REPROS THERAPEUTICS INC.
Form 10-K
March 18, 2013

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

Form 10-K

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

For the fiscal year ended December 31, 2012

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

Repros Therapeutics Inc.

(Exact name of registrant as specified in its charter)

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

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

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

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock, $.001 par value	The Nasdaq Stock Market LLC
Series A Warrants	The Nasdaq Stock Market LLC
Series B Warrants	The Nasdaq Stock Market LLC
Rights to purchase Series One Junior Participating Preferred Stock	The Nasdaq Stock Market LLC

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

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

Yes ¨ No x

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 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 x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x 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. x

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 definitions of "large accelerated filer," accelerated filer" and “smaller reporting company” in Rule 12b-2 of the Exchange Act.:

Large accelerated filer ¨ Accelerated filer x

Non-accelerated filer ¨ (Do not check if smaller reporting company) Smaller reporting company ¨

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

The aggregate market value of the common stock held by non-affiliates of the registrant was approximately $134,073,146 as of June 30, 2012, the last business day of the registrant's most recently completed second fiscal quarter, based on the closing sales price of the registrant's common stock on the Nasdaq Capital Market on such date of $9.08 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 8, 2013, there were 18,643,986 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 2013 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, 2012, are incorporated by reference into Part III of this Form 10-K.

REPROS THERAPEUTICS INC
2012 FORM 10-K ANNUAL REPORT

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This Annual Report on Form 10-K contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. The words "may," "anticipate," "believe," "expect," "estimate," "project," "suggest," "intend" and similar expressions are intended to identify 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.

PART I

ITEM 1. Business

Overview

Repros Therapeutics Inc. (the "Company," "Repros," or "we," "us" or "our") was organized on August 20, 1987. We are a development stage biopharmaceutical company focused on the development of new drugs to treat hormonal and reproductive system disorders. Both of our product candidates have exhibited strong efficacy results in every study completed to date, and we believe the studies presently underway will place both programs on a clear late stage clinical development path.

We are developing Androxal®, an oral therapy that normalizes testicular function, for the treatment of low testosterone due to secondary hypogonadism. Secondary hypogonadism is associated with obesity and we believe it is among the most common causes of low testosterone in men. It is estimated that 13 million men in the U.S. experience low levels of testosterone, and the condition is becoming recognized with more frequency. As of 2012, sales of preparations for the treatment of low testosterone have exceeded $1 billion in the U.S. and first tier pharmaceutical companies have entered the low testosterone marketplace.

We believe Androxal® is highly differentiated from currently marketed testosterone treatments or those treatments in late stage development because it is an oral therapy and it treats the cause of secondary hypogonadism, which is inadequate pituitary hormones. We believe that by treating the cause of secondary hypogonadism, Androxal® also has the potential to maintain reproductive status and potentially improve overall metabolic profiles.

In December 2011, we completed a Phase 2B study of Androxal® in men with secondary hypogonadism, but naïve to testosterone treatment, at the Food and Drug Administration's (the "FDA") recommendation. Top line results of this study demonstrated that Androxal® was generally well tolerated compared to placebo and that there were no drug related serious adverse events that led to discontinuation. We met with the FDA in May 2012 to discuss the design of pivotal Phase 3 efficacy studies for Androxal® as well as the components of the overall drug development program required for a New Drug Application ("NDA") submission. During this meeting, we agreed upon registration requirements for Androxal® oral therapy for the treatment of secondary hypogonadism. On July 9, 2012, we announced that we reached an agreement with the FDA for the design of the pivotal efficacy studies for Androxal® for the treatment of secondary hypogonadism. The pivotal studies are being conducted under a Special Protocol Assessment ("SPA"). The first pivotal study was fully enrolled in November 2012 and we continue to enroll subjects into the second pivotal study. Additionally, we have completed enrollment into a 500 subject open label safety study in February 2013 and completed enrollment into a one year dual-energy X ray absorptiometry ("DEXA") study in January 2013. Depending on study enrollment and the completion of other studies, we believe we may be able to submit an NDA by mid 2014.

We are also developing Proellex®, an orally administered selective blocker of the progesterone receptor in women, for the treatment of uterine fibroids and endometriosis. Uterine fibroids and endometriosis affect millions of women of reproductive age. Proellex® has shown statistically significant results in previous Phase 2 studies for endometriosis and uterine fibroids. We completed a low dose escalating study as permitted by the FDA in late 2011, to determine both signals of efficacy and safety for low oral doses of the drug. There was no evidence of elevations of liver enzymes over baseline, suggesting these lower doses avoid the type of adverse events seen at much higher doses in earlier studies. On October 8, 2012, we announced that the FDA has agreed to a reclassification of the full clinical hold to a partial clinical hold on low dose oral Proellex® to allow us to conduct a Phase 2 study in the treatment of endometriosis. We initiated this study in November 2012 and we believe full enrollment will be achieved in the second quarter of 2013.

The FDA has accepted an Investigational New Drug Application (“IND”) for vaginally delivered Proellex® and, as a result, we commenced a Phase 2 vaginal administration study for uterine fibroids in the first quarter of 2012 and reported final study results in January 2013. We then requested, and were granted, an end of Phase 2 meeting with the FDA, scheduled for the last half of May 2013, to discuss a Phase 3 study design for uterine fibroids. Additionally, we have begun enrolling subjects who completed the Phase 2 study into a one year open label safety trial in order to begin collecting long term safety data which we expect the FDA to require in connection with the submission of an NDA.

As of December 31, 2012, we had accumulated losses of $209.9 million, approximately $24.2 million in cash and cash equivalents, and our accounts payable and accrued expenses were approximately $3.8 million. On February 1, 2012, we completed a registered direct offering to certain institutional investors, including certain existing shareholders, of 2,463,537 shares of our common stock at a price per share of $4.50. Net proceeds to us, after deducting the placement agent's fees and offering expenses, were approximately $10.3 million. On September 7, 2012, we completed a private placement of 2,145,636 shares of our common stock at a price per share of $11.00. Net proceeds to us, after deducting offering expenses, were approximately $23 million. We anticipate that our current liquidity will be sufficient to continue these planned studies into the first quarter of 2014; however, significant additional capital will be required for us to complete the development of our product candidates through NDA approval. We continue to explore potential additional financing alternatives (including corporate partnering opportunities) that would provide sufficient funds to enable us to continue to develop our two product candidates through NDA approval; however, there can be no assurance that we will be successful in raising any such additional funds on a timely basis or at all. The foregoing matters raise substantial doubt about our ability to continue as a going concern.

Our Research and Development Program

Our product development pipeline is summarized in the table below:

Product Candidate (Indication)	Status	Next Expected Milestone(s)
Androxal®		
		Complete first Phase 3 pivotal study (Q2 2013)
		Complete open label safety study (Q4 2013)
Secondary Hypogonadism	Phase 3	
		Complete DEXA study (Q4 2013)
Proellex®		
		Initiate a Phase 3 study (vaginal delivery) (Q3 2013)
Uterine Fibroids	Phase 2	
Endometriosis		
	Phase 2	Complete Phase 2 study (oral delivery) (Q4 2013)

Androxal®

Product Overview

Our primary product candidate, Androxal®, 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. Androxal® treats the underlying mechanism that causes secondary hypogonadism and restores normal testicular function. Unlike testosterone replacement which suppresses testicular function, Androxal® does not impair the reproductive status of men being treated for low testosterone.

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 and this decline can be accelerated by obesity, sometimes leading to testosterone deficiency. The leading therapy for low testosterone is AndroGel®, a commercially available testosterone replacement cream marketed by Abbott Laboratories for the treatment of low testosterone, which we believe has had and continues to have significant sales 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, a pituitary defect which is characterized by suboptimal levels of LH (luteinizing hormone) and FSH (follicle stimulating hormone). LH and FSH are the pituitary hormones that stimulate testicular testosterone and sperm production, respectively. Men with secondary hypogonadism can be readily distinguished from those that have primary testicular failure via assessment of the levels of secretions of pituitary hormones, as men with primary testicular failure experience elevated secretions of pituitary hormones. In secondary hypogonadism, the low levels of LH and FSH fail to provide adequate hormone signaling to the testes, causing testosterone levels to drop to a level where we believe pituitary secretions fall under the influence of estrogen, which is enhanced in obese men, thus further suppressing the testicular stimulation from the pituitary.

Androxal® acts centrally to restore testicular function and, hence, normal testosterone in the body. The administration of exogenous testosterone can restore serum testosterone levels, but does not restore testicular function and thereby generally leads to the cessation of, or significant reduction in, sperm production. Androxal®, by contrast, restores levels of both LH and FSH, which stimulate testicular testosterone and sperm production, respectively.

