populations treated for longer periods of time.

*Secondary Hypogonadism with Fertility Maintenance/Improvement*

During the second quarter of 2008, we initiated a 24-patient Phase 2b proof-of-concept clinical trial (ZA-201) for a new indication in which we are monitoring the effects of Androxal on male fertility and testicular function in patients being treated for low testosterone as compared to Testim®, a popular marketed topical testosterone medication. We anticipate holding an end of Phase 2 meeting with the FDA during the second half of 2009. At this time it is too early in the clinical development process to estimate when or even if a NDA will be filed with Androxal for this indication.

-6-

---

## **Table of Contents**

### *Type 2 Diabetes*

In April 2008, we submitted a White Paper, based on the results from a previously conducted non-pivotal Phase 2 clinical trial (ZA-003) with Androxal® for the treatment of testosterone deficiency due to secondary hypogonadism, to the Division of Reproductive and Urology Products. The data we believe demonstrated that in subjects with a serum glucose of greater than or equal to 105mg/dL, there was a statistically significant reduction in fasting serum glucose and a higher response rate to treatment in the Androxal®-group than the placebo or AndroGel® groups. In November 2008, after the FDA reviewed this paper we received guidance from them suggesting that we open a new IND with the Division of Metabolic and Endocrine Products, or DMEP, for the investigation of Androxal as a potential treatment for type 2 diabetes mellitus. We plan to submit a new IND for this indication to the DMEP in the first half of 2009. We anticipate conducting a Phase 2b proof-of-concept clinical trial with Androxal after feedback from the FDA. At this time it is too early in the clinical development process to estimate when or even if a NDA will be filed with Androxal for this indication. This new indication replaces our previously announced plan to develop Androxal in men with adult-onset idiopathic hypogonadotrophic hypogonadism, or AIHH, with concomitant plasma glucose and lipid elevations, all of which are components of Metabolic Syndrome.

### *Secondary Hypogonadism*

We were previously developing Androxal in the United States to treat testosterone deficiency due to secondary hypogonadism by restoring normal testosterone production in males with functional testes and diminished pituitary function, a common condition in the aging male. Based on a Type C meeting held with the FDA on October 15, 2007 we believe that we do not have a clear clinical path to develop Androxal for this indication in the U.S. at this time. Although we believe Androxal could be developed outside of the U.S., due to the limited European market for this indication and our limited internal resources we do not intend to pursue approval outside of the U.S. at this time.

During 2008, we continued our Androxal long-term Open Label Safety Study (ZA-003ext) for the treatment of low testosterone due to secondary hypogonadism and preclinical animal safety studies that we believe can be used to support potential future Androxal clinical NDA regulatory submissions.

### **Other Products**

We continue limited 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. VASOMAX is currently on partial clinical hold in the U.S.

### **Business Strategy**

Our business strategy is to concentrate our resources on the clinical development of Proellex for uterine fibroids, anemia associated with uterine fibroids and endometriosis in order to achieve commercialization as soon as practicable. In addition, we are accumulating safety results from all three Proellex indications in order to expedite the development of Proellex. Secondly we are continuing to pursue proof-of-concept clinical trials of Androxal for treatment of patients that want to maintain their fertility while being treated for testosterone deficiency and also to treat patients with type 2 diabetes. We intend to expand the development of Androxal after receiving the proper feedback from the Food and Drug Administration, or FDA, once our Phase 2b proof-of-concept clinical trials are completed and when funding permits.

We continue to utilize third party clinical regulatory organizations for assistance with our clinical development programs for both drugs; however, we anticipate adding certain critical functions, including but not limited to employees experienced in drug commercialization, during the next several years as the products complete their clinical development programs in order to be able to commence product sales efforts in the event FDA approval is achieved. We will continue to explore corporate partner opportunities for assistance in the clinical development and commercialization of our products or for capital funding, as appropriate.

### **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 2008 were for the payment of contract research organizations and consultants in connection with our clinical trials of Proellex for the treatment of uterine fibroids, endometriosis and for Androxal for testosterone deficiency. We believe that these expenses will continue to be our primary R&D expenses in the near future.

**Proellex License Agreement with National Institutes of Health**

In 1999, we licensed rights to Proellex from the National Institutes of Health, or 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

-7-

---



## **Table of Contents**

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 a first indication by June 30, 2009. We have requested a meeting with the NIH to defer such date along with certain other milestones prior to such deadline. Although we believe we have a good working relationship with the NIH and even though the NIH has amended our agreement on several other occasions, no assurances can be given that such date or milestones will be revised.

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 again agree to amend this agreement to our satisfaction. Failure to comply with the material terms contained in the license agreement could result in termination of such agreement, which would prohibit us from further development of Proellex and severely harm our business prospects. 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. In 2006, we 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.

In addition, under a December 2008 Purchase Request, we committed to the purchase of \$3 million of the bulk active ingredient of Proellex which is to be produced under a new scaled-up amended manufacturing process by Gedeon Richter. Under this Purchase Request we are obligated to make four payments of \$750,000 each aggregating \$3 million which are expected to be made during 2009, assuming that the manufacturer meets the criteria of the Purchase Request. We expect to receive this material in the fourth quarter of 2009 and recognize the expense associated with this purchase when this material is received from the manufacturer. This Purchase Request contains certain provisions in which any dollars paid to this manufacturer under the Purchase Request will be returned if the manufacturer cannot meet their obligations under this Purchase Request by March 31, 2010. This Purchase Request also provides that the payment criteria and terms of the purchase shall be amended if the new terms are agreed to by both parties.

We have a five year supply agreement with Diagnostic Chemical Limited, doing business as BioVectra, for the supply of the bulk active pharmaceutical ingredient used in 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 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 intend to develop capabilities for the marketing, sale and distribution of pharmaceutical products. We anticipate that we will market and sell Proellex in the U.S. and potentially out-license Proellex outside of the U.S. if such out-licensing is appropriate. In the future we will incur significant additional expenditures to develop a sales and marketing organization.

## **Table of Contents**

### **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, two pending U.S. patent applications, and several foreign patents and pending applications made by the NIH regarding Proellex. We also have five pending U.S. patent applications, four foreign PCT applications and 45 foreign pending patent applications 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 two issued U.S. patents and seven pending patent applications. Foreign coverage of our Androxal product candidate includes 33 issued foreign patents and 63 foreign pending patent applications. The issued patents and pending applications relate to methods and compositions for treating certain conditions including the treatment of testosterone deficiency in men, the treatment of metabolic syndrome and conditions associated therewith, and the treatment of infertility in hypogonadal 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 re-examination proceedings, which led the PTO to determine that the amended claims are patentable in view of those publications under consideration and a re-examination certificate was issued. However, we believe that the amended claims are invalid based on additional prior art publications, and our request for re-examination by the PTO in light of a number of these additional publications and other publications cited by the PTO, has been granted. All of the claims have been finally rejected in the re-examination. The patent holder has appealed the rejections and has recently filed a Request for Oral Hearing. We also believe that the second of these two patents is invalid in view of published prior art not considered by the PTO. Nevertheless, there is no assurance that either patent will ultimately be found invalid over the prior art. If such patents are not invalidated by the PTO we may be required to obtain a license from the holder of such patents in order to develop Androxal further or attempts may be made to undertake further legal action to invalidate such patents. 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. 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, formerly being developed by TAP Pharmaceuticals in partnership with Schering AG, has been tested and discontinued due to side effects up through Phase 3 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 \$282 million in North America. 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. In addition, other companies are developing other products that would compete with Androxal. We believe we can compete with AndroGel and the other replacement therapies because we believe that Androxal avoids the

## **Table of Contents**

abnormally high peaks of testosterone levels and elevated levels of DHT which can be associated with current testosterone replacement therapies like AndroGel. Based on our clinical trial supply cost to date, we currently expect that Androxal, if approved, can compete favorably on a cost basis with current testosterone replacement therapies.

### **Governmental Regulation**

Our research and development activities, preclinical studies and clinical trials, and 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 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

## **Table of Contents**

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.

## **Employees and Consultants**

### *Employees*

As of March 13, 2009, we had 10 full-time employees. We also utilize consultants as well as contract research organizations and other outside specialty firms for various services such as preclinical and clinical trial support, manufacturing, regulatory approval advice and accounting and human resource management. 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

-11-

---



**Table of Contents**

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, during the year 2008 we engaged five U.S. contract research organizations to conduct our clinical trials in the United States and ex-U.S. for the treatment of anemia associated with uterine fibroids, chronic treatment of symptoms associated with uterine fibroids and for the treatment of symptoms associated with endometriosis. In addition, one of these CROs is also conducting our current open label safety study with Androxal for the treatment of testosterone deficiency. Under our arrangements with these CROs, we design the protocols for the clinical trials and direct the CROs in their efforts.

-12-

---

**Table of Contents**

**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***

*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. We expect our current capital to be sufficient to fund our operations through at least the second quarter of 2009, 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.

*The current worldwide financial crisis and economic downturn may likely affect our suppliers and contractors, and could materially affect our ability to do business.*

The current worldwide financial crisis has reduced the availability of liquidity and credit to fund or support the continuation and expansion of business operations worldwide. Recent financial market conditions have resulted in significant write-downs of asset values by financial institutions, and have caused many financial institutions to seek additional capital, to merge with larger and stronger institutions and, in some cases, to fail. Many lenders and institutional investors have reduced and, in some cases, ceased to provide funding to borrowers. Continued disruption of the credit markets could adversely affect the credit capacity of our suppliers, contractors and insurance providers and could result in cancellations, suspensions or project delays. If one or more of our suppliers or contractors experiences difficulties that result in a reduction or interruption in supplies or services to us, or they fail to meet any of

our manufacturing requirements, our business could be adversely impacted until we are able to secure alternative sources, if any. If our insurance providers are not able to meet their obligations, we could also be adversely impacted. In addition to these factors, please refer to the risk factor titled, 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 for a discussion of additional adverse events that could arise from the failure of our independent contractors.

-13-

---

**Table of Contents**

*The U.S. government's actions to address the financial crises may not be effective to stabilize the financial markets or to increase the availability of credit.*

In response to the financial crises affecting the banking system and financial markets and going concern threats to investment banks and other financial institutions, legislation was enacted that provides the U.S. Treasury the authority to, among other things, purchase mortgage-backed and other securities from financial institutions for the purpose of stabilizing the financial markets. In addition, legislation has been enacted to stimulate general U.S. and global economic recovery, both in the United States and overseas. Since enactment of the legislation, the global capital markets have continued to experience extreme levels of volatility and the credit markets have not yet shown any significant increase in the availability of credit. There can be no assurance what impact this legislation ultimately will have on the financial markets. If actions taken pursuant to the legislation are not successful in stabilizing the financial markets and increasing the availability of credit, it could have a material adverse effect on our business, financial condition and results of operations or the trading price of our common stock.

*Our product candidates are in clinical development, and if we are not able to successfully complete their development 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 development. 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. In addition, we are focusing our resources on the development of Proellex which will further delay the development and commercialization of Androxal.

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. Previous clinical trials for Proellex and Androxal have been conducted only in limited 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, anemia associated with uterine fibroids and endometriosis. Furthermore, the only data that we obtained to date relating to Androxal is to treat testosterone deficiency. We will be required to demonstrate through larger-scale clinical trials that these product candidates are safe and effective for use in a diverse population before we can seek regulatory approvals for their commercial sale which we have only recently initiated for Proellex in our registration Pivotal Phase 3 trials. There is typically an extremely high rate of attrition from the failure of drug candidates proceeding through clinical trials. We are also required to complete our two-year rat carcinogenicity studies as well as other preclinical studies 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.

*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, 2008, we had a deficit of approximately \$147.2 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. The uncertainties relating to the foregoing matters raises substantial doubt about our ability to continue as a going concern.

-14-

---

**Table of Contents**

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

*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. The final results from our clinical development programs may be negative, may not meet expectations or may be perceived negatively. The designs of our 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. Because of the nature of clinical trials, 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;

convincing the FDA that we have selected valid endpoints for use in proposed clinical trials, such as those we recently changed in our Androxal clinical trials after our meeting with the FDA;

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.*

**Table of Contents**

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; as was the case with our development for the initial indication of Androxal that we are no longer pursuing;

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

-16-

---

**Table of Contents**

Androxal, or if any NDA we submit is not approved by the FDA, we will be unable to commercialize that product. The FDA can and does reject NDAs and requires additional clinical trials, even when drug candidates achieve favorable results in large-scale Phase 3 clinical trials. If we fail to commercialize Proellex or Androxal, we will 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. 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.

-17-

---

**Table of Contents**

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

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

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

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

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

Currently, we do not have the ability internally to manufacture the product candidates that we need to conduct our clinical trials. In 2006, we 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. This was recently modified under the December 2008 purchase request described above under Business-Manufacturing.

We have a five year supply agreement with Diagnostic Chemical Limited, doing business as BioVectra, for the supply of the bulk active pharmaceutical ingredient used in 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 Androxal, for future clinical trials but may need to arrange for increased quantities 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

**Table of Contents**

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

*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, or CROs, and universities, in certain areas that are particularly relevant to our research and product development plans, such as the conduct of clinical trials. We have hired four CROs to conduct our Pivotal Phase 3 and Open Label Safety clinical trials with Proellex for the treatment of anemia associated with uterine fibroids and chronic treatment of uterine fibroids. In addition, we also hired one of these same CROs to conduct a Phase 2 clinical trial 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.

In addition, we have no control over the financial health of our independent contractors. The current worldwide financial crisis, described in our second risk factor above, may contribute to the likelihood of the financial failure of one or more of our independent contractors. Several of our independent contractors are in possession of valuable and sensitive information relating to the safety and efficacy of our product candidates, and several others provide services to a significant percentage of the patients enrolled in the respective clinical trials in which such independent contractors participate. Should one or more of these independent contractors become insolvent, or otherwise are not able to continue to provide services to us, as a result of the current worldwide financial crisis or otherwise, the clinical trial in which such contractor participates could become significantly delayed and we may be adversely affected as a result of the delays and additional expenses associated with such event.