We tested Androxal® in two studies designed to show that Androxal® improved testosterone levels as well as AndroGel® in men with secondary hypogonadism. These studies indicated that Androxal® had a superior ability to improve testosterone levels when compared to AndroGel® and that the improvement was statistically significant. In the meeting held on November 8, 2010, the FDA determined that improved testosterone levels would be sufficient provided that both placebo and Androxal® maintained sperm counts in a statistically significant manner as compared to an approved topical testosterone.

Androxal® is required to undergo the full regulatory approval process, including pivotal Phase 3 trials, long-term open label safety studies and a dual-energy X ray absorptiometry (DEXA) study, as well as other requirements. Androxal® is closely related chemically to the drug, Clomid®, which is approved for use in women to treat certain infertility disorders. Clomid® contains both the trans and cis isomers of clomiphene citrate; Androxal® contains only the trans isomer. 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 reduced half-life and lack of cis isomer 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 any necessary 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.

Treatment for Secondary Hypogonadism in Men Wishing to Preserve Testicular Function (Reproductive Status)

On November 8, 2010, we held a Type B meeting with the FDA to discuss whether the FDA would review our protocols for a Phase 3 trial of Androxal® in men with secondary hypogonadism under an SPA. In the meeting, the FDA recommended that a Phase 2B study in men with secondary hypogonadism but naïve to testosterone treatment be conducted if we desired the protocols to be reviewed under an SPA. The FDA further opined that such Phase 2B study would provide for a more solid data base for design of Phase 3 studies and eventual approval of such studies under an SPA.

We have completed the Phase 2B trial which consisted of four arms; placebo, two doses of Androxal® and topical testosterone. In this study, at baseline the men exhibited morning testosterone less than 250 ng/dl and there was no statistical difference between the groups in testosterone at baseline. At the end of the three month dosing period, median morning testosterone levels were placebo (196 ng/dl), 12.5 mg Androxal® (432 ng/dl), 25 mg Androxal® (416 ng/dl) and Testim® (393 ng/dl). A comparison of final median morning testosterone in all three of the active arms to placebo showed them to be highly statistically different and there was no statistical difference observed between these active arms. This trial also showed that Androxal® was able to maintain sperm counts in men being treated for their low testosterone levels, whereas Testim® resulted in suppressed sperm levels.

On July 9, 2012, we announced that we reached an agreement with the FDA for the design of the pivotal efficacy studies for Androxal® for the treatment of secondary hypogonadism. The pivotal studies are being conducted under an SPA. The first pivotal study was fully enrolled in November 2012 and we continue to enroll subjects into our second pivotal study. Based on the completed enrollment into our first pivotal study, we believe we will have top line results from this study in the second quarter of 2013.

The 500 subject, six month open label safety study completed enrollment in February 2013 at 28 U.S. clinical sites. Additionally, we have completed enrollment into a one year, 150 subject DEXA study in January 2013 at 10 U.S. clinical sites. This study is on the critical path to submission of the NDA. Depending on study enrollment and the completion of other studies, we believe we may be able to submit an NDA by mid 2014.

Unlike testosterone replacement therapies, Androxal® maintains the normal daily rhythm of testosterone peaks and valleys. We previously conducted three studies in which 24 hour testosterone levels were obtained and, unlike topical testosterone, morning testosterone was the maximum concentration observed, consistent with the normal circadian rhythm in men. These studies provide evidence that one assessment of testosterone between 8 a.m. and 10 a.m. correlates to the maximum value of testosterone for a given subject on a given day. Additionally, we conducted one additional 24 hour study which showed that Androxal®'s action in maintaining the normal rhythm is both predictable and dose-dependent.

We believe the advantages of oral delivery, maintenance of testicular function and additional metabolic benefits will be important differentiating factors for Androxal®, should it be approved. There can be no assurance, however, that we will be successful in implementing this strategy or that the FDA will approve our drug for commercial use.

Proellex®

Product Overview

Proellex®, our product candidate for female reproductive health, is a new chemical entity that acts as a selective blocker of the progesterone receptor and is being developed for the treatment of symptoms associated with uterine fibroids and endometriosis. There are currently no FDA-approved orally administered drug treatments for the long-term treatment of either uterine fibroids or endometriosis. The National Uterine Fibroids Foundation estimates that 80% of all women in the U.S. have uterine fibroids, and one in four of these women have symptoms severe enough to require treatment. According to the Endometriosis Association, endometriosis affects 6.3 million women in the U.S. and Canada and millions more worldwide.

The current standards of care for uterine fibroids and endometriosis consist of surgery or short-term treatment with gonadotropin-releasing hormone ("GnRH") agonists drugs, such as Lupron®. GnRH agonists induce a low estrogen, menopausal-like state and promote bone loss and are not recommended for use for more than six months.

We have conducted numerous studies with Proellex® dosing approximately 700 women with the drug. All Proellex® studies completed to date exhibited strong efficacy signals, whether in uterine fibroids or endometriosis. In a 120 patient study of Proellex® as a treatment of uterine fibroids conducted in the United States (roughly 40 subjects per arm), both a 12.5 and 25 mg dose of Proellex® were compared to placebo. In this study each of the 12.5 and 25 mg doses achieved highly statistically significant results when compared to placebo when menstrual bleeding was assessed ($p<0.0001$). The two doses also achieved highly statistically significant improvement in quality of life measures using the Uterine Fibroid Symptom Quality of Life questionnaire developed and validated by Georgetown University and used in the development of device like treatments of uterine fibroids such as uterine artery embolization. There was no statistical difference in efficacy measures between the two doses. Importantly, in the Phase 2 U.S. trial a significant percentage of women stopped menstruating. Proellex® resulted in the induction of amenorrhea (cessation of menses), which we believe is a strong surrogate signal of efficacy. Over 80% of women on both the 12.5 and 25 mg doses exhibited no menses during the three month trial, whereas all women on placebo exhibited at least one menses.

Up until the summer of 2009, all side effects exhibited in the studies were considered manageable and the benefit of Proellex® far outweighed the risk. However, in Phase 3 efficacy and larger Phase 3 safety studies in diverse populations, a small number of subjects exhibited serious adverse effects associated with elevated liver enzymes. As a result of these findings, we elected to stop the trials and the FDA subsequently placed Proellex® on full clinical hold. All women that experienced elevated liver enzymes and returned for follow-up visits returned to baseline conditions with no overnight hospitalization necessary. An analysis of all the subjects that experienced such serious adverse effects showed that the effect only occurred in a small percentage of subjects that were exposed to the 50 mg dose of the drug for any period of time. Based on these findings, we petitioned the FDA to allow us to conduct a low dose study to demonstrate both safety and signals of efficacy in low oral doses of Proellex®, up to 12 mg administered per day. The FDA upgraded the full clinical hold to a partial hold to allow the low dose study to be conducted. In addition, we undertook two related initiatives: (i) the exploration of vaginal delivery as an alternative administrative route to bypass first-pass liver effects and reduce systemic exposure, which is currently in a Phase 2 study; and (ii) the screening of second generation molecules that do not possess the specific structures that may have induced the liver toxicity exhibited at higher doses of Proellex®.

Low Dose Oral Study

Pursuant to the terms of the partial clinical hold currently in place as a result of the liver toxicity exhibited by Proellex®, the FDA allowed us to run a single study to test low oral doses of Proellex® for signals of safety and efficacy. The study tested 5 different doses of Proellex® (1, 3, 6, 9 and 12 mg), with 1 mg being the first dose tested. Each dose was then compared to placebo with weekly assessments of liver function during both the placebo and drug period. Subjects were dosed with the active drug for 10 weeks, which allowed for adequate time to determine the impact of a given dose on trends in liver function. Each dose was tested in up to 12 different subjects and assessment of pharmacokinetic parameters was obtained at the start of dosing and the end of the dosing period to determine overall and maximum drug exposure for a given dose. We also monitored changes in menstrual bleeding patterns and ovulation as well as changes in endometrial thickness. The FDA required that an independent Drug Safety Monitoring Board be established and that the informed consent clearly state the liver toxicity previously experienced with

Proellex®. We have completed this study and have announced that there was no evidence of elevations of liver enzymes over baseline, suggesting these lower doses avoid the type of adverse events seen at much higher doses in earlier studies.

On July 16, 2012, we announced that we held a teleconference with the FDA to discuss the development of low dose oral Proellex® as a treatment for endometriosis. Subsequently, on October 8, 2012, we announced that the FDA has agreed to reclassify the full clinical hold to a partial clinical hold on low dose oral Proellex® to allow us to conduct a Phase 2 study in the treatment of endometriosis. We initiated this 90 subject, four month active dosing study in November 2012 and we believe full enrollment will be achieved in the second quarter of 2013. Depending on study enrollment, we expect to release results from this study in the fourth quarter of 2013.

Vaginal Administration

We are assessing vaginal administration of Proellex® to avoid first pass liver effects and achieve higher reproductive tract concentrations of the drug while minimizing systemic exposure. We reported results from two in vivo animal studies which confirmed reduced maximum circulating concentrations of the drug when administered vaginally, as well as efficacy signals at substantially lower doses than oral administration. The FDA has accepted an IND for vaginally delivered Proellex® and, as a result, we commenced a Phase 2 vaginal administration study for uterine fibroids in the first quarter of 2012. In January 2013, we reported the final study results which indicated the 12 mg dose achieved statistically significant improvement in menstrual bleeding, uterine fibroid symptoms and reduction in fibroid volume even with the low number of subjects enrolled into the study (n=12 @ 12 mg). Based on these findings, the Company believes the 12 mg dose is appropriate for further development. We have requested, and were granted, an end of Phase 2 meeting with the FDA, scheduled for the last half of May 2013, to discuss a Phase 3 study design for the vaginally delivered Proellex® as a treatment for uterine fibroids.

Additionally, we have begun enrolling subjects who completed the Phase 2 study into a one year open label safety trial in order to begin collecting long term safety data which we expect the FDA to require in connection with the submission of an NDA. The majority of the women being dosed with 12 mg in the Phase 2 study have elected to enroll into the open label safety study.

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® has been on partial clinical hold in the U.S. since 1998, and no further development activities are planned.

Business Strategy

We plan to focus our clinical program on (i) conducting Phase 3 secondary hypogonadism trials for Androxal®, (ii) conducting a Phase 3 vaginal administration trial for Proellex® for uterine fibroids and (iii) conducting a Phase 2 trial for low dose oral Proellex® for endometriosis. We anticipate that our current liquidity will be sufficient to continue these planned studies into the first quarter of 2014; however, significant additional capital will be required for us to complete the development of our product candidates through NDA approval. We will continue to explore corporate partnering opportunities for assistance in the clinical development funding and commercialization of our products, as appropriate; however, there can be no assurance that an acceptable corporate partnering opportunity will be successfully completed or that we will be successful in raising the additional funds.

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 ("R&D") expenses for 2012 were for the payment for 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, amortization of capitalized patent costs and internal research and development supplies. We believe that these expenses will continue to be our primary R&D expenses in 2013.

Proellex® License Agreement with the National Institutes of Health

In 1999, we licensed rights to Proellex® from the National Institutes of Health ("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, currently 2017. 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. If we fail to achieve the benchmarks specified in the commercial development plan attached to the license agreement or meet payment obligations, the NIH can terminate the license agreement and we lose our rights to develop and commercialize Proellex®. We and the NIH periodically update the commercial development plan. 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, the NIH will agree to revised objectives. The NIH also has the ability to terminate the agreement for an uncured material breach of the agreement, if we do not keep Proellex® reasonably available to the public after commercial launch or if we cannot reasonably satisfy unmet health and safety needs, among other reasons.

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 the NIH are in good standing.

The NIH retains, on behalf of the government, a nonexclusive, nontransferable, worldwide license to practice the inventions licensed under the licensed patents by or on behalf of the government. For the purpose of encouraging basic research, the NIH retains the right to grant nonexclusive research licenses to third parties. Due to the work that was done on Proellex® at the NIH prior to our license agreement, the government also has certain rights to use the product in the event of a national emergency pursuant to the Patent and Trademark Laws Amendments Act of 1980, as amended.

Manufacturing

We have a supply agreement with Diagnostic Chemical Limited, doing business as BioVectra, for the supply of the bulk active pharmaceutical ingredient used in Androxal®. This agreement runs through July of 2013, subject to automatic one year renewals and the ability of either party to terminate upon 12 months prior notice. 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 necessary quantities of Androxal® for our clinical trials and anticipate utilizing them for the remainder of our clinical supply and for commercial production if Androxal® is approved for sale. Though our relationship with BioVectra remains good, we believe that alternate manufacturers capable of manufacturing Androxal® could be identified if necessary.

Gedeon Richter was our third-party manufacturer of the active pharmaceutical ingredient for Proellex®. Due to the clinical hold, we cancelled our development and supply contract with Gedeon Richter; however, we have a large supply of Proellex® currently available for our current and planned clinical trial efforts. In the event we require an additional supply of Proellex®, we believe that we have maintained a good relationship with Gedeon Richter and that an agreement could be reached with Gedeon Richter to provide such supply when and if needed.

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 Androxal® and Proellex®. 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 have no experience in the sales, marketing and distribution of pharmaceutical products. We anticipate that we will outsource such activities to larger pharmaceutical companies, who may also conduct later stage pivotal trials of our product candidates. These companies are more capable of distributing the products to the market place. In the normal course of business we continue to explore possible partnerships with various pharmaceutical companies. If in the future we fail to reach or elect not to enter into an arrangement with a collaborative partner with respect to the sales and marketing of any of our future potential product candidates, we would need to develop a sales and marketing organization with supporting distribution capability in order to market such products directly. Significant additional expenditures would be required for us to develop such a sales and marketing organization.

Patents and Proprietary Information

Our ability to compete effectively with other companies is materially dependent on the proprietary nature of our patents and technologies. We actively seek patent protection for our proprietary technology in the United States and abroad.

Under a license agreement with the NIH, we have exclusive rights to four 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 six pending U.S. patent applications, 92 foreign pending patent applications and 10 granted foreign patents that cover various formulations of Proellex® and methods for using Proellex®.

Therapeutic uses of our Androxal® product candidate are covered in the United States by seven issued U.S. patents and six pending patent applications. Foreign coverage of therapeutic uses of our Androxal® product candidate includes 59 issued foreign patents and 52 foreign pending patent applications. The issued patents and pending applications relate to methods for treating certain conditions including the treatment of testosterone deficiency in men, the treatment of diabetes mellitus Type 2, 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. We requested re-examination of one of these patents by the U.S. Patent and Trademark Office ("PTO") based on prior art. The patent holder amended the claims in the re-examination proceedings, which led the PTO to determine that the amended claims were patentable in view of those publications under consideration and a re-examination certificate was issued. We subsequently filed a second request for re-examination by the PTO in light of a number of additional publications. The request was granted and all of the claims were finally rejected by the PTO in the re-examination. The patent holder appealed the rejections to the PTO Board of Patent Appeals and Interferences (the "PTO Board") which ultimately reversed the rejections of several dependent claims in view of those publications under consideration. The patent holder filed a Notice of Appeal to the Federal Circuit on September 28, 2010 contesting the rejections maintained by the PTO Board. A decision was rendered by the Federal Circuit on December 12, 2011, affirming the rejection of the appealed claims. We expect that a re-examination certificate will be issued confirming the patentability of the remaining claims; however, if such a re-examination certificate were to issue, we believe that our development of Androxal® would not infringe any of the remaining claims and that all of the remaining claims are invalid on various grounds including additional prior art publications. We also believe that the second of these two patents is invalid in view of published prior art not considered by the PTO. If necessary, we intend to vigorously defend any and all claims against the holder of such patents in a court of competent jurisdiction in order to develop Androxal® further. Adverse determinations in litigation proceedings could require us to seek licenses which may not be available on commercially reasonable terms, or at all, or subject us to significant liabilities, in which case we may not be able to successfully commercialize or out-license Androxal® until such patents expire or are otherwise no longer in force.

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 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. AndroGel® is marketed by Abbott Laboratories (“Abbott”). There is another topical gel, Testim®, currently marketed by Auxilium Pharmaceuticals, and a transdermal patch, AndroDerm®, marketed by Watson Pharmaceuticals. Eli Lilly and Company also entered into a licensing agreement with a third party for a late stage topical testosterone treatment called Axiron®, which has recently become available in pharmacies. In addition, other companies such as QTRX Pharmaceuticals and Clarus Therapeutics, Inc. 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®, besides being the only late stage oral therapy, is the only drug in development that normalizes testicular function and may provide additional metabolic benefits. 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.

Our main competitors for the treatment of uterine fibroids and endometriosis are GnRH agonists, especially Lupron®, the current therapeutic standard of care for uterine fibroids. Lupron® is marketed by Abbott, which has far greater resources and marketing capabilities than we have. Recently Abbott has licensed a Phase 3-ready molecule from Neurocrine Biosciences for the treatment of endometriosis. Gedeon Richter and Watson Pharmaceuticals have also entered into an exclusive license agreement to develop and market Esmya™ (an orally active selective progesterone receptor modulator) in the U.S. and Canada. 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.

Government 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 (an “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 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. This was evidenced when Proellex®, our product candidate for uterine fibroids and endometriosis, was placed on clinical hold by the FDA in summer 2009 due to liver toxicity data resulting from our clinical trials. Though the full clinical hold has been upgraded to a partial clinical hold, there can be no assurance that the partial hold will be lifted at any time.