*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

-19-

---

## **Table of Contents**

liabilities or for liabilities in excess of our insurance limits, our assets may not be sufficient to cover such claims and our business operations could be impaired.

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

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

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, and the use of approved progestin-based contraceptives for the treatment of endometriosis. 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.

Furthermore, Neurocrine Biosciences Inc. is developing a GnRH antagonist for the treatment of 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 10 full-time employees at the present time, including Joseph S. Podolski, Paul Lammers, Louis Ploth, Jr., Andre van As and Ronald Wiehle. We are highly dependent on Messrs. Podolski and Ploth and Drs. Lammers, van As and Wiehle for the management of our company and the development of our technologies. Messrs. Podolski and Ploth and Drs. Lammers and van As have employment agreements with us. There can be no assurance that any of these officers 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 any of our officers could delay or curtail our research and product development efforts.

*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

-20-

---

## **Table of Contents**

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.

*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.*

We have adopted certain anti-takeover provisions, including a rights agreement. 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. We recently amended the rights agreement to permit Efficacy Capital to acquire up to 40% of our outstanding common stock subject to a standstill agreement.

The rights agreement and certain 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.

*Our largest equity investor may exert control over important decisions affecting our governance and our operations, and their interests may differ from those of the other stockholders.*

Efficacy Capital Ltd. ( Efficacy ) currently owns, directly or indirectly, 28.3% of our common stock and is permitted under our rights plan to own up to 40% of our common stock. In addition, Mark Lappe, a managing partner of Efficacy Capital, serves as our chairman of the board of directors. Circumstances may arise in which Efficacy's interests could be in conflict with those of our other stockholders. Because Efficacy can exert significant control given their large equity position, conflicts of interest could be resolved in a manner adverse to us. It is possible that there will be situations where Efficacy's interests are in conflict with our interests, and they could exert influence to resolve these conflicts in a manner adverse to us.

### ***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.

*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 re-examination proceedings, which led the PTO to determine that the amended claims are patentable in view of those publications under consideration and a

re-examination certificate was issued. However, we believe that the amended claims are invalid based on additional prior art publications, and our request for re-examination by the PTO in light of a number of these additional publications and other publications cited by the PTO, has been granted. All of the claims have been finally rejected in the re-examination. The patent holder has appealed the rejections and has recently filed a Request for Oral Hearing. We also believe that the second of these two patents is invalid in view of published prior art not considered by the PTO. Nevertheless, there is no

-21-

---

## **Table of Contents**

assurance that either patent will ultimately be found invalid over the prior art. If such patents are not invalidated by the PTO we may be required to obtain a license from the holder of such patents in order to develop Androxal further or attempts may be made to undertake further legal action to invalidate such patents. 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.

-22-

---

**Table of Contents**

*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

**Table of Contents**

enforceability 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.

**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**

At a Special Meeting of Stockholders on December 16, 2008 our stockholders approved an amendment to our Restated Certificate of Incorporation, as amended, to increase the number of shares of our common stock authorized for issuance from 20,000,000 shares to 30,000,000 shares, and, as a result, increase the total number of authorized shares from 25,000,000 to 35,000,000. The number of authorized shares of preferred stock will remain at 5,000,000.

For 13,212,109

Against 281,373

Abstain 21,116

**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 Global Market, during the periods presented.

	Price Range	
	High	Low
<b>2007</b>		
First Quarter	\$14.67	\$9.16
Second Quarter	15.09	9.51
Third Quarter	14.38	9.88
Fourth Quarter	12.96	6.99
<b>2008</b>		
First Quarter	\$10.20	\$8.11
Second Quarter	11.09	8.21
Third Quarter	10.00	5.31
Fourth Quarter	11.25	5.68
<b>2009</b>		
First Quarter (January 2nd through March 3rd)	\$13.94	\$6.88

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 3, 2009, the last sale price of our common stock, as reported by the NASDAQ Global Market, was \$7.92 per share. On March 3, 2009, there were approximately 169 holders of record and approximately 3,750 beneficial holders of our common stock.

**Table of Contents**

**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*

We are party to a rights agreement, as amended, 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% or more of our outstanding common stock, except that Efficacy Capital Ltd. is permitted to acquire beneficial ownership of up to 40% of our common stock before these rights become exercisable.

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, June 30, 2005, January 10, 2008 and October 10, 2008.

**Table of Contents**

*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.**

**COMPARE 5-YEAR CUMULATIVE TOTAL RETURN  
AMONG REPROS THERAPEUTICS, INC.,  
NASDAQ COMBINED INDEX AND NASDAQ PHARMAEUTICALS  
ASSUMES \$100 INVESTED ON JAN, 1, 2004  
ASSUMES DIVIDEND REINVESTED  
FISCAL YEAR ENDING DEC.. 31, 2008**

-26-

---

**Table of Contents****ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA**

## Selected Consolidated Financial Data

The statement of operations data for the years ended December 31, 2008, 2007 and 2006, and the balance sheet data as of December 31, 2008 and 2007, have been derived from our financial statements, included elsewhere in this Annual Report on Form 10-K. The statement of operations data for the years ended December 31, 2005 and 2004, and the balance sheet data as of December 31, 2006, 2005 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:**

	2008	2007	2006	2005	2004
Revenues and Other Income:					
Licensing fees	\$	\$	\$	\$	\$
Research and development grants				4	118
Interest income	433	1,508	596	630	104
Gain on disposal of fixed assets					
Other income					35
Total revenues	433	1,508	596	634	257
Expenses:					
Research and development	22,575	12,420	11,912	6,101	2,471
General and administrative	3,060	2,788	2,879	1,924	1,483
Total expenses	25,635	15,208	14,791	8,025	3,954
Net loss	\$ (25,202)	\$ (13,700)	\$ (14,195)	\$ (7,391)	\$ (3,697)
Net loss per share – basic and diluted (1)	\$ (1.88)	\$ (1.09)	\$ (1.40)	\$ (0.77)	\$ (0.72)
Shares used in loss per share calculation	13,372	12,524	10,147	9,647	5,117
<b>BALANCE SHEET DATA:</b>					
Cash, cash equivalents and marketable securities	\$ 19,470	\$ 25,903	\$ 6,736	\$ 16,832	\$ 5,536
Total assets	22,603	27,599	7,849	17,682	6,606
Deficit accumulated during the development stage	(147,242)	(122,040)	(108,340)	(94,145)	(86,754)
Total stockholders' equity	\$ 15,614	\$ 24,060	\$ 3,790	\$ 16,955	\$ 5,992

(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.

-27-

---

**Table of Contents**

**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**

Repos Therapeutics Inc. (the Company, RPRX, Repos, or we, us or our) was organized on August 28, 1999. We are a development stage biopharmaceutical company focused on the development of oral small molecule drugs for major unmet medical needs.

Our current product pipeline (with the respective status of development) consists of the following:

**Proellex®** (female reproductive health)

Phase 3 three-month pre-surgical treatment for women with anemia due to excessive menstrual bleeding associated with uterine fibroids, or anemia associated with uterine fibroids, who may consider having a subsequent hysterectomy

Phase 3 chronic treatment of symptoms associated with uterine fibroids

Phase 2 chronic treatment of symptoms associated with endometriosis

**Androxal®** (male reproductive health)

Phase 2b proof-of-concept trial in men being treated for low testosterone levels who want to improve or maintain their fertility and/or sperm number and function

We intend to file an Investigational New Drug Application, or IND, in the first half of 2009 for Androxal as a treatment for type 2 diabetes

Our lead drug, Proellex®, is a selective blocker of the progesterone receptor and previously was primarily being developed for the chronic treatment of symptoms associated with uterine fibroids and endometriosis. During the first quarter of 2008 we filed an IND for Proellex for a new indication as a short course pre-surgical treatment of anemia associated with uterine fibroids.

Uterine fibroids, anemia associated with uterine fibroids and endometriosis affect a significant number of women of childbearing age in the developed world. There is no currently-approved effective long-term drug treatment for uterine fibroids or endometriosis. In the United States alone, approximately 300,000 women per year undergo a hysterectomy as a result of severe uterine fibroids.

During the first quarter of 2008 we initiated activities relating to the following Proellex clinical trials for patients with uterine fibroids:

Two 65-patient registration Pivotal Phase 3 clinical trials (ZPU-301 and ZPU-302) with Proellex as a pre-surgical treatment for women with anemia associated with uterine fibroids who may consider having a subsequent hysterectomy

Two 75-patient registration Pivotal Phase 3 clinical trials (ZPU-303 and ZPU-304) with Proellex for the chronic treatment of symptoms associated with uterine fibroids

Two 400-patient Open Label Safety Trials (ZPU-305 and ZPU-306) with Proellex for the chronic treatment of symptoms associated with uterine fibroids

During 2008 we also had the following ongoing clinical development activities relating to Proellex:

One U.S. Open Label Safety clinical trial (ZPU-003ext) with Proellex for the treatment of symptoms associated with uterine fibroids which was conducted with patients previously treated in our prior U.S. Phase 2 (ZPU-003) clinical trial

One U.S. Phase 2 clinical trial (ZPE-201) with Proellex for the treatment of symptoms associated with endometriosis

Several Phase 1 clinical safety trials

-28-

---

**Table of Contents**

Continued preclinical animal safety studies

Manufacturing/production related activities

We currently do not have reliable estimates regarding the timing of our Proellex clinical trials. The length of time required to complete Phase 1, Phase 2 and Phase 3 clinical trials and long-term open label safety studies may vary substantially according to factors relating to the particular clinical trial, such as the type and intended use of the drug candidate, the clinical trial design and the ability to enroll suitable patients. We have had difficulty recruiting patients into our Proellex clinical trials primarily due to the various test procedures that are required for a patient to be treated for these three indications, which includes multiple endometrial biopsies. In addition, patients being treated for anemia associated with uterine fibroids who may elect to have hysterectomies post treatment have encountered both patients and doctors not wanting to be a part of those clinical trials due to this requirement. We have recently removed this requirement and will leave this procedure up to the patient and their physician. Notwithstanding the uncertainty described above, we currently estimate completion of our Proellex projects and the submission of a NDA under the following timelines:

Pre-surgical treatment of anemia associated with uterine fibroids	2010 Late
Treatment of symptoms associated with uterine fibroids	2010-2011 Late
Treatment of symptoms associated with endometriosis	2010-2011

Our second product candidate, Androxal<sup>®</sup>, is a single isomer of clomiphene citrate and is an orally active proprietary small molecule compound. We were previously developing Androxal in the United States to treat testosterone deficiency due to secondary hypogonadism by restoring normal testosterone production in males with functional testes and diminished pituitary function, a common condition in the aging male. Based on a Type C meeting held with the Food and Drug Administration, or FDA, on October 15, 2007 we believe that we do not have a clear clinical path to develop Androxal for this indication in the U.S. at this time. Although we believe Androxal could be developed outside of the U.S., due to the limited European market for this indication and our limited internal resources we do not intend to pursue approval outside of the U.S. at this time.

During the second quarter of 2008, we initiated a 24-patient Phase 2b proof-of-concept clinical trial (ZA-201) for a new indication in which we are monitoring the effects of Androxal on male fertility and testicular function in patients being treated for low testosterone as compared to Testim<sup>®</sup>, a popular marketed topical testosterone medication. We anticipate holding an end of Phase 2 meeting with the FDA during the second half of 2009. At this time it is too early in the clinical development process to estimate when or even if a NDA will be filed with Androxal for this indication.

In April 2008, Repros submitted a White Paper to the Division of Reproductive and Urology Products, which we believe demonstrated in a previous conducted non-pivotal Phase 3 clinical trial (ZA-003) with Androxal for the treatment of testosterone deficiency due to secondary hypogonadism, that there was a statistically significant reduction in fasting plasma glucose and a higher response rate in subjects with a plasma glucose of greater than or equal to 105mg/dL who were treated with Androxal as compared with the placebo or Androgel<sup>®</sup>, a popular marketed topical testosterone medication. In November 2008, we received guidance from the FDA suggesting submission of a new IND to the Division of Metabolic and Endocrine Products, or DMEP, for the investigation of Androxal as a potential treatment for type 2 diabetes. We plan to submit a new IND for this indication to the DMEP in the first half of 2009. We anticipate conducting a Phase 2b proof-of-concept clinical trial with Androxal post feedback from the FDA relating to this indication. At this time it is too early in the clinical development process to estimate when or even if a NDA will be filed with Androxal for this indication. This new indication replaces our previously announced plan to develop Androxal in men with adult-onset idiopathic hypogonadotropic hypogonadism, or AIHH, with concomitant plasma glucose and lipid elevations, all of which are components of Metabolic Syndrome.

During 2008, we also continued our Androxal 104 patient long-term Open Label Safety Study (ZA-003ext) and preclinical animal safety studies that will be used to support any potential future Androxal clinical regulatory submissions.



We also continue to maintain our patent portfolio of 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.

The clinical development of pharmaceutical products is a complex undertaking, and many products that begin the clinical development process do not obtain regulatory approval. The costs associated with our clinical trials may be impacted by a number of internal and external factors, including the number and complexity of clinical trials necessary to obtain regulatory approval, the number of eligible patients necessary to complete our clinical trials and any difficulty in enrolling these patients, and the length of time to complete our clinical trials. Given the uncertainty of these potential costs, we recognize that the total costs we will incur for the clinical development of our product candidates may exceed our current estimates. We do, however, expect these costs to increase in year 2009 as compared to year 2008 as we continue with later-stage clinical trials, increase patient randomization into our larger open label safety clinical trials, potentially initiate new clinical trials for additional indications and seek to obtain regulatory approvals.