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 ("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 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 develop, no assurance can be given that it will approve satisfactory prices for the products.

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

Third-Party Reimbursement and Pricing Controls

In the United States and elsewhere, sales of pharmaceutical products depend in significant part on the availability of reimbursement to the consumer from third-party payers, such as government and private insurance plans. Third-party payers are increasingly challenging the prices charged for medical products and services. Should any of our product candidates be approved for any commercial sales, 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 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 (“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 (“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

See Item 3 of Part I of this Annual Report on Form 10-K for our fiscal year ended December 31, 2012.

Employees and Consultants

Employees

At December 31, 2012, we had 21 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 agreements with other entities that limit their availability to us. Our advisors are required to sign an agreement providing that, if appropriate, they are to disclose and assign to us any ideas, discoveries and inventions they develop in the course of providing consulting services. We also use consultants for various administrative needs. None of our advisors are otherwise affiliated with us.

In addition to the advisors described above, we continue to engage U.S. contract research organizations for data management for the conduct of clinical trials. Under our arrangements with these contract research organizations, we design the protocols for the clinical trials and direct the contract research organizations in their efforts. We own all of the data associated with the clinical trials.

Recent Developments

On January 29, 2013, 872,133 Series A Warrants and 713,741 Series B Warrants were exercised using the cashless exercise provision of the Warrant Agreements, resulting in the issuance of 1,483,831 shares of our common stock.

On February 5, 2013, we announced that Dr. Joachim F. Wernicke, Ph.D, M.D. had accepted our offer to be the Company's Chief Medical Officer. Dr. Wernicke has over 30 years of experience in clinical development and regulatory matters. From 2004 until his retirement in 2012, Dr. Wernicke was part of the Global Patient Safety group at Eli Lilly and Company ("Lilly") where he was at various times responsible for Cymbalta, Strattera, Zyprexa, Symbyax, and Effient. He was also involved in the development and approval of Strattera and Cymbalta between 1999 and 2004 and clinical development and regulatory matters related to Prozac and other central nervous system drugs during his earlier tenure at Lilly from 1984 to 1990. During his career, he has also served as the VP of Clinical and Regulatory Affairs for Cyberonics, Inc. and as a consultant for various pharmaceutical, biotechnology, and medical device companies. Dr. Wernicke received a Ph.D. in biochemistry from U.C.L.A. in 1974, and an M.D. from U.C. Irvine in 1979, followed by a child neurology fellowship.

Available Information

Our Internet site (www.reprosrx.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 (the "SEC" or "Commission"), 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).

Item 1A. Risk Factors

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

Risks Relating to Our Business

Our ability to continue as a going concern may require that we raise additional funds no later than the first quarter of 2014, without which we may need to cease our business operations and begin liquidation proceedings.

Based upon the successful completion of our 2012 financings and our current expense and revenue assumptions, we anticipate that we will need to obtain additional financing no later than the first quarter of 2014. If our expenses are greater than expected or our clinical trials take longer than expected, we may be required to raise additional funds prior to that time. We will continue to explore various financing alternatives to address our liquidity needs. No assurance can be given that we will be successful in obtaining additional financing on acceptable terms or at all. We anticipate that if we are able to secure additional financing, that such financing will result in significant dilution of the ownership interests of our stockholders and may provide certain rights to the new investors senior to the rights of our current stockholders, including but not limited to, voting rights and rights to proceeds in the event of a sale or liquidation of the Company. We expect to continue to incur significant losses for the foreseeable future, and we may never achieve or sustain profitability. In the event that we are unable to obtain adequate financing to conduct operations, we may need to cease our business operations and begin liquidation proceedings. If we need to liquidate our assets, we would likely realize significantly less from them than the values at which they are carried on our financial statements. The funds resulting from the liquidation of our assets would be used first to pay off the debt owed to any secured and unsecured creditors before any funds would be available to pay our stockholders, and any shortfall in the proceeds would directly reduce the amounts available for distribution, if any, to our creditors and to our stockholders. In the event we were required to liquidate, it is highly unlikely that stockholders would receive any value for their shares.

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

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 clinical trials for Androxal® and Proellex®. Based on our current and planned clinical programs, we expect to need to raise additional capital no later than the first quarter of 2014 or earlier if our expenses are greater than anticipated. We will continue 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. In recent years, the general economic and capital market conditions in the United States have deteriorated significantly and have increased the cost of capital, and there is no certainty that a recovery in the capital and credit markets, enabling us to raise capital in an amount to sufficiently fund our long-term plans, will occur in 2013 or beyond. If these economic conditions continue or become worse, our future cost of equity or debt capital and access to the capital markets could be adversely affected. If we cannot raise adequate funds, 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.

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. To date, long-term safety and efficacy have not been demonstrated in clinical trials for any of our product candidates and, in fact, our product candidate Proellex® is currently on partial clinical hold with the FDA due to safety issues experienced in our earlier Phase 2 and Phase 3 clinical trials for endometriosis and uterine fibroids, respectively.

In addition, previous clinical trials for 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 Androxal® to treat testosterone deficiency. We will be required to demonstrate through larger-scale clinical trials that these product candidates are safe and effective for use in a diverse population before we can seek regulatory approvals for their commercial sale.

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 Androxal®, Proellex®, 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 Androxal® or Proellex®, we may not be able to generate sufficient revenues or raise the additional capital necessary 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, 2012, we had accumulated losses of $209.9 million, approximately $24.2 million in cash and cash equivalents, and our accounts payable and accrued expenses were approximately $3.8 million. On September 7, 2012, we completed a private placement of 2,145,636 shares of our common stock, which resulted in net proceeds to us, after deducting operating expenses, of $23 million. As a result we believe we have sufficient cash to continue our clinical trials into the first quarter of 2014.

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 our products, we expect our total operating losses to increase for at least the next few years. Our ability to achieve profitability will depend on, among other things, successfully completing the development of our products, obtaining regulatory approvals, establishing marketing, sales and manufacturing capabilities or collaborative arrangements with others that possess such capabilities, and raising sufficient funds to finance our activities. There can be no assurance that we will be able to achieve profitability or that profitability, if achieved, can be sustained.

Raising additional funds by issuing securities or through collaboration and licensing arrangements may cause dilution to our 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 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 Androxal®, Proellex®, 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®, and failure of the FDA to lift the partial clinical hold on Proellex®, or unfavorable results or decisions or negative perceptions regarding any of such clinical trials, could cause our stock price to decline significantly.

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 had only 21 full-time employees at December 31, 2012, including our President and Chief Executive Officer, Joseph S. Podolski. We are highly dependent on Mr. Podolski and our professional staff for the management of our company and the development of our technologies. Mr. Podolski has an employment agreement with us. There can be no assurance that any of these employees will remain with us through development of our current product candidates. The loss of the services of any of our employees 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 may enter into collaboration arrangements with strategic partners to develop and commercialize our product candidates. For our collaboration efforts to be successful, we must identify partners whose competencies complement ours. We must also successfully enter into collaboration agreements with them on terms

attractive to us and integrate and coordinate their resources and capabilities with our own. We may be unsuccessful in entering into collaboration agreements with acceptable partners or negotiating favorable terms in these agreements. In addition, we may face a disadvantage in seeking to enter into or negotiating collaborations with potential partners because other potential collaborators may have greater management and financial resources than we do. Also, we may be unsuccessful in integrating the resources or capabilities of these collaborators. In addition, our collaborators may prove difficult to work with or less skilled than we originally expected. If we are unsuccessful in our collaborative efforts, our ability to develop and market product candidates could be severely limited.

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.

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.

Risks Relating to Our Product Development Efforts

Changes in existing regulations and the adoption of new regulations may increase our costs and otherwise adversely affect our business, results of operations and financial condition.

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. Additional government regulation may be established that could prevent or delay regulatory approval of our product candidates or materially increase our costs. 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.

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 and our lack of sufficient capital, 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;
-

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.

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 adequate funding to continue clinical trials;
- 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;
- the timing of discussions and meetings with the FDA or other regulatory authorities regarding the scope or design of our clinical trials; and
- acceptability to the FDA of data obtained from clinical studies conducted in Europe or other non-United States jurisdictions.

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. In fact, the FDA placed Proellex® on clinical hold in summer 2009 due to liver toxicity data resulting from our clinical trials. Though the full clinical hold has been upgraded to a partial clinical hold, there can be no assurance that the partial hold will be lifted at any time.

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 Androxal® and Proellex®, 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 Androxal® and Proellex® are successfully completed, we will be able to submit an 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 Androxal® or Proellex®, 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 Androxal® or Proellex®, we may be unable to generate sufficient revenues to continue operations or attain profitability and our reputation in the industry and in the investment community would likely be damaged.

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 (“CROs”), and universities, in certain areas that are particularly relevant to our research and product development plans, such as for data management for the conduct of clinical trials. 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. 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, 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.

The risk of accidental contamination or injury resulting from our handling and disposing of hazardous materials and chemicals may expose us to litigation.

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 have a material adverse effect on us.

Risks Relating to Manufacturing Our Products

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

Currently, we do not have the ability internally to manufacture the product candidates that we need to conduct our clinical trials. We terminated our supply agreement with Gedeon Richter for the manufacturing of Proellex® due to the clinical hold imposed by the FDA in August 2009; however, we have a large supply of Proellex® currently available for our current and planned clinical trial efforts. In the event we require an additional supply of Proellex®, we believe that we have maintained a good relationship with Gedeon Richter and that an agreement could be reached with Gedeon Richter to provide such supply when and if needed, but we cannot assure you this will be the case.

We have a supply agreement with Diagnostic Chemical Limited, doing business as BioVectra, for the supply of the bulk active pharmaceutical ingredient used in Androxal®. This agreement runs through July of 2013, subject to automatic one year renewals and the ability of either party to terminate upon 12 months prior notice. 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. The Company believes that should an issue with BioVectra arise an alternative supplier could be identified, but we cannot assure you this will be the case.

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 Androxal®, Proellex®, 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.

Identification of previously unknown problems with respect to a product, manufacturer or facility may result in restrictions on the product, manufacturer or facility.

The FDA stringently applies regulatory standards for the manufacturing of our products. 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. Any of the foregoing could have a material adverse effect on us.

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. Future clinical trials of our product candidates, if any, will require increased quantities for future commercial sales 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.

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

Risks Relating to Product Commercialization

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. 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 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 Androxal® does not provide a treatment regime that is more beneficial than AndroGel®, the current standard of care for the treatment of testosterone deficiency, or otherwise provide patient benefit, it likely will not be accepted favorably by the market. If any products we may develop do not achieve market acceptance, then we will not generate sufficient revenue to achieve or maintain profitability.

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

- new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete;
- unforeseen complications arise with respect to use of our products; or
- sufficient third-party insurance coverage or reimbursement does not remain available.

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 controls. 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.

Our liability insurance may neither provide adequate coverage nor may it always be available on favorable terms or at all.

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

commercial liability insurance coverage for our clinical trials. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for any of our product candidates. However, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or for liabilities in excess of our insurance limits, our assets may not be sufficient to cover such claims and our business operations could be impaired.

We face significant competition from 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.

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 (which was acquired by Abbott Laboratories). Abbott 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®. Eli Lilly and Company also entered into a licensing agreement with a third party for a late stage topical testosterone treatment called Axiron®, which has recently become available in pharmacies. There can be no assurance that our product candidates will be more successful than competitive products. In addition, other potential competitors may be developing testosterone therapies similar to ours.

The 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, Abbott has recently licensed a Phase 3–ready molecule from Neurocrine Biosciences Inc. for the treatment of endometriosis. Gedeon Richter and Watson Pharmaceuticals have also entered into an exclusive license agreement to develop and market Esmya™ (an orally selective progesterone receptor modulator) in the U.S. and Canada.

Risks Relating to Our Intellectual Property

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. We requested re-examination of one of these patents by the U.S. Patent and Trademark Office ("PTO") based on prior art. The patent holder amended the claims in the re-examination proceedings, which led the PTO to determine that the amended claims were patentable in view of those publications under consideration and a re-examination certificate was issued. We subsequently filed a second request for re-examination by the PTO in light of a number of additional publications. The request was granted and all of the claims were finally rejected by the PTO in the re-examination. The patent holder appealed the rejections to the PTO Board of Patent Appeals and Interferences (the "PTO Board") which ultimately reversed the rejections of several dependent claims in view of those publications under consideration. The patent holder filed a Notice of Appeal to the Federal Circuit on September 28, 2010 contesting the rejections maintained by the PTO Board. A decision was rendered by the Federal Circuit on December 12, 2011, affirming the rejection of the appealed claims. We expect that a re-examination certificate will be issued confirming the patentability of the remaining claims; however, if such a re-examination certificate were to issue, we believe that our development of Androxal® would not infringe any of the remaining claims and that all of the remaining claims are invalid on various grounds including additional prior art publications. We also believe that the second of these two patents is invalid in view of published prior art not considered by the PTO. If necessary, we intend to vigorously defend any and all claims against the holder of such patents in a court of competent jurisdiction in order to develop Androxal® further. Adverse determinations in litigation proceedings could require us to seek licenses which may not be available on commercially reasonable terms, or at all, or subject us to significant liabilities, in which case we may not be able to successfully commercialize or out-license Androxal® until such patents expire or are otherwise no longer in force.

We licensed our rights to Proellex® from the NIH and our inability to fulfill our commitments and obligations under such license may result in forfeiture of our rights.

Our rights to Proellex® are licensed exclusively to us from the NIH under a license agreement. This license agreement contains numerous detailed performance obligations, with time sensitive dates for compliance, relating to clinical development and commercialization activities required by us or our designated third-party providers, as well as additional financial milestones and royalties. Failure to achieve the benchmarks specified in the commercial development plan attached to the license agreement or meet payment obligations could result in termination of the license agreement and the loss of our rights to develop and commercialize Proellex®. 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, the NIH will agree to revised objectives. The NIH also has the ability to terminate the agreement for an uncured material breach of the agreement, if we do not keep Proellex® reasonably available to the public after commercial launch or if we cannot reasonably satisfy unmet health and safety needs, among other reasons.

There can be no assurance 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 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 us 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 or warrants..

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 candidates, Androxal® and Proellex®, 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 issued patents and/or pending patent applications relating to Proellex® or Androxal®, or any patents that have been or may be issued to our licensor, such as the patent(s) and application(s) underlying our Proellex® compound, when issued, will be valid and enforceable;
- any patents will provide meaningful protection to us;
- others will not be able to design around the patents; or
- our patents will provide a competitive advantage or have commercial application.

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

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

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

proceedings, the cost and delay of such proceedings would most likely have a material adverse effect on our business.

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

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

We cannot protect our intellectual property rights throughout the world.

Filing, prosecuting, and defending patents on all of our drug discovery technologies and all of our potential drug candidates throughout the world would be prohibitively expensive. Competitors may use our technologies to develop their own drugs in jurisdictions where we have not obtained patent protection. These drugs may compete with our drugs, if any, and may not be covered by any of our patent claims or other intellectual property rights. The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. Many countries, including certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties (for example, the patent owner has failed to “work” the invention in that country or the third party has patented improvements). In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of the patent. Compulsory licensing of life-saving drugs is also becoming increasingly popular in developing countries either through direct legislation or international initiatives. Such compulsory licenses could be extended to include some of our drug candidates, which could limit our potential revenue opportunities. Moreover, the legal systems of certain countries, particularly certain developing countries, do not favor the aggressive enforcement of patents and other intellectual property protection, particularly those relating to biotechnology and/or pharmaceuticals, which makes it difficult for us to stop the infringement of our patents. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

Risks Related to our Common Stock and Warrants

The trading price of our common stock has been volatile and is likely to be volatile in the future.

The trading price of our common stock has been highly volatile. Since January 1, 2011 through March 8, 2013, the sale price of our stock price has fluctuated from a low of $2.37 to a high of $19.12. The market price for our common stock and warrants will be affected by a number of factors, including:

- the denial or delay of regulatory clearances or approvals of our drug candidates or receipt of regulatory approval of competing products;
- our ability to accomplish clinical, regulatory and other product development milestones;
- the ability of our product candidates, if they receive regulatory approval, to achieve market success;
- the performance of third-party manufacturers and suppliers;
- actual or anticipated variations in our results of operations or those of our competitors;
- developments with respect to patents and other intellectual property rights;
- sales of common stock or other securities by us or our stockholders in the future;

- additions or departures of key scientific or management personnel;

- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our products;

- trading volume of our common stock and warrants;

- investor perceptions about us and our industry;

- public reaction to our press releases, other public announcements and SEC and other filings;

- the failure of analysts to cover our common stock, or changes in analysts' estimates or recommendations;

- the failure by us to meet analysts' projections or guidance;

- general market conditions and other factors unrelated to our operating performance or the operating performance of our competitors; and

- the other factors described elsewhere in these "Risk Factors" or the section titled "Risk Factors" contained in our other public filings.

The stock prices of many companies in the biotechnology industry have experienced wide fluctuations that have often been unrelated to the operating performance of these companies. Following periods of volatility in the market price of a company's securities, securities class action litigation often has been initiated against a company. If any class action litigation is initiated against us, we may incur substantial costs and our management's attention may be diverted from our operations, which could significantly harm our business.