**Table of Contents**

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.

As with most biotechnology companies with drug candidates in development, the path to marketing approval by the U.S. Food and Drug Administration, or the FDA, and comparable foreign agencies for each such candidate is long and uncertain. The regulatory process, both domestically and abroad, is a multi-year process with no certainty when and if a drug candidate will be approved for commercial use. The development path for a particular drug candidate typically includes a variety of clinical trials. While we have a general estimate of the timeframe for our clinical trials, the actual anticipated completion dates for each of our drug candidates are uncertain due to a wide variety of risks, including those described in the risk factors in this 2008 Form 10-K. The length of time for a clinical trial may vary substantially according to factors relating to the particular clinical trial, such as the type and intended use of the drug candidate, the clinical trial design and the ability to enroll suitable patients. For example, we have revised our original estimates for clinical trial completion and related New Drug Application, or NDA, dates on several occasions over the past two years based on data received from our clinical trials to date. In addition, it may be necessary to undertake additional unanticipated clinical trials during the development path.

We will not receive any revenue from commercial sales unless we, or a potential partner, complete the clinical trial process, obtain regulatory approval, and successfully commercialize one or more of our product candidates. Similarly, we do not have a reasonable basis to predict when or if material net cash inflows from the commercialization and sale of our drug candidates will occur. To date, we have not commercialized any of our drug candidates to any material extent and in fact may never do so. For a discussion of the risks and uncertainties associated with the timing and costs of completing the development of the Company's drug candidates, see the section titled "Risk Factors."

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, 2008, the Company had an accumulated deficit of \$147.2 million and had cash and cash equivalents of \$19.5 million. We have experienced negative cash flows from operations since inception and have funded our activities to date primarily from equity financings and corporate collaborations. Based on our current planned clinical programs, we will need to raise additional capital in the third quarter of 2009. We believe we can secure additional cash resources through either the sale of our equity securities or through potential regional out-licensing of Proellex. It is possible that our current clinical trial activities will be more costly and take longer than we anticipate; accordingly, there can be no assurance that additional capital will not be necessary prior to the time anticipated.

We believe that we will secure sufficient capital to continue our currently planned clinical programs without any significant delay or impact on such programs, assuming that the results of our ongoing Proellex clinical trials are favorable. If the results of these trials are unfavorable, there can be no assurance that the Company will be successful in obtaining additional capital in amounts sufficient to continue to fund its operations through either the out-licensing of Proellex, the sale of equity securities, or other alternative sources of funding, which outcome would have a material adverse effect on the Company. The uncertainties relating to the foregoing matters raise substantial doubt about our ability to continue as a going concern over the next twelve months.

Our common stock is traded on the NASDAQ Global Market under our ticker symbol, RPRX. Effective January 8, 2008, 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.

We are 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 10 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.

We had an accumulated deficit of \$147.2 million as of December 31, 2008. The value of the tax asset associated with this accumulated deficit can be substantially diminished in value to us due to various tax regulations, including change in control provisions in the tax code. 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

**Table of Contents**

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 our 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*

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. Debt securities for which we have the ability and intent to hold to maturity are classified as held to maturity. Securities we designate 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. Due to the volatility of the financial markets at December 31, 2008, we had no marketable securities and held our cash in either an insured bank account or a money market mutual fund backed by U.S. Securities. At December 31, 2007, all securities were classified as trading securities.

Prior to the disruption of the financial markets, our investments typically included 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, excluding taxable auction securities. These securities were classified as trading securities and were valued in our financial statements at their fair value. Our policy required that the average life of the investment portfolio, excluding taxable auction securities, may not exceed 24 months.

*Capitalized Patent Costs*

We capitalize the cost associated with building our patent library for Proellex and Androxal. As of December 31, 2008, other assets consist of capitalized patent costs in the amount of \$1,713,000. 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 \$27,000, \$10,350, and \$71 in 2008, 2007 and 2006, respectively. Of the \$1,713,000 in capitalized patents, \$759,000 related to Proellex patents and \$954,000 related to Androxal patents.

We review 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 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 believe that our capitalized patent costs are not impaired as of December 31, 2008.

*Accrued Expenses*

We estimate accrued expenses as part of our process of preparing financial statements. Examples of areas in which subjective judgments may be required include costs associated with services provided by contract organizations for clinical trials, preclinical development and manufacturing of clinical materials. We accrue for costs incurred as the services are being provided by monitoring the status of the trials or services provided and the invoices received from our external service providers. In the case of clinical trials, a portion of the estimated cost normally relates to the projected cost to treat a patient in our trials, and we recognize this cost over the estimated term of the study based on

the number of patients enrolled in the trial on an ongoing basis, beginning with patient enrollment. As actual costs become known to us, we adjust our accruals. To date, our estimates have not differed significantly from the actual costs incurred. However, we are expanding the level of our clinical trials and related services. As a result, we anticipate that our estimated accruals for clinical services will be more material to our operations in future periods. Subsequent changes in estimates may result in a material change in our accruals, which could also materially affect our balance sheet and results of operations.

-31-

---

**Table of Contents***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.

*Share-Based Compensation*

We have two stock-based compensation plans at December 31, 2008, 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 use the Black-Scholes option pricing model to estimate the fair value of our stock options. 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.

*Income Taxes*

We have had losses since inception and, therefore, have not been subject to federal income taxes. We have accumulated approximately \$2.6 million of research and development tax credits. As of December 31, 2008, we had approximately \$129.9 million of net operating loss, or NOL, carry-forwards for federal income tax purposes. Additionally, approximately \$2.4 million of NOLs, and approximately \$81,000 of research and development tax credits, expired in 2008. 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.

**RECENT ACCOUNTING PRONOUNCEMENTS**

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. SFAS No. 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. Issued in February 2008, FSP 157-1 *Application of FASB Statement No. 157 to FASB Statement No. 13 and Other Accounting Pronouncements That Address Fair Value Measurements for Purposes of Lease Classification or Measurement under Statement 13* removed leasing transactions accounted for under Statement 13 and related guidance from the scope of SFAS No. 157. FSP 157-2 *Partial Deferral of the Effective Date of Statement 157* (FSP 157-2), deferred the effective date of SFAS No. 157 for all nonfinancial assets and nonfinancial liabilities to fiscal years beginning after November 15, 2008. The implementation of SFAS No. 157 for financial assets and financial liabilities, effective January 1, 2008, did not have a material impact on our consolidated financial position and results of operations. The implementation of SFAS No. 157 for nonfinancial assets and nonfinancial liabilities will not have a material impact on our consolidated financial position and results of operations.

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 did not apply the fair value option under SFAS 159, which is elective. We have reclassified all

cash flows, related to our trading securities, from operating to investing activities in the accompanying statement of cash flows to reflect the nature of the investments in accordance with paragraph 16 of SFAS 159.

In April 2008, the FASB issued FSP 142-3, Determination of the Useful Life of Intangible Assets , (FSP 142-3). FSP 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, Goodwill and Other Intangible Assets . FSP 142-3 is effective for fiscal years beginning after December 15, 2008. The implementation of this standard will not have a material impact on our consolidated financial position and results of operations.

-32-

---

**Table of Contents****Results of Operations***Comparison of Years Ended December 31, 2008 and 2007*

**Revenues and Other Income.** Total revenues and other income, which was comprised of interest income for the years ended 2008 and 2007, decreased 71% to \$433,000 in 2008 as compared to \$1.5 million for 2007. This decrease was primarily due to lower combined cash, cash equivalents and marketable securities balances and reduced interest rate yields that have occurred as we moved our cash investments solely into money market mutual fund.

**Research and Development Expenses.** Research and development, or R&D, expenses include contracted services relating to our clinical product development activities which include preclinical studies, clinical trials, regulatory affairs and bulk manufacturing scale-up activities and bulk active ingredient purchases for preclinical and clinical trials primarily relating to our two products in clinical development, which are Proellex and Androxal. Research and development expenses also include internal operating expenses relating to our general research and development activities. R&D expenses increased 82% or approximately \$10.2 million to \$22.6 million for the year ended 2008 as compared to \$12.4 million in 2007. Our primary R&D expenses for 2008 and 2007 are shown in the following table (in thousands):

<b>Research and Development</b>	<b>December 31, 2008</b>	<b>December 31, 2007</b>	<b>Variance</b>	<b>Change (%)</b>
Proellex clinical development	\$ 17,788	\$ 6,661	\$ 11,127	167%
Androxal clinical development	2,370	3,938	(1,568)	(40)%
Payroll and benefits	1,154	889	265	30%
Operating and occupancy	1,263	932	331	36%
<b>Total</b>	<b>\$ 22,575</b>	<b>\$ 12,420</b>	<b>\$ 10,155</b>	<b>82%</b>

To date through December 31, 2008 we have incurred approximately \$36.8 million for the development of Proellex and approximately \$13.6 million for the development of Androxal. These accumulated costs exclude any internal operating expenses. We are currently developing Proellex for three indications which include a pre-surgical treatment of anemia associated with uterine fibroids, a chronic treatment of symptoms associated with uterine fibroids and as a chronic treatment of symptoms associated with endometriosis. We are currently developing Androxal as a treatment for men with low testosterone that want to maintain or improve their fertility and sperm function. In addition, we are exploring the feasibility of developing Androxal as a treatment for Type 2 diabetes. Prior to 2008, we were developing Androxal as a treatment for men with low testosterone due to secondary hypogonadism.

Proellex clinical development expenses increased 167% or approximately \$11.1 million to approximately \$17.8 million for the year ended 2008 as compared to \$6.7 million in 2007. The increase in Proellex clinical development expenses is shown in the following table (in thousands):

<b>Proellex Clinical Development</b>	<b>December 31, 2008</b>	<b>December 31, 2007</b>	<b>Variance</b>	<b>Change (%)</b>
Clinical trials	\$ 14,547	\$ 3,301	\$ 11,246	341%
Preclinical studies	1,679	1,639	40	2%
Formulation and dosage	1,378	1,486	(108)	(7)%
Other	184	235	(51)	(22)%
<b>Total</b>	<b>\$ 17,788</b>	<b>\$ 6,661</b>	<b>\$ 11,127</b>	<b>167%</b>

Prior to 2008 we were developing Proellex for two indications which include a chronic treatment of symptoms associated with uterine fibroids and endometriosis. During the first quarter of 2008 we filed an IND with Proellex for a new indication as a short course pre-surgical treatment of anemia associated with uterine fibroids. Proellex clinical



expenses for the years ended 2008 and 2007 include Phase 1, Phase 2, Phase 3 and long-term Open Label Safety study activities.

Preclinical study expenses reflect animal safety activities required by the FDA to file a NDA. Formulation and dosage expenses reflect activities associated with the bulk scale-up and purchase of active drug to conduct clinical trials and to meet any potential future NDA submission requirements.

-33-

---

**Table of Contents**

Androxal clinical development expenses decreased 40% or approximately \$1.6 million to \$2.4 million for the year ended 2008 as compared to \$3.9 million in 2007. The decrease in Androxal clinical development expenses is shown in the following table (in thousands):

<b>Androxal Clinical Development</b>	<b>December 31, 2008</b>	<b>December 31, 2007</b>	<b>Variance</b>	<b>Change (%)</b>
Clinical trials	\$ 1,006	\$ 2,587	(\$1,581)	(61)%
Preclinical studies	1,178	967	211	22%
Formulation and dosage	161	304	(143)	(47)%
Other	25	80	(55)	(69)%
<b>Total</b>	<b>\$ 2,370</b>	<b>\$ 3,938</b>	<b>(\$1,568)</b>	<b>(40)%</b>

Prior to 2008 we were developing Androxal as a treatment for testosterone deficiency due to secondary hypogonadism by restoring normal testosterone production in males with functional testes. As a result of a Type C meeting held with the Food and Drug Administration, or FDA, on October 15, 2007 we believe that we do not have a clear clinical path to develop Androxal for this indication in the U.S. at this time and discontinued clinical efforts for that indication except for the continuation of a long-term Open Label Safety study that was already underway and we believe could be used as safety data for our other indications. During 2008 we initiated a clinical development program with Androxal as a treatment for men being treated for low testosterone that want to maintain or improve their sperm function during treatment.

Clinical trial expenses during 2008 and 2007 primarily reflect a non-Pivotal Phase 3 and long-term Open Label Safety study activities. Preclinical study expenses reflect animal safety activities required by the FDA to file a NDA. Formulation and dosage expenses reflect activities associated with the bulk scale-up and purchase of active drug to conduct clinical trials and to meet any potential future NDA submission requirements.

R&D payroll and benefit expense include salaries, non-cash stock option compensation expense and fringe benefits which increased 30% or approximately \$265,000 to \$1.2 million for the year ended 2008 as compared to \$889,000 in 2007. This increase is primarily due to an increase in headcount and an increase in non-cash stock option compensation of \$135,000. Included in payroll and benefit expense is a charge for non-cash stock option expense of \$389,000 for the year ended 2008 as compared to \$255,000 in the year 2007.

R&D operating and occupancy increased 36% or approximately \$331,000 to approximately \$1.3 million for the year ended 2008 as compared to \$932,000 in 2007. The increase in 2008 is primarily due to an increase in clinical development related consulting expenses of approximately \$348,000.

General and Administrative Expenses. General and administrative expenses, or G&A, increased 10% to approximately \$3.1 million for 2008 as compared to \$2.8 million for 2007. Our primary G&A expenses for 2008 and 2007 are shown in the following table (in thousands):

<b>General and Administrative</b>	<b>December 31, 2008</b>	<b>December 31, 2007</b>	<b>Variance</b>	<b>Change (%)</b>
Payroll and benefits	\$ 1,478	\$ 1,489	(\$11)	(1)%
Operating and occupancy	1,582	1,299	283	22%
<b>Total</b>	<b>\$ 3,060</b>	<b>\$ 2,788</b>	<b>\$ 272</b>	<b>10%</b>

G&A payroll and benefit expense of \$1.5 million for both 2008 and 2007, include salaries, bonuses, non-cash stock option compensation expense and fringe benefits. Included in payroll and benefit expense is a charge for non-cash stock option expense of \$482,000 for the year ended 2008 as compared to \$625,000 in the year 2007. Additionally, salaries for the year ended 2008 were \$891,000 as compared to \$763,000 for 2007.

G&A operating and occupancy expenses, which include expenses to operate as a public company, increased 22% or approximately \$283,000 to \$1.6 million in 2008 as compared to \$1.3 million in 2007. The increase is primarily due to an increase in professional services of \$321,000 offset by a decrease in various administrative and travel expenses.

*Comparison of Years Ended December 31, 2007 and 2006*

Revenues and Other Income. Total revenues and other income, which was comprised of interest income for the years ended 2007 and 2006, increased 153% to \$1.5 million in 2007 as compared to \$596,000 for 2006. This increase was primarily due to an increase

**Table of Contents**

in invested marketable securities as a result of the completion of our public offering on February 5, 2007 in which we received approximately \$33.1 million in net proceeds.

Research and Development Expenses. R&D expenses include contracted services relating to our clinical product development activities which include preclinical studies, clinical trials, regulatory affairs and bulk manufacturing scale-up activities and bulk active ingredient purchases for preclinical and clinical trials primarily relating to our two products in clinical development, which are Proellex and Androxal. Research and development expenses also include internal operating expenses relating to our general research and development activities. R&D expenses increased 4% or approximately \$508,000 to \$12.4 million for the year ended 2007 as compared to \$11.9 million in 2006. Our primary R&D expenses for 2007 and 2006 are shown in the following table (in thousands):

	<b>December 31, 2007</b>	<b>December 31, 2006</b>	<b>Variance</b>	<b>Change (%)</b>
<b>Research and Development</b>				
Proellex clinical development	\$ 6,661	\$ 6,581	\$ 80	1%
Androxal clinical development	3,938	4,180	(242)	(6)%
Payroll and benefits	889	519	370	71%
Operating and occupancy	932	632	300	47%
Total	\$ 12,420	\$ 11,912	\$ 508	4%

Proellex clinical development expenses increased 1% or approximately \$80,000 to approximately \$6.7 million for the year ended 2007 as compared to \$6.6 million in 2006. The increase in Proellex clinical development expenses is shown in the following table (in thousands):

	<b>December 31, 2007</b>	<b>December 31, 2006</b>	<b>Variance</b>	<b>Change %</b>
<b>Proellex Clinical Development</b>				
Clinical trials	\$ 3,301	\$ 3,365	(\$64)	(2)%
Preclinical studies	1,639	806	833	103%
Formulation and dosage	1,486	2,313	(827)	(36)%
Other	235	97	138	142%
Total	\$ 6,661	\$ 6,581	\$ 80	1%

During 2007 and 2006 Proellex was being developed to treat symptoms associated with uterine fibroids and endometriosis. Clinical trial expenses primarily reflect Phase 1, Phase 2 and long-term Open Label Safety study activities. Preclinical study expenses reflect animal safety activities required by the FDA to file a NDA. Formulation and dosage expenses reflect activities associated with the bulk scale-up and purchase of active drug to conduct clinical trial activities and to meet any potential future NDA submission requirements.

Androxal clinical development expenses decreased 6% or approximately \$242,000 to \$3.9 million for the year ended 2007 as compared to \$4.2 million in 2006. The decrease in Androxal clinical development expenses is shown in the following table (in thousands):

	<b>December 31, 2007</b>	<b>December 31, 2006</b>	<b>Variance</b>	<b>Change %</b>
<b>Androxal Clinical Development</b>				

Edgar Filing: REPROS THERAPEUTICS INC. - Form 10-K

Clinical trials	\$	2,587	\$	3,219	(\$632)	(20%)
Preclinical studies		967		717	250	35%
Formulation and dosage		304		124	180	145%
Other		80		120	(40)	(33%)
Total	\$	3,938	\$	4,180	(\$242)	(6%)

During 2007 and 2006 Androxal was being developed to treat testosterone deficiency due to secondary hypogonadism by restoring normal testosterone production in males with functional testes and diminished pituitary function, a common condition in the aging male. Clinical trial expenses during these periods primarily reflect non-Pivotal Phase 3 and long-term Open Label Safety study activities. Preclinical study expenses reflect animal safety activities required by the FDA to file a NDA. Formulation and dosage expenses reflect activities associated with the bulk scale-up and purchase of active drug to conduct clinical trial activities and to meet any potential future NDA submission requirements.

R&D payroll and benefit expense include salaries, non-cash stock option compensation expense and fringe benefits which increased 71% or approximately \$370,000 to \$889,000 for the ended 2007 as compared to \$519,000 in 2006. This increase is

-35-

---

**Table of Contents**

primarily due to the hiring of a Chief Medical Officer in December 2006 and related expenses in which we incurred a full year of expense during 2007. We also incurred approximately \$255,000 in non-cash stock option expense for the year ended 2007 as compared to \$127,000 in the year 2006.

R&D operating and occupancy increased 47% or approximately \$300,000 to \$932,000 for the year ended 2007 as compared to \$632,000 in 2006. The increase in 2007 is primarily due to an increase in clinical development related consulting expenses of approximately \$242,000 and an increase in travel expenses of \$32,000.

General and Administrative Expenses. G&A expenses decreased 3% to approximately \$2.8 million for 2007 as compared to \$2.9 million for 2006. The decrease in expenses is primarily due to a decrease of \$156,000 in professional services. Our primary G&A expenses for 2007 and 2006 are shown in the following table (in thousands):

<b>General and Administrative</b>	<b>December 31, 2007</b>	<b>December 31, 2006</b>	<b>Variance</b>	<b>Change %</b>
Payroll and benefits	\$ 1,489	\$ 1,522	(\$33)	(2)%
Operating and occupancy	1,299	1,357	(58)	(4)%
Total	\$ 2,788	\$ 2,879	(\$91)	(3)%

G&A payroll and benefit expense, include salaries, bonuses, non-cash stock option compensation expense and fringe benefits which decreased 2% or approximately \$33,000 to \$1,489,000 for the year ended 2007 as compared to \$1,522,000 in 2006. The decrease is primarily due to a reduction in non-cash stock option compensation which was approximately \$625,000 for the year ended 2007 as compared to \$662,000 in the prior year.

G&A operating and occupancy expenses decreased 4% or approximately \$58,000 to \$1.3 million in 2007 as compared to \$1.4 million in 2006. The decrease is primarily due to a reduction in professional services offset by an increase in various administrative and travel expenses.

**Off-Balance Sheet Arrangements**

As of December 31, 2008, we did not have any off-balance sheet arrangements except operating leases.

**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.

On October 2, 2008, we completed a direct registered offering of 2.4 million shares of our common stock at a purchase price of \$6.50 per share for net proceeds after expenses of approximately \$15.6 million pursuant to an effective shelf registration statement. Certain of the purchasers in this offering were granted in their purchase agreements an option to purchase an aggregate of up to \$10 million of additional shares of our common stock at the greater of the fair market value, defined as the average of the closing prices for the 30 trading days immediately prior to the date of exercise, or \$7.80 per share. Such option becomes exercisable at such time as we have less than \$10 million in cash and cash equivalents and expires on September 29, 2009. In addition, the purchasers who received such option also received a right of first offer to purchase their respective pro-rata portion of any future financings, excluding certain corporate activities that expire on September 29, 2010.

As part of the terms of the October 2, 2008 financing, we amended our Standstill Agreement with Efficacy Capital Ltd. to permit Efficacy Capital to own up to 40% of our outstanding shares of stock and to permit Efficacy Capital to designate two directors to serve on our Board of Directors. Pursuant to that amendment, the Board increased its number to nine and appointed Mark Lappe, a Managing Partner of Efficacy Capital, and John C. Reed, M.D., Ph.D., President and CEO of Burnham Institute for Medical Research, to the vacancies on the Board created by such increase. The Company amended its Rights Agreement to reflect the increase to 40% described above. Prior to this on January 9, 2008, we entered into an amendment to our rights agreement to permit Efficacy Capital to acquire up to 33% of our outstanding common stock, subject to a standstill agreement. The standstill agreement contains customary covenants and obligations restricting Efficacy from taking certain actions with respect to its shares.

We plan to use the proceeds from the October 2, 2008 financing to fund our research and development activities, including the ongoing registration Pivotal Phase 3 trials of its lead product candidate, Proellex, as a pre-surgical short course treatment of anemia associated with uterine fibroids and as a chronic treatment of uterine fibroids and our Phase 2 clinical trial for the treatment of endometriosis as well as for working capital and general corporate purposes.

In November 2008, we filed a Form S-3 shelf registration statement (Reg. No. 333-155265) to register up to 6,282,052 shares of our common stock, which includes 1,282,052 shares related to the purchase option provided to the investors described above and an

**Table of Contents**

additional 5 million shares for future offerings. This registration statement was declared effective on November 26, 2008 and remains effective for three years after such date.

We also completed a public offering on February 5, 2007 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 \$33.1 million and 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 and cash equivalents of approximately \$19.5 million as of December 31, 2008 as compared to cash, cash equivalents and marketable securities of \$25.9 million as of December 31, 2007.

Net cash of approximately \$21.7 million, \$13.6 million, and \$10.1 million was used in operating activities during 2008, 2007, and 2006, respectively. The major uses of cash for operating activities during 2008 was to fund our clinical development programs and associated administrative costs, net of interest income, of \$25.2 million. Cash provided by investing activities was \$23.6 million in 2008 primarily from the sale of trading marketable securities. Cash provided by financing activities in 2008 was approximately \$15.9 million primarily relating to the direct registered offering of 2.4 million shares of our common stock at a purchase price of \$6.50 per share for net proceeds after expenses of approximately \$15.6 and the payment of \$327,320 by Efficacy Capital as disgorgement of short swing profits.

We have had losses since inception and, therefore, have not been subject to federal income taxes. We have accumulated approximately \$2.6 million of research and development tax credits. As of December 31, 2008 we had approximately \$129.9 million of NOLs for federal income tax purposes. Additionally, approximately \$2.4 million of NOLs, and approximately \$81,000 of research and development tax credits expired in the year 2008. 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. Based on our current planned clinical programs, we will need to raise additional capital in the third quarter of 2009. 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, 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. The uncertainties relating to the foregoing matters raise substantial doubt about our ability to continue as a going concern over the next twelve months.





**Table of Contents****Contractual Obligations and Commercial Commitments**

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, 2008, 2007 and 2006, was approximately \$59,000, \$63,000 and \$53,000, respectively. Future minimum lease payments under non-cancelable leases with original terms in excess of one year as of December 31, 2008, are as follows (in thousands):

2009	60
2010	30
Total	\$ 90

In addition, in December 2008 we committed to the purchase of \$3 million of the bulk active ingredient of Proellex which is to be produced under a new scaled-up amended manufacturing process by Gedeon Richter. Under this Purchase Request we are obligated to make four payments of \$750,000 each aggregating \$3 million which are expected to be made during 2009, assuming that the manufacturer meets the criteria of the Purchase Request. We expect to receive this material in the fourth quarter of 2009 and recognize the expense associated with this purchase when this material is received from the manufacturer. This Purchase Request contains certain provisions in which any dollars paid to this manufacturer under the Purchase Request will be returned if the manufacturer can not meet their obligations under this Purchase Request by March 31, 2010. This Purchase Request also contains language in which both parties may amend the payment criteria and terms of the purchase if the new terms are agreed to by both parties.

In addition to our lease agreement listed above and manufacturing agreements disclosed under Part I Item 1. Business Manufacturing, we have entered into several substantial agreements with four CROs to conduct our Proellex clinical trials. Even though these are substantial contracts and the term on one of them is estimated to potentially last through the year 2010, all contracts can be cancelled and we would only be responsible for services rendered through the cancellation period.

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

**Interest Rate Risk.** We had cash and cash equivalents of approximately \$19.5 million as of December 31, 2008 which is primarily held in a money market mutual fund backed by U.S. government securities. Although this cash account is subject to fluctuations in interest rates and market conditions, no significant gain or loss on this account is expected to be recognized in earnings. We do not invest in derivative securities.

**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 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

**Table of Contents**

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, 2008.

PricewaterhouseCoopers LLP, an independent registered public accounting firm, has audited and issued their report on the effectiveness of our internal control over financial reporting as of December 31, 2008, which appears herein.

**Changes in Internal Control**

There have been no changes in our internal control over financial reporting during our quarter ended December 31, 2008 that have materially affected, or is reasonable likely to materially affect, our internal control over financial reporting.

**ITEM 9B. OTHER INFORMATION**

Not applicable.

**Table of Contents**

**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 2009 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, 2008.

**ITEM 11. EXECUTIVE COMPENSATION**

The information required by this item is hereby incorporated by reference from the information in our proxy statement for our 2009 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, 2008.

**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 2009 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, 2008.

**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 2009 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, 2008.

**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 2009 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, 2008.

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

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

<b>Financial Statements</b>	<b>Page</b>
<u>Report of Independent Registered Public Accounting Firm</u>	F-1
<u>Reports of Independent Public Accountants</u>	F-3
<u>Consolidated Balance Sheets as of December 31, 2008 and 2007</u>	F-9
<u>Consolidated Statements of Operations for the Years Ended December 31, 2008, 2007 and 2006 and (unaudited) from Inception (August 20, 1987) through December 31, 2008</u>	F-10
<u>Consolidated Statement of Stockholders' Equity (from inception)</u>	F-11
<u>Consolidated Statements of Cash Flows for the Years Ended December 31, 2008, 2007 and 2006 and (unaudited) from Inception (August 20, 1987) through December 31, 2008</u>	F-17
Notes to Consolidated Financial Statements	F-18

All financial statement 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.