Our inability to comply with the listing requirements of the Nasdaq Capital Market could result in our common stock and/or warrants being delisted, which could affect their market price and liquidity and reduce our ability to raise capital.

We are required to meet certain qualitative and financial tests (including a minimum closing bid price of $1.00 per share for our common stock) to maintain the listing of our common stock and/or warrants on the Nasdaq Capital Market. If we do not maintain compliance with the continued listing requirements for the Nasdaq Capital Market

within specified periods and subject to permitted extensions, our common stock and/or warrants may be recommended for delisting (subject to any appeal we would file). If our common stock or warrants are delisted, it could be more difficult to buy or sell our common stock and/or our warrants and to obtain accurate quotations, and the price of our common stock and/or warrants could suffer a material decline. Delisting would also impair our ability to raise capital.

The market price of our common stock may fall below the exercise price of our Series B Warrants.

The Series B Warrants are exercisable at any time at or prior to 5:00 p.m. Eastern time on February 8, 2016. The market price of our common stock may fall below the exercise price for such warrants prior to their expiration. Any Series B Warrants not exercised by such date of expiration will expire and be worthless and we will be under no further obligation to the holders of such warrants.

Item 1B. Unresolved Staff Comments

None.

ITEM 2. Properties

We lease our current property under a lease agreement that expires in June 2015. 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

On March 1, 2010, we were served with a lawsuit where we were named as a co-defendant along with one of our clinical regulatory service providers ("CRO") relating to the Proellex® clinical trial study. The lawsuit was filed in the State of Tennessee, 30th Judicial District Chancery Court at Memphis by an investigator and claims that the CRO did not pay it amounts owing to it relating to the Proellex® study. We did not engage the investigator and under our agreement with the CRO, we believe the CRO is responsible for any such costs or damages regarding such lawsuit. Pursuant to a Settlement Agreement and Mutual Release entered into in October 2009, such CRO, on behalf of itself and its agents, released us from all claims which could be asserted by them against us. We believe such release covers the claims set forth in this lawsuit. The CRO failed to respond to the lawsuit, and a default judgment was entered against it in the amount of $172,901.29. We intend to vigorously defend any and all claims asserted by the investigator. An estimate of the possible costs or expenses to defend ourselves in this matter or risk of exposure under the litigation cannot be made at this time. See "Patents and Proprietary Information" in Item 1 for a description of

judicial and regulatory proceedings involving patent matters.

ITEM 4. MiNE SAFETY DISCLOSURES

Not applicable.

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 Capital Market under the symbol “RPRX”. The following table shows the high and low sale prices per share of our common stock as reported by the Nasdaq Stock Market during the periods presented. Prices per share of our common stock have been adjusted to reflect the 1-for-4 reverse split of our common stock that was effected on October 14, 2010.

	Price Range	
	High	Low
2011		
First Quarter	$6.85	$2.37
Second Quarter	6.49	4.52
Third Quarter	6.74	3.70
Fourth Quarter	5.48	3.34
2012		
First Quarter	$5.36	$3.73
Second Quarter	9.88	3.68
Third Quarter	16.37	7.82
Fourth Quarter	17.00	11.75
2013		
First Quarter (January 1st through March 8th)	$19.12	$9.51

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 8, 2013, the last sale price of our common stock, as reported by the Nasdaq Capital Market, was $10.16 per share. On March 8, 2013, there were approximately 160 holders of record and approximately 4,900 beneficial holders of our common stock.

Dividend Policy

General

We have never declared or paid cash dividends on our capital stock. We currently intend to retain our future earnings, if any, for use in our business and therefore do not anticipate paying cash 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.

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, 2015. 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, 2015, 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.

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, October 10, 2008 and September 9, 2010.

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.

	12/07	12/08	12/09	12/10	12/11	12/12
Repros Therapeutics Inc.	**100.00**	**112.88**	**8.55**	**8.15**	**12.93**	**42.25**
NASDAQ Composite	**100.00**	**59.03**	**82.25**	**97.32**	**98.63**	**110.78**
NASDAQ Pharmaceutical	**100.00**	**97.45**	**104.75**	**111.47**	**123.06**	**164.89**

ITEM 6. sELECTED CONSOLIDATED FINANCIAL DATA

The statement of operations data for the years ended December 31, 2012, 2011 and 2010, and the balance sheet data as of December 31, 2012 and 2011, 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, 2009 and 2008, and the balance sheet data as of December 31, 2010, 2009 and 2008 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 of America 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:
(In thousands, except per share data)

	2012	2011	2010	2009	2008
Revenues and Other Income					
Interest income	$3	$2	$—	$4	$433
Other income	—	—	421	547	—
Total revenues	3	2	421	551	433
Expenses:					
Research and development	13,343	8,682	2,904	23,062	22,575
General and administrative	4,827	3,811	2,285	4,723	3,060
Total expenses	18,170	12,493	5,189	27,785	25,635
Net loss	$(18,167)	$(12,491)	$(4,768)	$(27,234)	$(25,202)
Net loss per share – basic and diluted (1)(2)	$(1.18)	$(1.04)	$(0.59)	$(6.28)	$(7.54)
Shares used in loss per share calculation(2)	15,346	11,961	8,057	4,336	3,343

(1) See "Note 2. Summary of Significant Accounting Policies" of Notes to our Consolidated Financial Statements incorporated by reference into this prospectus for a description of the computation of loss per share.

(2) The basic and diluted net loss per share and shares used in loss per share calculation have been adjusted to reflect the one-for-four reverse stock split that was effected on October 14, 2010.

BALANCE SHEET DATA:
(In thousands)

	2012	2011	2010	2009	2008
Cash, cash equivalents and marketable securities	$24,212	$4,565	$2,957	$1,886	$19,470
Total assets	26,832	6,064	4,465	2,960	22,603
Deficit accumulated during the development stage	(209,902)	(191,735)	(179,244)	(174,476)	(147,242)

Total stockholders' equity	$23,034	$4,666	$	$3,167	$562	$15,614

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

The Company was organized on August 20, 1987. We are a development stage biopharmaceutical company focused on the development of new drugs to treat hormonal and reproductive system disorders.

Our primary product candidate, Androxal®, 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. Androxal® treats the underlying mechanism that causes secondary hypogonadism and restores normal testicular function.

We have completed a Phase 2B study of Androxal® in men with secondary hypogonadism, but naïve to testosterone treatment, at the FDA’s recommendation. We have since announced top line results of this study that Androxal® was generally well tolerated compared to placebo and there were no drug related serious adverse events that led to discontinuation. We met with the FDA in May 2012 to discuss the design of pivotal Phase 3 efficacy studies for Androxal® as well as the components of the overall drug development program required for a New Drug Application (“NDA”) submission. During this meeting, we agreed upon registration requirements for Androxal® oral therapy for the treatment of secondary hypogonadism. On July 9, 2012, we announced that we reached an agreement with the FDA for the design of the pivotal efficacy studies for Androxal® for the treatment of secondary hypogonadism. The pivotal studies are being conducted under a Special Protocol Assessment (“SPA”). Depending on study enrollment and the completion of other studies, we believe we may be able to submit an NDA by mid 2014.

Proellex®, our product candidate for female reproductive health, is a new chemical entity that acts as a selective blocker of the progesterone receptor and is being developed for the treatment of symptoms associated with uterine fibroids and endometriosis. We have conducted numerous studies with Proellex® dosing approximately 700 women with the drug. Up until the summer of 2009, all side effects exhibited in the studies were considered manageable and the benefit of Proellex® far outweighed the risk. However, in Phase 3 efficacy and larger Phase 3 safety studies in diverse populations, a small number of subjects exhibited serious adverse effects associated with elevated liver

enzymes. As a result of these findings, we elected to stop the trials and the FDA subsequently placed Proellex® on full clinical hold. All women that experienced elevated liver enzymes and returned for follow-up visits returned to baseline conditions with no overnight hospitalization necessary. An analysis of all the subjects that experienced such serious adverse effects showed that the effect only occurred in a small percentage of subjects that were exposed to the 50 mg dose of the drug for any period of time. Based on these findings, the Company petitioned the FDA to allow it to conduct a low dose study to demonstrate both safety and signals of efficacy in low oral doses of Proellex®, up to 12 mg administered per day. We completed the low dose escalating study in late 2011 and the results demonstrated no evidence of elevations of liver enzymes over baseline, suggesting these lower doses avoid the type of adverse events seen at much higher doses in earlier studies. On October 8, 2012, we announced that the FDA has agreed to a reclassification of the full clinical hold to a partial clinical hold on low dose oral Proellex® to allow us to conduct a Phase 2 study in the treatment of endometriosis. We initiated this study in November 2012 and we believe full enrollment will be achieved in the second quarter of 2013.