<b>Exhibit Number</b>	<b>Identification Of Exhibit</b>
3.1(a)	Restated Certificate of Incorporation. Exhibit 3.3 to the Company's Registration Statement on Form SB-2 (No. 33-57728-FW), as amended (Registration Statement), is incorporated herein by reference.
3.1(b)	Certificate of 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.
3.1(d)	Certificate of Amendment to Restated Certificate of Incorporation, dated as of December 16, 2008. Exhibit 3.1(d) to the Company's Current Report on Form 8-K as filed with the Commission on December 23, 2008 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.

-41-

---

**Table of Contents**

<b>Exhibit Number</b>	<b>Identification Of Exhibit</b>
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	Fourth Amendment to Rights Agreement, dated as of January 9, 2008, between the Company and Computershare Trust Company, Inc. (as successor in interest to Computershare Investor Services, LLC). Exhibit 4.5 to the Company's Current Report on Form 8-K as filed with the Commission on January 10, 2008 is incorporated herein by reference.
4.7	Fifth Amendment to Rights Agreement, dated as of October 10, 2008, between the Company and Computershare Trust Company, Inc. (as successor in interest to Computershare Investor Services, LLC). Exhibit 4.6 to the Company's Current Report on Form 8-K as filed with the Commission on January 10, 2008 is incorporated herein by reference.
4.8	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 Repros Therapeutics 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 Repros Therapeutics 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+	Repros Therapeutics 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+	



Edgar Filing: REPROS THERAPEUTICS INC. - Form 10-K

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.

-42-

---

**Table of Contents**

<b>Exhibit Number</b>	<b>Identification Of Exhibit</b>
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.
10.17	Fourth Amendment to PHS Patent License Agreement, as amended, dated December 9, 2003 between the Company and certain agencies of the United States Public Health Service within the Department of Health and Human Services. Exhibit 10.1 to the Company's Current Report on Form 8-K as filed with the Commission on March 19, 2007 is incorporated herein by reference.
10.18	Waiver to PHS Patent License Agreement, as amended, dated March 8, 2007 between the Company and certain agencies of the United States Public Health Service within the Department of Health and Human Services. Exhibit 10.2 to the Company's Current Report on Form 8-K as filed with the Commission on March 19, 2007 is incorporated herein by reference.
10.19++	Fifth Amendment to PHS Patent License Agreement, as amended, dated March 15, 2007 between the Company and certain agencies of the United States Public Health Service within the Department of Health and Human Services. Exhibit 10.3 to the Company's Current Report on Form 8-K as filed with the Commission on March 19, 2007 is incorporated herein by reference.
10.20	Standstill Agreement, dated as of January 9, 2008, between the Company and Efficacy Capital. Exhibit 10.1 to the Company's Current Report on Form 8-K as filed with the Commission on January 10, 2008 is incorporated herein by reference.
10.21	First Amendment to Standstill Agreement, dated July 28, 2008, between the Company and Efficacy Capital. Exhibit 10.2 to the Company's Current Report on Form 8-K as filed with the Commission on July 28, 2008 is incorporated herein by reference.
10.22	Second Amendment to Standstill Agreement, dated October 2, 2008, between the Company and Efficacy Capital. Exhibit 10.3 to the Company's Current Report on Form 8-K as filed with the Commission on October 3, 2008 is incorporated herein by reference.
10.23	Common Stock Purchase Agreement, dated September 29, 2008 between the Company and Efficacy Capital. Exhibit 10.1 to the Company's Current Report on Form 8-K as filed

with the Commission on September 29, 2008 is incorporated herein by reference.

- 10.24 Amended and Restated Common Stock Purchase Agreement, dated September 29, 2008 between the Company and the affiliate or Vermillion Asset Management LLC named therein. Exhibit 10.4 to the Company's Current Report on Form 8-K as filed with the Commission on October 3, 2008 is incorporated herein by reference.
- 10.25 Common Stock Purchase Agreement, dated September 29, 2008 between the Company and Dr. John C. Reed. Exhibit 10.4 to the Company's Current Report on Form 8-K as filed with the Commission on September 29, 2008 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)

**Table of Contents**

<b>Exhibit Number</b>	<b>Identification Of Exhibit</b>
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.	

**Table of Contents**

**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  
Chief Executive Officer

Dated: March 16, 2009

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ Joseph S. Podolski Joseph S. Podolski	Chief Executive Officer and Director (Principal Executive Officer)	March 16, 2009
/s/ Louis Ploth, Jr. Louis Ploth, Jr.	Chief Financial Officer, VP Business Development, Director and Secretary  (Principal Financial Officer and Principal Accounting Officer)	March 16, 2009
/s/ Mark Lappe Mark Lappe	Chairman of the Board	March 16, 2009
/s/ Daniel F. Cain Daniel F. Cain	Director	March 16, 2009
/s/ Jean L. Fourcroy, M.D., Ph.D., M.P.H. Jean L. Fourcroy, M.D., Ph.D., M.P.H.	Director	March 16, 2009
/s/ Jeffrey R. Harder Jeffrey R. Harder	Director	March 16, 2009
/s/ Nola Masterson Nola Masterson	Director	March 16, 2009
/s/ David Poorvin, Ph.D. David Poorvin, Ph. D.	Director	March 16, 2009
/s/ John C. Reed, M.D., Ph.D.	Director	March 16, 2009

John C. Reed, M.D., Ph.D.

-45-

---

**Table of Contents****Report of Independent Registered Public Accounting Firm**

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

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations and cash flows for each of the three years in the period ended December 31, 2008, and the statements of stockholders equity for each of the seven years in the period ended December 31, 2008 present fairly, in all material respects, the financial position of Repros Therapeutics, Inc. and subsidiary (collectively, the Company), a development stage company, at December 31, 2008 and 2007, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2008, and cumulatively for the period January 1, 2002 through December 31, 2008 (not separately presented) in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2008, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control Over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our audits. We did not audit the cumulative totals of the Company for the period from August 20, 1987 (date of inception) to December 31, 2001, which totals reflect a deficit of \$75.8 million accumulated during the development stage. The cumulative totals for the period January 1, 1994 to December 31, 2001 were audited by other auditors who have ceased operations. Those auditors expressed unqualified opinions on the consolidated financial statements for the three years in the period ended December 31, 2001, the three years in the period ended December 31, 2000, the three years in the period ended December 31, 1999, the three years in the period ended December 31, 1998, the three years in the period ended December 31, 1997, and the three years in the period ended December 31, 1996 dated February 6, 2002, February 2, 2001, February 2, 2000, January 26, 1999, March 24, 1998, and March 11, 1997, respectively. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included 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. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company is a development stage company, has an accumulated deficit, and projects it will need to raise additional capital in 2009. These matters raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to this matter are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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





**Table of Contents**

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 16, 2009

F-2

---

**Table of Contents**

**THE FOLLOWING REPORT IS A COPY OF A REPORT PREVIOUSLY ISSUED BY AR THUR  
ANDERSEN LLP AND HAS NOT BEEN REISSUED BY ARTHUR ANDERSEN LLP.  
REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS**

To Zonagen, Inc.:

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

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

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

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

/S/ ARTHUR ANDERSEN LLP

Houston, Texas

February 6, 2002

F-3

---

**Table of Contents**

**THE FOLLOWING REPORT IS A COPY OF A REPORT PREVIOUSLY ISSUED BY AR THUR  
ANDERSEN LLP AND HAS NOT BEEN REISSUED BY ARTHUR ANDERSEN LLP.  
REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS**

To Zonagen, Inc.:

We have audited the accompanying consolidated balance sheets of Zonagen, Inc. (a Delaware corporation in the development stage), and subsidiary (collectively, the Company ) as of December 31, 2000 and 1999, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2000. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Zonagen, Inc., and subsidiary as of December 31, 2000 and 1999, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2000, in conformity with accounting principles generally accepted in the United States.

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

/S/ ARTHUR ANDERSEN LLP

Houston, Texas

February 2, 2001

F-4

---

**Table of Contents**

**THE FOLLOWING REPORT IS A COPY OF A REPORT PREVIOUSLY ISSUED BY AR THUR  
ANDERSEN LLP AND HAS NOT BEEN REISSUED BY ARTHUR ANDERSEN LLP.  
REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS**

To Zonagen, Inc.:

We have audited the accompanying consolidated balance sheets of Zonagen, Inc. (a Delaware corporation in the development stage), and subsidiary (collectively, the Company ) as of December 31, 1999 and 1998, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 1999. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Zonagen, Inc., and subsidiary as of December 31, 1999 and 1998, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 1999, in conformity with accounting principles generally accepted in the United States.

/S/ ARTHUR ANDERSEN LLP

Houston, Texas

February 2, 2000

F-5

---

**Table of Contents**

**THE FOLLOWING REPORT IS A COPY OF A REPORT PREVIOUSLY ISSUED BY AR THUR  
ANDERSEN LLP AND HAS NOT BEEN REISSUED BY ARTHUR ANDERSEN LLP.  
REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS**

To Zonagen, Inc.:

We have audited the accompanying balance sheets of Zonagen, Inc. (a Delaware corporation in the development stage), and subsidiary (collectively, the Company ) as of December 31, 1998 and 1997, and the related statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 1998. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Zonagen, Inc., and subsidiary as of December 31, 1998 and 1997, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 1998, in conformity with generally accepted accounting principles.

/S/ ARTHUR ANDERSEN LLP

Houston, Texas

January 26, 1999

F-6

---

**Table of Contents**

**THE FOLLOWING REPORT IS A COPY OF A REPORT PREVIOUSLY ISSUED BY AR THUR  
ANDERSEN LLP AND HAS NOT BEEN REISSUED BY ARTHUR ANDERSEN LLP.  
REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS**

To Zonagen, Inc.:

We have audited the accompanying balance sheets of Zonagen, Inc. (a Delaware corporation in the development stage), and subsidiary (collectively, the Company ) as of December 31, 1997 and 1996, and the related statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 1997. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Zonagen, Inc., and subsidiary as of December 31, 1997 and 1996, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 1997, in conformity with generally accepted accounting principles.

/S/ ARTHUR ANDERSEN LLP

Houston, Texas

March 24, 1998

F-7

---

**Table of Contents**

**THE FOLLOWING REPORT IS A COPY OF A REPORT PREVIOUSLY ISSUED BY AR THUR  
ANDERSEN LLP AND HAS NOT BEEN REISSUED BY ARTHUR ANDERSEN LLP.  
REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS**

To Zonagen, Inc.:

We have audited the accompanying consolidated balance sheets of Zonagen, Inc. (a Delaware corporation in the development stage), and subsidiary as of December 31, 1996 and 1995, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 1996. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with generally accepted audited standards. 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 also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

As discussed in Note 1 to the consolidated financial statements, the Company has operated as a development stage enterprise since its inception by devoting substantially all of its efforts to raising capital and performing research and development. In order to complete the research and development and other activities necessary to commercialize its products, additional financing will be required. Management's current projections indicate that the Company can conserve its cash resources to maintain the Company's operations through 1997. Management's plans in regard to those matters are also described in Note 1.

In our opinion, based on our audits, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Zonagen, Inc., and subsidiary as of December 31, 1996 and 1995, and the results of their operations and cash flows for each of the three years in the period ended December 31, 1996, in conformity with generally accepted accounting principles.

/S/ ARTHUR ANDERSEN LLP

Houston, Texas

March 11, 1997

F-8

---

**Table of Contents****REPOS THERAPEUTICS INC. AND SUBSIDIARY**

(A development stage company)

**CONSOLIDATED BALANCE SHEETS**

(in thousands except share and per share amounts)

	<b>December 31, 2008</b>	<b>December 31, 2007</b>
<b>ASSETS</b>		
<b>Current Assets</b>		
Cash and cash equivalents	\$ 19,470	\$ 1,779
Marketable securities		24,124
Prepaid expenses and other current assets	1,392	479
Total current assets	20,862	26,382
<b>Fixed Assets, net</b>	28	47
<b>Other Assets, net</b>	1,713	1,170
Total assets	\$ 22,603	\$ 27,599
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
<b>Current Liabilities</b>		
Accounts payable	\$ 5,132	\$ 2,281
Accrued expenses	1,857	1,258
Total current liabilities	6,989	3,539
<b>Commitments &amp; Contingencies (note 10)</b>		
<b>Stockholders Equity</b>		
Preferred Stock, \$.001 par value, 5,000,000 shares authorized, none issued and outstanding		
Common Stock, \$.001 par value, 30,000,000 and 20,000,000 shares authorized, respectively, 17,111,939 and 14,711,939 shares issued, respectively; 15,174,904 and 12,774,904 shares outstanding, respectively	17	15
Additional paid-in capital	168,787	152,033
Cost of treasury stock, 1,937,035 shares	(5,948)	(5,948)
Deficit accumulated during the development stage	(147,242)	(122,040)
Total stockholders equity	15,614	24,060
Total liabilities and stockholders equity	\$ 22,603	\$ 27,599

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





**Table of Contents**

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

	<b>For the Year Ended December 31,</b>			<b>From Inception</b>
	<b>2008</b>	<b>2007</b>	<b>2006</b>	<b>(August 20, 1987)</b>
				<b>through December 31, 2008 (unaudited)</b>
<b>Revenues and other income</b>				
Licensing fees	\$	\$	\$	\$ 28,755
Product royalties				627
Research and development grants				1,219
Interest income	433	1,508	596	16,293
Gain on disposal of fixed assets				102
Other income				35
<b>Total revenues and other income</b>	<b>433</b>	<b>1,508</b>	<b>596</b>	<b>47,031</b>
<b>Expenses</b>				
Research and development	22,575	12,420	11,912	147,268
General and administrative	3,060	2,788	2,879	37,274
Other expense				388
<b>Total expenses</b>	<b>25,635</b>	<b>15,208</b>	<b>14,791</b>	<b>184,930</b>
<b>Loss from continuing operations</b>	<b>(25,202)</b>	<b>(13,700)</b>	<b>(14,195)</b>	<b>(137,899)</b>
Loss from discontinued operations				(1,828)
Gain on disposal of discontinued operations				939
<b>Net loss before cumulative effect of changes in accounting principles</b>	<b>(25,202)</b>	<b>(13,700)</b>	<b>(14,195)</b>	<b>(138,788)</b>
Cumulative effect of changes in accounting principles				(8,454)
<b>Net loss</b>	<b>\$ (25,202)</b>	<b>\$ (13,700)</b>	<b>\$ (14,195)</b>	<b>\$ (147,242)</b>
<b>Loss per share basic and diluted</b>	<b>\$ (1.88)</b>	<b>\$ (1.09)</b>	<b>\$ (1.40)</b>	
Shares used in loss per share calculation:				
Basic	13,372	12,524	10,147	
Diluted	13,372	12,524	10,147	

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



**Table of Contents**

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

	<b>Preferred Stock Shares</b>	<b>Common Stock Shares</b>	<b>Additional Paid-in Capital</b>	<b>Deferred Compensation</b>	<b>Treasury Stock Shares</b>	<b>Development Stage</b>	<b>Deficit Accumulated During the</b>	<b>Total Stockholders Equity</b>
	<b>Amount</b>	<b>Amount</b>	<b>Amount</b>	<b>Amount</b>	<b>Amount</b>	<b>Amount</b>	<b>Amount</b>	<b>Amount</b>
Exchange of common stock (\$.004 per share) for technology rights and services from founding stockholders	\$	245,367	\$	\$	1	\$	\$	\$
Net Loss							(28)	(28)
<b>BALANCE AT DECEMBER 31, 1987 (unaudited)</b>		245,367		1			(28)	(27)
Net Loss							(327)	(327)
<b>BALANCE AT DECEMBER 31, 1988 (unaudited)</b>		245,367		1			(355)	(354)
Proceeds from issuance of common stock		65,431		3				3
Net Loss							(967)	(967)
<b>BALANCE AT DECEMBER 31, 1989 (unaudited)</b>		310,798		4			(1,322)	(1,318)
Proceeds from issuance of common stock		467						
Net Loss							(1,426)	(1,426)
<b>BALANCE AT DECEMBER 31, 1990 (unaudited)</b>		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		 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	1	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)  
F-11

---

**Table of Contents**

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

	Preferred Stock Shares	Common Stock Amount	Common Stock Shares	Additional Paid-in Capital	Deferred Compensation	Treasury Stock Shares	Treasury Stock Amount	Development Stage	Deficit Accumulated During the	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				(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)
<b>BALANCE AT DECEMBER 31, 1995</b>	<b>504,850</b>	<b>1</b>	<b>4,098,124</b>	<b>4</b>	<b>22,473</b>	<b>(113)</b>	<b>(16,940)</b>	<b>5,425</b>
Deferred compensation resulting from grant of options					86	(86)		
Amortization of deferred compensation						54		54
Exercise of warrants to purchase common stock for cash, January through December 1996 (\$3.63 per share)			227,776		827			827
Conversion of Series A preferred stock into	(507,563)	(1)	1,396,826	2	(1)			



common stock, January through November 1996					
Issuance of options for services, January 12, 1996			99		99
Exercise of options to purchase common stock for cash, February through November 1996 (\$0.01 to \$5.50 per share)		23,100	75		75
Issuance of common stock for agreement not to compete, April 13, 1996		19,512	200		200
Exercise of warrants to purchase Series A preferred stock under cashless exercise provision, June 5, 1996	2,713				
Issuance of Series B preferred stock for cash, September 30, 1996, and October 11, 1996 (\$10.00 per share), net of offering costs of \$2,557	1,692,500	2	14,366		14,368
Conversion of Series B preferred stock into common stock, November through December 1996	(177,594)	268,058			
Net loss				(9,470)	(9,470)

(continued)

F-12

**Table of Contents**

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

	Preferred Stock		Common Stock		Additional Paid-in Capital		Deferred Compensation	Treasury Shares	Stock Development Stage	Deficit Accumulated During the	Total Stockholders Equity
	Shares	Amount	Shares	Amount							
BALANCE AT DECEMBER 31, 1996	1,514,906	\$ 2	6,033,396	\$ 6	\$ 38,125	\$ (145)		\$	\$ (26,410)	\$ 11,578	
Deferred compensation resulting from grant of options					2,110	(2,110)					
Amortization of deferred compensation						854				854	
Exercise of options to purchase common stock for cash, January through December 1997 (\$0.00 to \$22.25 per share)			90,955		522					522	
Exercise of warrants to purchase common stock for cash, January through December 1997 (\$3.63 and \$3.07 per share)			22,368		75					75	
Issuance of common stock for a cashless exercise of Series A preferred stock warrants, February through			81,294								

September 1997 Exercise of Series A preferred stock warrants to purchase common stock for cash, April 1997 (\$11.00 per share)			818		3		3
Issuance of common stock for a cashless exercise of Series B preferred stock warrants, April through November 1997			88,223				
Exercise of Series B preferred stock warrants to purchase common stock for cash, April through July 1997 (\$11.00 per share)			17,169		125		125
Issuance of common stock as final purchase price for acquisition of FTI, January 31, 1997 (\$9.833 per share)			305,095	1			1
Issuance of common stock as final debt payment on FTI acquisition, January 31, 1997 (\$9.833 per share)			19,842		94		94
Conversion of 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)
Net loss					(13,174)
					(13,174)

(continued)  
F-13

**Table of Contents**

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

	<b>Preferred Stock Shares</b>	<b>Common Stock Shares</b>	<b>Additional Paid-in Capital</b>	<b>Deferred Compensation</b>	<b>Treasury Stock Shares</b>	<b>Development Stage</b>	<b>Deficit Accumulated During the</b>	<b>Total Stockholders Equity</b>	
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)	
<b>BALANCE AT DECEMBER 31, 1999</b>	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)  
F-14

**Table of Contents**

**REPOS THERAPEUTICS INC. AND SUBSIDIARY**  
(A development stage company)  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY**  
(in thousands except share and per share amounts)

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



Edgar Filing: REPROS THERAPEUTICS INC. - Form 10-K

through  
December 2001  
Net loss (839) (839)

BALANCE AT  
DECEMBER 31,  
2001 \$ 11,765,516 \$ 12 \$ 113,898 \$ (11) 415,300 \$ (7,484) \$ (75,846) \$ 30,569

Amortization of  
deferred  
compensation 11 11

Exercise of  
options to  
purchase  
common stock  
for cash, January  
and  
February 2002  
(\$0.64 to \$2.94  
per share) 31,265 21 21

Issuance of  
common stock  
through  
employee stock  
purchase plan for  
cash, June 2002 4,824 6 6

Issuance of  
common stock to  
Employees 105,000 111 111

Issuance of  
common stock to  
Board of  
Director  
members for  
services, March  
through  
December 2002 11,572 15 15

Net loss (3,882) (3,882)

BALANCE AT  
DECEMBER 31,  
2002 \$ 11,918,177 \$ 12 \$ 114,051 \$ 415,300 \$ (7,484) \$ (79,728) \$ 26,851

Issuance of  
common stock to  
Board of  
Director  
members for  
services,  
February  
through  
May 2003 10,871 14 14

Table of Contents 113

Edgar Filing: REPROS THERAPEUTICS INC. - Form 10-K

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				2,641		(5,060,000)		15,539						18,180	
Exercise of options to		26,700		85										85	

purchase common stock for cash, January and February 2005 (\$2.94 to \$3.47 per share)									
Noncash stock compensation related to stock option bonus program			(15)						(15)
Amortization of deferred compensation				104					104
Net loss							(7,391)		(7,391)
BALANCE AT DECEMBER 31, 2005									
	\$	12,016,636	\$ 12	\$ 117,166	\$ (130)	1,937,035	\$ (5,948)	\$ (94,145)	\$ 16,955
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				
Stock option compensation				789					789
Net loss							(14,195)		(14,195)

(continued)  
F-15

**Table of Contents**

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

	<b>Preferred Stock Shares</b>	<b>Common Stock Shares</b>	<b>Additional Paid-in Capital</b>	<b>Deferred Compensation</b>	<b>Treasury Stock Shares</b>	<b>Stock Amount</b>	<b>Development Stage</b>	<b>Deficit Accumulated During the</b>	<b>Total Stockholders Equity</b>
Balance at December 31, 2006	\$	12,087,997	\$ 12	\$ 118,066	\$	1,937,035	\$ (5,948)	\$ (108,340)	\$ 3,790
Exercise of options to purchase common stock for cash, January and April @ \$2.40 & \$8.00 per share		13,942		37					37
Issuance of 2,610,000 shares of common stock at \$13.75 per share									
February 5, 2007, net of offering costs of \$2,835		2,610,000	3	33,050					33,053
Stock option compensation				880					880
Net loss							(13,700)		(13,700)
Balance at December 31, 2007	\$	14,711,939	\$ 15	\$ 152,033	\$	1,937,035	\$ (5,948)	\$ (122,040)	\$ 24,060
Stock based option compensation				871					871
Proceeds from a shareholder transaction				327					327
Issuance of 2,400,000		2,400,000	\$ 2	\$ 15,556					15,558

shares of  
common stock  
at \$6.50 per  
share October 2,  
2008, net of  
offering costs of  
\$41,458

Net loss \$ (25,202) (25,202)

Balance at  
December 31,  
2008

	\$ 17,111,939	\$ 17	\$ 168,787	\$ 1,937,035	\$ (5,948)	\$ (147,242)	\$ 15,614
--	---------------	-------	------------	--------------	------------	--------------	-----------

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

F-16

---

**Table of Contents**

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

	<b>For the Year Ended December 31,</b>			<b>From Inception</b>
	<b>2008</b>	<b>2007</b>	<b>2006</b>	<b>(August 20, 1987)</b>
				<b>through December 31, 2008 (unaudited)</b>
<b>Cash Flows from Operating Activities</b>				
Net loss	\$ (25,202)	\$ (13,700)	\$ (14,195)	\$ (147,242)
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				1,339
Noncash decrease in accounts payable				(1,308)
Depreciation and amortization	50	34	18	3,882
Noncash expenses related to stock-based transactions	871	880	789	5,357
Common stock issued for agreement not to compete				200
Series B Preferred Stock issued for consulting services				18
Changes in operating assets and liabilities (net effects of purchase of businesses in 1988 and 1994):				
Increase in receivables				(199)
Increase in inventory				(4,447)
(Increase) decrease in prepaid expenses and other current assets	(913)	(251)	6	(1,090)
Increase (decrease) in accounts payable and accrued expenses	3,449	(520)	3,332	8,184
Net cash used in operating activities	(21,745)	(13,557)	(10,050)	(131,614)
<b>Cash Flows from Investing Activities</b>				
Change in trading marketable securities	24,124	(18,527)	9,067	(191)
Capital expenditures	(4)	(6)	(64)	(2,371)
Purchase of technology rights and other assets	(569)	(357)	(223)	(3,770)
Proceeds from sale of PP&E				225
Cash acquired in purchase of FTI				3
				138

Edgar Filing: REPROS THERAPEUTICS INC. - Form 10-K

Proceeds from sale of subsidiary, less \$12,345 for operating losses during 1990 phase-out period				
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	23,551	(18,890)	8,780	(3,929)
<b>Cash Flows from Financing Activities</b>				
Proceeds from issuance of common stock, net of offering costs	15,558	33,053		151,015
Exercise of stock options		37	241	363
Proceeds from a shareholder transaction	327			327
Proceeds from issuance of preferred stock				23,688
Purchase of treasury stock				(21,487)
Proceeds from issuance of notes payable				2,839
Principal payments on notes payable				(1,732)
Net cash provided by financing activities	15,885	33,090	241	155,013
<b>Net increase (decrease) in cash and cash equivalents</b>	17,691	643	(1,029)	19,470
<b>Cash and cash equivalents at beginning of period</b>	1,779	1,136	2,165	
<b>Cash and cash equivalents at end of period</b>	\$ 19,470	\$ 1,779	\$ 1,136	\$ 19,470

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

F-17

**Table of Contents****1. ORGANIZATION AND OPERATIONS:**

Repros Therapeutics 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 oral small molecule drugs for major unmet medical needs that treat male and female reproductive disorders.

Our lead drug, Proellex<sup>®</sup>, is a selective blocker of the progesterone receptor and is being developed for the treatment of symptoms associated with uterine fibroids and endometriosis. We are also developing Proellex as a short course pre-surgical treatment for anemia associated with excessive menstrual bleeding associated with uterine fibroids, or anemia associated with uterine fibroids. There is no currently approved effective long-term orally administered drug treatment for uterine fibroids or endometriosis. In the United States alone, approximately 300,000 women per year undergo a hysterectomy as a result of severe uterine fibroids.

Our second product candidate, Androxal<sup>®</sup>, is a single isomer of clomiphene citrate and is an orally active proprietary small molecule compound. We are developing Androxal for men of reproductive age with low testosterone levels who want to improve or maintain their fertility and/or sperm function while being treated for low testosterone. In November 2008, we received guidance from the FDA suggesting submission of a new IND to the Division of Metabolic and Endocrine Products, or DMEP, for the investigation of Androxal as a potential treatment for type 2 diabetes. We plan to submit a new IND for this indication to the DMEP as soon as practicable.