The FDA has accepted an Investigational New Drug Application (“IND”) for vaginally delivered Proellex® and, as a result, we commenced a Phase 2 vaginal administration study for uterine fibroids in the first quarter of 2012 and reported the final study results in January 2013. We have requested, and were granted, an end of Phase 2 meeting with the FDA, scheduled for the last half of May 2013, to discuss a Phase 3 study design for the vaginally delivered Proellex® for the treatment of uterine fribroids. Additionally, we have begun enrolling subjects who completed the Phase 2 study into a one year open label safety trial in order to begin collecting long term safety data which we expect the FDA to require in connection with the submission of an NDA.

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® has been on partial clinical hold in the U.S. since 1998, and no further development activities are planned.

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.

As with most biotechnology companies with drug candidates in development, the path to marketing approval by 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 Annual Report on 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. A clinical hold can also result in unpredictable delays and added costs. 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 on, among other factors, 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, 2012, we had accumulated losses of $209.9 million, approximately $24.2 million in cash and cash equivalents, and our accounts payable and accrued expenses were approximately $3.8 million. On February 1, 2012, we completed a registered direct offering to certain institutional investors, including certain existing shareholders, of 2,463,537 shares of our common stock at a price per share of $4.50. Net proceeds to us, after deducting the placement agent's fees and offering expenses, were approximately $10.3 million. On September 7, 2012, we completed a private placement of 2,145,636 shares of our common stock at a price per share of $11.00. Net proceeds to us, after deducting offering expenses, were approximately $23 million. We anticipate that our current liquidity will be sufficient to continue these planned studies into the first quarter of 2014; however, significant additional capital will be required for us to complete the development of our product candidates through NDA approval. We continue to explore potential additional financing alternatives (including corporate partnering opportunities) that would provide sufficient funds to enable us to continue to develop our two product candidates through NDA approval; however, there can be no assurance that we will be successful in raising any such additional funds on a timely basis or at all. The foregoing matters raise substantial doubt about our ability to continue as a going concern.

At December 31, 2012, we had 21 full-time employees who utilize the services of contract research organizations, contract manufacturers and various consultants to assist us in performing clinical and regulatory services for the clinical development of our products. We are substantially dependent on our various contract groups to adequately perform the activities required to obtain regulatory approval of our products.

The value of the tax asset associated with the December 31, 2012 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 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 on, among other things, 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.

Capitalized Patent Costs

The Company capitalizes the cost associated with building its patent library for its Androxal® and Proellex® products. As of December 31, 2012 and 2011, other assets consist of capitalized patent costs in the amount of $2.2 million and $1.4 million, 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 $152,000, $109,000 and $76,000 in 2012, 2011 and 2010, respectively.

Of the $2.2 million in capitalized patent costs at December 31, 2012, $1,642,000 related to Androxal® and $519,000 related to Proellex® patents.

We review capitalized patent and patent application 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.

Should the Company not continue development of either drug candidate or should the Company not continue as a going concern, the remaining capitalized patent costs may not be recoverable, which would result in charges to operating results in future periods.

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, 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.

Research &Development Expenses

Research and Development ("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 had one stock-based compensation plan at December 31, 2012, the 2011 Equity Incentive Plan. Accounting standards generally require 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. 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 net operating losses since inception and, therefore, have not been subject to federal income taxes. We have accumulated approximately $1.4 million of research and development tax credits. As of December 31, 2012, we had approximately $156.4 million of net operating loss ("NOL") carryforwards for federal income tax purposes. Additionally, approximately $13.9 million of NOLs, and approximately $814,000 of research and development tax credits, expired in 2012. Accounting standards require 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 net operating 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. Additionally, if the Company has an opportunity to use this NOL to off-set tax liabilities in the future, the use of this asset would be restricted based on Internal Revenue Service, state and local NOL use guidelines. The Company's public offerings completed on February 5, 2007, October 2, 2008, September 11, 2009, October 13, 2009, February 8, 2011, February 1, 2012, the sale and issuance of the ATM Shares, the issuance of unregistered shares as part of the settlement agreements we entered into with certain of our creditors since October of 2009 and the private placement of shares completed on September 7, 2012, may have created a change of ownership for Federal Income tax purposes. The Company has not completed 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.

Results of Operations

Comparison of Years Ended December 31, 2012 and 2011

Revenues and Other Income

Total revenues and other income increased 50% to $3,000 in 2012 as compared to $2,000 for 2011. This increase was primarily due to an increase of $1,000 in interest income due to higher cash balances.

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, Androxal® and Proellex®. Research and development expenses also include internal operating expenses relating to our general research and development activities. R&D expenses increased 54% or approximately $4.7 million to $13.3 million for the year ended 2012 as compared to $8.7 million in 2011. Our primary R&D expenses for 2012 and 2011 are shown in the following table (in thousands):

Research and Development	December 31, 2012	December 31, 2011	Variance	Change (%)
Androxal® clinical development	$ 8,516	$ 5,118	$ 3,398	66 %
Proellex® clinical development	1,776	1,008	768	76 %
Payroll and benefits	2,137	1,307	830	64 %
Operating and occupancy	914	1,249	(335)	(27)%
Total	$ 13,343	$ 8,682	$ 4,661	54 %

The increase in Androxal® clinical development expenses for the year ended 2012 as compared to 2011 was primarily due to the commencement of the Phase 3 studies in men with secondary hypogonadism, including two pivotal studies being conducted under an SPA, a six month open label safety study and a one year DEXA study. Clinical development expenses related to Proellex® increased due to the Phase 2 vaginal administration study for uterine

fibroids conducted in 2012.

To date through December 31, 2012 we have incurred approximately $28.4 million for the development of Androxal® and approximately $59 million for the development of Proellex®. These accumulated costs exclude any internal operating expenses.

Payroll and Benefits

R&D payroll and benefits expense for both 2012 and 2011, includes salaries, non-cash stock based compensation expense and fringe benefits and increased 64% or approximately $830,000 to $2.1 million for the year ended 2012 as compared to $1.3 million in 2011. This increase is primarily due to an increase in headcount. Included in payroll and benefit expense is a charge for non-cash stock based compensation expense of $880,000 for the year ended 2012 as compared to $540,000 in the year ended 2011.

Operating and Occupancy

R&D operating and occupancy decreased 27% or approximately $335,000 to approximately $914,000 for the year ended 2012 as compared to $1.2 million in 2011. This decrease is primarily due to a decrease in costs associated with our patent portfolio of approximately $242,000 and a reduction of $211,000 related to our product liability insurance premium, partially offset by an increase in consulting and other outside services of approximately $155,000 and an increase in amortization expense of $44,000 for the year ended 2012 as compared to 2011.

General and Administrative Expenses

General and administrative expenses (“G&A”) increased 27% or approximately $1.0 million to $4.8 million for 2012 as compared to $3.8 million in 2011. Our primary G&A expenses for 2012 and 2011 are shown in the following table (in thousands):

General and Administrative	December 31, 2012	December 31, 2011	Variance	Change (%)	
Payroll and benefits	$ 3,081	$ 2,364	$ 717	30	%
Operating and occupancy	1,746	1,447	299	21	%
Total	$ 4,827	$ 3,811	$ 1,016	27	%

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G&A payroll and benefits expense for both 2012 and 2011, includes salaries, non-cash stock based compensation expense and fringe benefits and increased 30% or approximately $717,000 to $3.1 million for the year ended 2012 as compared to $2.4 million in 2011. Included in payroll and benefit expense is a charge for non-cash stock based compensation expense of $1.9 million for the year ended 2012 as compared to $1.7 million in the year 2011. Additionally, salaries for the year ended 2012 were $1.1 million as compared to $528,000 for 2011. The increase in salaries of approximately $526,000 is primarily due to an increase in headcount and the discontinuation of the salary reduction program put in place in August 2009.

G&A operating and occupancy expense, which includes expenses to operate as a public company, increased 21% or approximately $299,000 to $1.7 million in 2012 as compared to $1.4 million in 2011. The increase is primarily due to an increase in professional services.

Comparison of Years Ended December 31, 2011 and 2010

Revenues and Other Income

Total revenues and other income decreased 100% to $2,000 in 2011 as compared to $421,000 for 2010. This decrease was primarily due to a decrease of $421,000 in other income. In 2010, the Company recognized $244,000 in other income related to grant revenue received from The Department of the Treasury for investment in a qualifying therapeutic discovery project under Section 48D of the Internal Revenue Code. Additionally, we recognized approximately $177,000 in non-cash other income from settlements with certain vendors in 2010.