Previously we were developing Androxal in the United States to treat testosterone deficiency due to secondary hypogonadism by restoring normal testosterone production in males with functional testes and diminished pituitary function, a common condition in the aging male. Based on a Type C meeting held with the Food and Drug Administration, or FDA, on October 15, 2007 we believe we do not have a clear clinical path to develop Androxal for this indication in the U.S. at this time. Although we believe Androxal could be developed outside of the U.S., due to the limited European market for this indication and our limited internal resources we do not intend to pursue approval outside of the U.S. at this time.

We also continue to maintain our patent portfolio of 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 January 9, 2008, we entered into an amendment to our rights agreement to permit Efficacy Capital to acquire up to 33% of our outstanding common stock, subject to a standstill agreement. The standstill agreement contains customary covenants and obligations restricting Efficacy from taking certain actions with respect to its shares. As part of the standstill agreement, we agreed to appoint Mark Lappe, Managing Partner at Efficacy, as a director should he elect to do so, and to provide Efficacy with observer rights at our board meetings.

On October 2, 2008, we completed a direct registered offering of 2.4 million shares of our common stock at a purchase price of \$6.50 per share for net proceeds after expenses of approximately \$15.6 million pursuant to an effective shelf registration statement. Certain of the purchasers in this offering were granted in their purchase agreements an option to purchase an aggregate of up to \$10 million of additional shares of our common stock at the greater of the fair market value, defined as the average of the closing prices for the 30 trading days immediately prior to the date of exercise, or \$7.80 per share. Such option becomes exercisable at such time as we have less than \$10 million in cash and cash equivalents and expires on September 29, 2009. In addition, the purchasers who received such option also received a right of first offer to purchase their respective pro-rata portion of any future financings, excluding certain corporate activities that expire on September 29, 2010.

In connection with this sale of our common stock, we filed a Form S-3 shelf registration statement (Reg. No. 333-155265) on November 10, 2008 to cover the issuance of up to 5,000,000 shares in future offerings and up to 1,282,052 shares underlying the purchase option described above. This registration statement, as amended, was declared effective on November 26, 2008 and will remain in effect for three years thereafter unless it is otherwise terminated or the shares underlying such registration statement are exhausted. In addition, we submitted to our stockholders at a special meeting held on December 16, 2008 a proposal to amend our Restated Certificate of Incorporation, as amended, to increase our authorized shares of common stock from 20 million shares to 30 million shares to cover the 5,000,000 shares that were registered in this registration statement, among other things. Our stockholders approved this proposal at the special meeting.





**Table of Contents**

As part of the terms of the October 2, 2008 financing, we amended our Standstill Agreement with Efficacy Capital Ltd. to permit Efficacy Capital to own up to 40% of our outstanding shares of stock and to permit Efficacy Capital to designate two directors to serve on our Board of Directors. Pursuant to that amendment, the Board increased its number to nine and appointed Mark Lappe, a Managing Partner of Efficacy Capital, and John C. Reed, M.D., Ph.D., President and CEO of Burnham Institute for Medical Research, to the vacancies on the Board created by such increase. The Company amended its Rights Agreement to reflect the increase to 40% described above.

The Company plans to use the proceeds from the financing to fund its research and development activities, including the ongoing pivotal Phase 3 trials of its lead product candidate, Proellex, as a pre-surgical short course treatment of anemia associated with uterine fibroids and as a chronic treatment of uterine fibroids and its Phase 2 clinical trial for the treatment of endometriosis as well as for working capital and general corporate purposes.

On July 3, 2008, Efficacy Capital paid \$327,320 to the Company as disgorgement of short swing profits under Section 16(b) of the Exchange Act as a result of certain inadvertent sales by Efficacy that occurred in March 2008 and that were within six months of certain purchases by Efficacy. The amount received from Efficacy has been reported as additional paid in capital during the year ended December 31, 2008. Efficacy is an affiliate of the Company as a result of its beneficial ownership of more than 10% of the Company's common stock.

As of December 31, 2008, we had accumulated losses of \$147.2 million and had cash and cash equivalents of \$19.5 million. We have experienced negative cash flows from operations since inception and have funded our activities to date primarily from equity financings and corporate collaborations. Our goal, if possible, is to move certain clinical activities into the latter part of the year post the receipt of additional funding without jeopardizing our current clinical development timeline. Based on our current planned clinical programs, we will need to raise additional capital in the third quarter of 2009. The uncertainties relating to the foregoing matters raise substantial doubt about our ability to continue as a going concern over the next twelve months.

We believe we can secure additional cash resources through either the sale of our equity securities or the potential regional out-licensing of Proellex. However, there can be no assurance that the Company will be successful in obtaining additional capital in amounts sufficient to continue to fund its operations and product development. If we are not able to raise capital through out-licensing Proellex or 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.

Our accumulated deficit of \$147.2 million primarily relates to costs that were incurred in research and development activities related to efforts to develop our product candidates 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.

**Table of Contents****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**

The Company considers all cash accounts and highly liquid investments having original maturities of three months or less to be cash and cash equivalents.

**MARKETABLE SECURITIES**

Management determines the appropriate classification of investments in debt and equity securities at the time of purchase and re-evaluates such designation as of each subsequent balance sheet date. Securities for which the Company has the ability and intent to hold to maturity are classified as held to maturity. Securities classified as trading securities are recorded at fair value. Gains and losses on trading securities, realized and unrealized, are included in earnings and are calculated using the specific identification method. Any other securities are classified as available for sale. Due to the current financial markets, as of December 31, 2008, as a means of protecting our cash resources, we invested all of our cash resources in either an insured bank account or a money market mutual fund that is backed by U.S. government securities. This money market mutual fund is recorded as cash and cash equivalents in the consolidated balance sheet and is a level one security, as defined by SFAS 157. At December 31, 2007 all securities were classified as trading securities and were all sold during 2008 without any losses.

Prior to September 30, 2008 the Company's investments typically included corporate bonds and notes, Euro-dollar bonds, taxable auction securities and asset-backed securities. The Company's investment policy is to require minimum credit ratings of A2/A and A1/P1 with maturities of up to three years, except taxable auction securities. The average life of the investment portfolio, other than taxable auction securities, may not exceed 24 months.

Marketable securities defined as trading securities consisted of the following at December 31, 2007 (in thousands):

	<b>December 31, 2008</b>	<b>December 31, 2007</b>
Corporate Bonds	\$	\$ 9,632
Taxable Auction Securities		6,400
Certificates of Deposit		4,503
Medium and Short Term Notes		2,594
Municipal Bonds		995
Total	\$	\$ 24,124

**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. Please also see discussion regarding Gedeon Richter in Note 10 for discussion of a prepaid commitment as of December 31, 2008.

**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 shorter of the useful life or the remaining term of the lease. Maintenance and repairs that do not improve or extend the life of assets are



**Table of Contents**

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 for its Proellex and Androxal products. As of December 31, 2008 and 2007, other assets consist of capitalized patent costs in the amount of \$1,713,000 and \$1,170,000 respectively. Patent costs, which include legal and application costs related to the patent portfolio, are being amortized over the lesser of 20 years or the estimated economic life of the patent. Amortization of patent cost expense was \$27,000, \$10,350 and \$71 in 2008, 2007 and 2006, respectively.

Of the \$1,713,000 in capitalized patent costs, \$759,000 related to Proellex and \$954,000 related to Androxal patents.

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, 2008.

**RESEARCH AND DEVELOPMENT GRANT REVENUE**

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 billed 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 depleted during 2005.

**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.

We estimate accrued expenses as part of our process of preparing financial statements. Examples of areas in which subjective judgments may be required include costs associated with services provided by contract organizations for clinical trials, preclinical development and manufacturing of clinical materials. We accrue for costs incurred as the services are being provided by monitoring the status of the trials or services provided and the invoices received from our external service providers. In the case of clinical trials, a portion of the estimated cost normally relates to the projected cost to treat a patient in our trials, and we recognize this cost over the estimated term of the study based on the number of patients enrolled in the trial on an ongoing basis, beginning with patient enrollment. As actual costs become known to us, we adjust our accruals. To date, our estimates have not differed significantly from the actual costs incurred. However, we are expanding the level of our clinical trials and related services. As a result, we anticipate that our estimated accruals for clinical services will be more material to our operations in future periods. Subsequent changes in estimates may result in a material change in our accruals, which could also materially affect our balance sheet and results of operations.

**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 applicable years all potential common stock equivalents were antidilutive and accordingly were not included in the computation.

**Table of Contents****SHARE-BASED COMPENSATION**

The Company has two stock-based compensation plans at December 31, 2008, which are described more fully in Note 8.

On January 1, 2006, the Company 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 the Company previously used. 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.

**RECENT ACCOUNTING PRONOUNCEMENTS**

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. SFAS No. 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. Issued in February 2008, FSP 157-1 Application of FASB Statement No. 157 to FASB Statement No. 13 and Other Accounting Pronouncements That Address Fair Value Measurements for Purposes of Lease Classification or Measurement under Statement 13 removed leasing transactions accounted for under Statement 13 and related guidance from the scope of SFAS No. 157. FSP 157-2 Partial Deferral of the Effective Date of Statement 157 (FSP 157-2), deferred the effective date of SFAS No. 157 for all nonfinancial assets and nonfinancial liabilities to fiscal years beginning after November 15, 2008. The implementation of SFAS No. 157 for financial assets and financial liabilities, effective January 1, 2008, did not have a material impact on our consolidated financial position and results of operations. The implementation of SFAS No. 157 for nonfinancial assets and nonfinancial liabilities will not have a material impact on our consolidated financial position and results of operations.

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 did not apply the fair value option under SFAS 159, which is elective. We have reclassified all cash flows, related to our trading securities, from operating to investing activities in the accompanying statement of cash flows to reflect the nature of the investments in accordance with paragraph 16 of SFAS 159.

In April 2008, the FASB issued FSP 142-3, Determination of the Useful Life of Intangible Assets, (FSP 142-3). FSP 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, Goodwill and Other Intangible Assets. FSP 142-3 is effective for fiscal years beginning after December 15, 2008. The implementation of this standard will not have a material impact on our consolidated financial position and results of operations.

**3. FIXED ASSETS:**

Fixed assets are as follows (in thousands):

	<b>December 31,</b>	
	<b>2008</b>	<b>2007</b>
Laboratory equipment	\$ 20	\$ 20
Office equipment	44	40
Leasehold improvements	38	38
Total fixed assets	102	98
Less Accumulated depreciation and amortization	74	51

Net Fixed Assets	\$ 28	\$ 47
------------------	-------	-------

F-22

---

**Table of Contents**

Depreciation and amortization was \$22,000, \$24,000 and \$20,000 for the years ended December 31, 2008, 2007, 2006, respectively.

**4. OPERATING LEASES:**

The Company leases laboratory and office space, and equipment pursuant to leases accounted for as operating leases. The lease for the Company's laboratory and office space expires in June 2010. Rental expense for the years ended December 31, 2008, 2007 and 2006, was approximately \$59,000, \$63,000 and \$53,000, respectively. Future minimum lease payments under non-cancelable leases with original terms in excess of one year as of December 31, 2008, are as follows (in thousands):

2009	\$ 60
2010	30
Total	\$ 90

**5. ACCRUED EXPENSES:**

Accrued expenses consist of the following (in thousands):

	<b>December 31,</b>	
	<b>2008</b>	<b>2007</b>
Research and development costs	\$ 1,573	\$ 955
Payroll	123	63
Patent costs	81	51
Other	80	189
Total	\$ 1,857	\$ 1,258

**6. FEDERAL INCOME TAXES:**

The Company has had losses since inception and, therefore, has not been subject to federal income taxes. As of December 31, 2008, the Company has accumulated approximately \$2.6 million of research and development tax credits. As of December 31, 2008, the Company had approximately \$129.9 million of net operating loss ( NOL ) carry-forwards for federal income tax purposes. Additionally, approximately \$3.4 million of NOLs, and approximately \$120,000 of research and development tax credits will expire in 2009.

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, together with changes in stock ownership, resulted in multiple ownership changes for federal income tax purposes. The Company estimates that the amount of pre-2007 NOL carryforwards and the credits available to offset taxable income is limited to approximately \$7.6 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 Company's public offerings completed on February 5, 2007 and October 2, 2008 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.



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

F-23

---

**Table of Contents**

	<b>December 31,</b>	
	<b>2008</b>	<b>2007</b>
Net operating loss carryforwards	\$ 44,169	\$ 36,691
Research and development tax credits	2,603	2,684
Accrued expenses	1,510	1,510
Total deferred tax assets	48,282	40,885
Capitalized patent costs	(582)	(398)
Total deferred tax liabilities	(582)	(398)
Less Valuation allowance	(47,700)	(40,487)
Net deferred tax assets	\$	\$

**7. STOCKHOLDERS' EQUITY:****PUBLIC OFFERINGS**

On October 2, 2008, we completed a direct registered offering of 2.4 million shares of our common stock at a purchase price of \$6.50 per share for net proceeds after expenses of approximately \$15.6 million pursuant to an effective shelf registration statement. Certain of the purchasers under this offering were granted in their purchase agreements an option to purchase an aggregate of up to \$10 million of additional shares of our common stock at the greater of the fair market value, defined as the average of the closing prices for the 30 trading days immediately prior to the date of exercise, or \$7.80 per share. Such option becomes exercisable at such time as we have less than \$10 million in cash and cash equivalents and expires on September 29, 2009. In addition, the purchasers who received such option also received a right of first offer to purchase their respective pro-rata portion of any future financings, excluding certain corporate activities that expire on September 29, 2010.

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 \$33.1 million.

**LOSS PER SHARE**

The following table presents information necessary to calculate loss per share for the three years ended December 31, 2008, 2007 and 2006 (in thousands, except per share amounts):

	<b>2008</b>	<b>2007</b>	<b>2006</b>
Net loss	\$ (25,202)	\$ (13,700)	\$ (14,195)
Weighted average common shares outstanding	13,372	12,524	10,147
Basic loss per share	\$ (1.88)	\$ (1.09)	\$ (1.40)
Weighted average common and dilutive potential common shares outstanding:			
Weighted average common shares outstanding	13,372	12,524	10,147
Assumed exercise of stock options	13,372	12,524	10,147
Diluted earnings per share	\$ (1.88)	\$ (1.09)	\$ (1.40)

Other potential common stock of 2,830,232, 1,555,565 and 1,469,148 for the years ended December 31, 2008, 2007 and 2006, 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 2008 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.

F-24

---

**Table of Contents**

As of December 31, 2008, there were 221,326 options available under the 2004 Plan and no available options under the 2000 Director Plan. The 2000 Director 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 other than with respect to the period of exercisability following termination of services. 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.

A summary of the status of the Company's option plans at December 31, 2008, 2007, and 2006 and changes during the years then ended is presented in the tables below:

	<b>Stock Options</b>	<b>Weighted Average Exercise Price</b>	<b>Remaining Weighted Average Contractual Term (Years)</b>	<b>Aggregate Intrinsic Value (In Thousands)</b>
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		
Granted	141,000	12.13		
Exercised	(13,942)	2.64		
Forfeited	(40,641)	19.51		
Outstanding at December 31, 2007	1,555,565	4.70		
Granted	240,000	9.01		
Exercised				
Forfeited	(7,000)	19.95		
Outstanding at December 31, 2008	1,788,565	5.22	5.57	\$ 9,475
Exercisable at December 31, 2008	1,273,564	4.44	5.14	\$ 7,744

The following table summarizes information about stock options outstanding at December 31, 2008:

<b>Range Of Exercise Prices</b>	<b>Number Outstanding</b>	<b>Weighted Average Remaining Life</b>	<b>Weighted Average Exercise Price</b>	<b>Number Exercisable</b>	<b>Weighted Average Exercise Price</b>
---------------------------------	-------------------------------	--	--	-------------------------------	--

Edgar Filing: REPROS THERAPEUTICS INC. - Form 10-K

\$2.40 to \$5.00	1,289,565	4.5	\$ 3.23	1,064,565	\$ 2.99
5.01 to 10.00	183,000	8.6	7.06	64,666	7.09
10.01 to 15.00	301,000	8.8	11.44	129,333	12.11
15.01 to 35.00	15,000	.8	29.41	15,000	29.41
	1,788,565			1,273,564	

The intrinsic value of options exercised during the years ended December 31, 2008, 2007 and 2006 was approximately zero, \$144,000 and \$132,000, respectively.

Stock-based compensation is outlined in the following table (in thousands):

	<b>2008</b>	<b>2007</b>	<b>2006</b>
R&D expense	\$ 389	\$ 255	\$ 127
G&A expense	482	625	662
Total expense	\$ 871	\$ 880	\$ 789

F-25

---

**Table of Contents**

At December 31, 2008, there was approximately \$1.8 million 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 1.8 years.

Estimated fair values of stock options granted have been determined using the Black-Scholes option pricing model with the following assumptions:

	<b>2008</b>	<b>2007</b>	<b>2006</b>
Risk-free interest rate	3.2%	4.6%	4.8%
Expected term	7 years	7 years	7 years
Volatility	77%	82%	85%
Dividend yield			
Fair value	\$6.51	\$9.29	\$6.49

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, Accounting for Stock-Based Compensation. Due to the adoption of SFAS 123(R) on January 1, 2006, we reclassified \$130,000 from deferred compensation to additional paid-in capital.

The Black-Scholes option pricing 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.

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

In 1999, we licensed rights to Proellex from the National Institutes of Health, or 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 a first indication by June 30, 2009. We have requested a meeting with the NIH to defer such date along with certain other milestones prior to such deadline. Although we believe we have a good working relationship with the NIH and even though the NIH has amended our agreement on several other occasions, no assurances can be given that such date or milestones will be revised.

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 again agree to amend this agreement to our satisfaction. Failure to comply with the material terms contained in the license agreement could result in termination of such agreement, which would prohibit us from further development of Proellex and severely harm our business prospects. 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.

**Table of Contents**

**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 commitments.

In addition, under a December 2008 Purchase Request, we committed to the purchase of \$3 million of the bulk active ingredient of Proellex which is to be produced under a new scaled-up amended manufacturing process by Gedeon Richter. Under this Purchase Request we are obligated to make four payments of \$750,000 each aggregating \$3 million which are expected to be made during 2009, assuming that the manufacturer meets the criteria of the Purchase Request. We expect to receive this material in the fourth quarter of 2009 and recognize the expense associated with this purchase when this material is received from the manufacturer. This Purchase Request contains certain provisions in which any dollars paid to this manufacturer under the Purchase Request will be returned if the manufacturer cannot meet their obligations under this Purchase Request by March 31, 2010. This Purchase Request also provides that the payment criteria and terms of the purchase shall be amended if the new terms are agreed to by both parties.

We have entered into several substantial agreements with four CROs to conduct our Proellex clinical trials. Even though these are substantial contracts and the term on one of them is estimated to potentially last through the year 2010, all contracts can be cancelled and we would only be responsible for services rendered through the cancellation period.

Our Androxal product candidate and its uses are covered in the United States by two issued U.S. patents and seven pending patent applications. Foreign coverage of our Androxal product candidate includes 33 issued foreign patents and 63 foreign pending patent applications. The issued patents and pending applications relate to methods and compositions for treating certain conditions including the treatment of testosterone deficiency in men, the treatment of metabolic syndrome and conditions associated therewith, and the treatment of infertility in hypogonadal 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 re-examination proceedings, which led the PTO to determine that the amended claims are patentable in view of those publications under consideration and a re-examination certificate was issued. However, we believe that the amended claims are invalid based on additional prior art publications, and our request for re-examination by the PTO in light of a number of these additional publications and other publications cited by the PTO, has been granted. All of the claims have been finally rejected in the re-examination. The patent holder has appealed the rejections and has recently filed a Request for Oral Hearing. We also believe that the second of these two patents is invalid in view of published prior art not considered by the PTO. Nevertheless, there is no assurance that either patent will ultimately be found invalid over the prior art. If such patents are not invalidated by the PTO we may be required to obtain a license from the holder of such patents in order to develop Androxal further or attempts may be made to undertake further legal action to invalidate such patents. If such licenses were not available on acceptable terms, or at all, we may not be able to successfully commercialize Androxal.

**11. RELATED PARTY TRANSACTIONS:**

A member of our Board of Directors is also a shareholder of a law firm that provides legal services to the Company. Total fees charged by the firm to the Company during the years ended December 31, 2008, 2007 and 2006 were \$275,000, \$256,000 and \$203,000, respectively.

**Table of Contents**

## 12. QUARTERLY FINANCIAL INFORMATION (UNAUDITED):

	<b>First Quarter Ended March 31, 2008</b>	<b>Second Quarter Ended June 30, 2008</b>	<b>Third Quarter Ended September 30, 2008</b>	<b>Fourth Quarter Ended December 31, 2008</b>
<b>(In thousands except per share amounts)</b>				
Revenues and other income:				
Interest income	\$ 269	\$ 91	\$ 45	\$ 28
Total revenues and other income	269	91	45	28
Expenses:				
Research and development	6,166	5,475	5,874	5,060
General and administrative	797	689	750	824
Total expenses	6,963	6,164	6,624	5,884
Net loss	\$ (6,694)	\$ (6,073)	\$ (6,579)	\$ (5,856)
Net loss per share basic and diluted	\$ (0.52)	\$ (0.48)	\$ (0.51)	\$ (0.39)
Shares used in loss per share calculation	12,775	12,775	12,775	15,149

	<b>First Quarter Ended March 31, 2007</b>	<b>Second Quarter Ended June 30, 2007</b>	<b>Third Quarter Ended September 30, 2007</b>	<b>Fourth Quarter Ended December 31, 2007</b>
<b>(In thousands except per share amounts)</b>				
Revenues and other income:				
Interest income	\$ 318	\$ 442	\$ 396	\$ 352
Total revenues and other income	318	442	396	352
Expenses:				
Research and development	3,028	3,207	3,196	2,989
General and administrative	941	609	568	670
Total expenses	3,969	3,816	3,764	3,659
Net loss	\$ (3,651)	\$ (3,374)	\$ (3,368)	\$ (3,307)
Net loss per share basic and diluted	\$ (0.31)	\$ (0.26)	\$ (0.26)	\$ (0.26)
Shares used in loss per share calculation	11,756	12,775	12,775	12,775

## 13. SUBSEQUENT EVENTS



On February 18, 2009 the Company's Board of Directors appointed Dr. Paul Lammers as the Company's President. That same day the Company's Board of Directors granted the Chief Executive Officer, the new President and the Chief Financial Officer 50,000, 300,000 and 20,000 stock options, respectively, at the closing price that day of \$8.80 per share under the Company's 2004 Stock Option Plan, or 2004 Plan. At that time the 2004 Plan had 221,326 options available. The remaining 148,674 options will not be effective until the Company's shareholders approve a modification to the 2004 Plan at its next Annual Meeting to be held on May 20, 2009.

F-28

---

**Table of Contents**

**INDEX TO EXHIBITS**

<b>Exhibit Number</b>	<b>Identification Of Exhibit</b>
3.1(a)	Restated Certificate of Incorporation. Exhibit 3.3 to the Company's Registration Statement on Form SB-2 (No. 33-57728-FW), as amended (Registration Statement), is incorporated herein by reference.
3.1(b)	Certificate of 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.
3.1(d)	Certificate of Amendment to Restated Certificate of Incorporation, dated as of December 16, 2008. Exhibit 3.1(d) to the Company's Current Report on Form 8-K as filed with the Commission on December 23, 2008 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	Fourth Amendment to Rights Agreement, dated as of January 9, 2008, between the Company and Computershare Trust Company, Inc. (as successor in interest to Computershare Investor Services, LLC). Exhibit 4.5 to the Company's Current Report on Form 8-K as filed with the Commission on January 10, 2008 is incorporated herein by reference.

- 4.7 Fifth Amendment to Rights Agreement, sated as of October 10, 2008, between the Company and Computershare Trust Company, Inc. (as successor in interest to Computershare Investor Services, LLC). Exhibit 4.6 to the Company's Current Report on Form 8-K as filed with the Commission on January 10, 2008 is incorporated herein by reference.
- 4.8 Form of Rights Certificate. Exhibit B to Exhibit 4.1 to the Rights Plan Registration Statement is incorporated herein by reference.
-

**Table of Contents**

<b>Exhibit Number</b>	<b>Identification Of Exhibit</b>
10.1+	Amended and Restated 1993 Employee and Consultant Stock Option Plan. Exhibit 10.3 to the Registration Statement is incorporated herein by reference.
10.2+	First Amendment to the Repros Therapeutics 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 Repros Therapeutics 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+	Repros Therapeutics 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.

Edgar Filing: REPROS THERAPEUTICS INC. - Form 10-K

- 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.
-

**Table of Contents**

<b>Exhibit Number</b>	<b>Identification Of Exhibit</b>
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.
10.17	Fourth Amendment to PHS Patent License Agreement, as amended, dated December 9, 2003 between the Company and certain agencies of the United States Public Health Service within the Department of Health and Human Services. Exhibit 10.1 to the Company's Current Report on Form 8-K as filed with the Commission on March 19, 2007 is incorporated herein by reference.
10.18	Waiver to PHS Patent License Agreement, as amended, dated March 8, 2007 between the Company and certain agencies of the United States Public Health Service within the Department of Health and Human Services. Exhibit 10.2 to the Company's Current Report on Form 8-K as filed with the Commission on March 19, 2007 is incorporated herein by reference.
10.19++	Fifth Amendment to PHS Patent License Agreement, as amended, dated March 15, 2007 between the Company and certain agencies of the United States Public Health Service within the Department of Health and Human Services. Exhibit 10.3 to the Company's Current Report on Form 8-K as filed with the Commission on March 19, 2007 is incorporated herein by reference.
10.20	Standstill Agreement, dated as of January 9, 2008, between the Company and Efficacy Capital. Exhibit 10.1 to the Company's Current Report on Form 8-K as filed with the Commission on January 10, 2008 is incorporated herein by reference.
10.21	First Amendment to Standstill Agreement, dated July 28, 2008, between the Company and Efficacy Capital. Exhibit 10.2 to the Company's Current Report on Form 8-K as filed with the Commission on July 28, 2008 is incorporated herein by reference.
10.22	Second Amendment to Standstill Agreement, dated October 2, 2008, between the Company and Efficacy Capital. Exhibit 10.3 to the Company's Current Report on Form 8-K as filed with the Commission on October 3, 2008 is incorporated herein by reference.
10.23	Common Stock Purchase Agreement, dated September 29, 2008 between the Company and Efficacy Capital. Exhibit 10.1 to the Company's Current Report on Form 8-K as filed with the Commission on September 29, 2008 is incorporated herein by reference.
10.24	Amended and Restated Common Stock Purchase Agreement, dated September 29, 2008 between the Company and the affiliate or Vermillion Asset Management LLC named therein. Exhibit 10.4 to the Company's Current Report on Form 8-K as filed with the Commission on October 3, 2008 is incorporated herein by reference.
10.25	Common Stock Purchase Agreement, dated September 29, 2008 between the Company and Dr. John C. Reed. Exhibit 10.4 to the Company's Current Report on Form 8-K as filed with the Commission on September 29, 2008 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)
-

**Table of Contents**

**Exhibit  
Number**

**Identification Of Exhibit**

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.