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 Androxal® and Proellex®. Research and development expenses also include internal operating expenses relating to our general research and development activities. R&D expenses increased 199% or approximately $5.8 million to $8.7 million for the year ended 2011 as compared to $2.9 million in 2010. Our primary R&D expenses for 2011 and 2010 are shown in the following table (in thousands):

Research and Development	Variance

	December 31, 2011	December 31, 2010	Change	Change (%)
Androxal® clinical development	$ 5,118	$ 383	$ 4,735	1236 %
Proellex® clinical development	1,008	1,169	(161)	(14)%
Payroll and benefits	1,307	573	734	128 %
Operating and occupancy	1,249	779	470	60 %
Total	$ 8,682	$ 2,904	$ 5,778	199 %

The increase in R&D expenses for the year ended 2011 as compared to 2010 was primarily due to an increase in Androxal® clinical development expenses which included a Phase 2B study for men with secondary hypogonadism and a Phase 2 study as a potential treatment for improving glycemic control in hypogonadal men with Type 2 diabetes. Clinical development expenses for Proellex® decreased for the year ended 2011 as compared to 2010 due to the completion of the dose escalating study allowed by the FDA to demonstrate both safety and signals of efficacy in low oral doses of the drug.

Through December 31, 2011 we have incurred approximately $19.8 million for the development of Androxal® and approximately $57.3 million for the development of Proellex®. These accumulated costs exclude any internal operating expenses.

Payroll and Benefits

R&D payroll and benefits expense for both 2011 and 2010, includes salaries, non-cash stock based compensation expense and fringe benefits and increased 128% or approximately $734,000 to $1.3 million for the year ended 2011 as compared to $573,000 in 2010. This increase is primarily due to an increase in headcount and the discontinuation of the salary reduction program put in place in August 2009. Included in payroll and benefit expense is a charge for non-cash stock based compensation expense of $540,000 for the year ended 2011 as compared to $241,000 in the year 2010.

Operating and Occupancy

R&D operating and occupancy increased 60% or approximately $470,000 to approximately $1.2 million for the year ended 2011 as compared to $779,000 in 2010. This increase is primarily due to an increase in costs related to our patent portfolio of approximately $252,000 and an increase in travel expenses of approximately $147,000 for the year ended 2011 as compared to 2010.

General and Administrative Expenses

General and administrative expenses ("G&A") increased 67% or approximately $1.5 million to $3.8 million for 2011 as compared to $2.3 million in 2010. Our primary G&A expenses for 2011 and 2010 are shown in the following table (in thousands):

General and Administrative	December 31, 2011	December 31, 2010	Variance	Change (%)
Payroll and benefits	$ 2,364	$ 627	$ 1,737	277 %
Operating and occupancy	1,447	1,658	(211)	(13)%
Total	$ 3,811	$ 2,285	$ 1,526	67 %

G&A payroll and benefits expense for both 2011 and 2010, includes salaries, non-cash stock based compensation expense and fringe benefits and increased 277% or approximately $1.7 million to $2.4 million for the year ended 2011 as compared to $627,000 in 2010. Included in payroll and benefit expense is a charge for non-cash stock based compensation expense of $1.7 million for the year ended 2011 as compared to $314,000 in the year 2010. Stock based compensation for 2011 includes a charge of $759,000 in June 2011 associated with 210,000 stock option awards issued under the 2011 Equity Incentive Plan approved by the stockholders of the Company on June 1, 2011 which vested immediately upon stockholders' approval. Additionally, salaries for the year ended 2011 were $528,000 as compared to $264,000 for 2010. The increase in salaries of approximately $263,000 is primarily due to an increase in headcount and the discontinuation of the salary reduction program put in place in August 2009 for all salaried employees other than Mr. Podolski, the Company's President and CEO, and Mr. Podolski's salary was revised to a 25% reduction on January 1, 2011.

G&A operating and occupancy expense, which includes expenses to operate as a public company, decreased 13% or approximately $211,000 to $1.4 million in 2011 as compared to $1.7 million in 2010. The decrease is primarily due to a decrease in professional services.

Off-Balance Sheet Arrangements

As of December 31, 2012, we did not have any off-balance sheet arrangements except the operating lease relating to our facility.

Liquidity and Capital Resources

Since our inception, we have financed our operations primarily with proceeds from private placements and public offerings of equity securities and with funds received under collaborative agreements. We have experienced negative cash flows from operations since inception. 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 existing and projected accounts payable and commitments, we believe we will need to raise additional capital by the first quarter of 2014 in order to continue operations on a normal basis. If our expenses are greater than expected or our revenues are less than expected, we may be required to raise additional funds prior to that time. Historically we have secured additional cash resources through the sale of our equity securities; however, there can be no assurance that the Company will be able to raise sufficient capital in the future.

On February 12, 2010, we entered into an Equity Distribution Agreement (the “Equity Distribution Agreement”) with Ladenburg Thalmann & Co. Inc. (“Ladenburg”), pursuant to which we may issue and sell from time to time through Ladenburg, as sales agent and/or principal, shares of our common stock having an aggregate offering price of up to $10 million (the “ATM Shares”). We have no obligation to sell any ATM Shares under the Equity Distribution Agreement. For the year ended December 31, 2012, we sold an aggregate of 100 ATM Shares at a weighted average share price of $5.07, for proceeds of approximately $500, net of expenses. Cumulative through December 31, 2012, we have sold 2,775,476 ATM Shares at a weighted average share price of $2.67, for proceeds of approximately $7.4 million, net of expenses. As of the date of this filing, the registration statement on Form S-3 registering the sale of the ATM Shares to the public has lapsed and, as a result, no additional ATM Shares may be sold under the Equity Distribution Agreement until a registration statement related to such shares is effective.

On February 8, 2011, we completed an underwritten public offering of 690,000 units (including the exercise of the underwriter’s over-allotment option), consisting of an aggregate of 2,760,000 shares of our common stock, Series A Warrants to purchase 2,070,000 shares of our common stock and Series B Warrants to purchase 1,690,500 shares of our common stock, at a price per unit of $17.15. Each unit consisted of four shares of our common stock, Series A Warrants exercisable for three shares of our common stock at an exercise price of $0.01 per share and Series B Warrants exercisable for 2.45 shares of our common stock at an exercise price of $2.49 per share. Net proceeds to us, after the underwriting discount and offering expenses, were approximately $10.7 million. The fair value of the Series A and Series B Warrants was determined using a Black-Scholes model with the following assumptions: risk-free interest rate of 0.18%; no dividend yield; volatility of 131.66% and an expected term of six months. This resulted in a fair value of the Series A and Series B Warrants of approximately $5.4 million, which has been recorded in Additional Paid-In Capital on our Condensed Consolidated Balance Sheet. As of December 31, 2012, 320,730 shares of our common stock have been issued from the exercise of the Series A Warrants at $0.01 per share and 121,079 shares of our common stock have been issued from the exercise of the Series B Warrants at $2.49 per share. The Series A and B Warrants have a five year term from the date of issuance. The Series B Warrants are callable by the Company in the event that the Company’s stock trades at $8.00 or more for a period of 20 trading days over any consecutive 30 trading day period. As of the date of this filing, our common stock has reached this price threshold, however, we have not yet required the exercise of the Series B Warrants pursuant to this provision. The Series A and B Warrants are also exercisable on a cashless basis. In addition, in no event may the Warrants be exercised if the holder would own 20% or more of the outstanding shares of the Company’s common stock following the exercise.

On February 1, 2012, we completed a registered direct offering to certain institutional investors, including certain existing shareholders, of 2,463,537 shares of our common stock at a price per share of $4.50. Net proceeds to us, after deducting the placement agent's fees and offering expenses, were approximately $10.3 million.

On September 7, 2012, we completed a private placement of 2,145,636 shares of our common stock at a price per share of $11.00. Net proceeds to us, after deducting offering expenses, were approximately $23 million. The private placement shares may be resold pursuant to our shelf registration statement on Form S-3, as amended (File No. 333-184159).

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 $24.2 million as of December 31, 2012 as compared to $4.6 million as of December 31, 2011. Additionally, we had accounts payable and accrued expenses of $3.8 million as of December 31, 2012 as compared to $1.4 million as of December 31, 2011.

Net cash of approximately $13.5 million, $9.8 million and $5.0 million was used in operating activities during 2012, 2011 and 2010, respectively. The major use of cash for operating activities during 2012 was to fund our clinical development programs and associated administrative costs. Cash used in investing activities was $608,000, $335,000 and $371,000 during 2012, 2011and 2010, respectively. The major use of cash for investing activities during 2012 was primarily for capitalized patent and patent application costs for Androxal® and Proellex®. Cash provided by financing activities was $33.8 million, $11.7 million and $6.4 million during 2012, 2011 and 2010, respectively. Cash provided by financing activities during 2012 was primarily due to the registered direct offering of 2,463,537 shares of our common stock at a price per share of $4.50 completed on February 1, 2012 and the private placement of 2,145,636 shares of our common stock at a price per share of $11.00 completed on September 7, 2012.

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. To satisfy our capital requirements, we are exploring ways to raise additional funds by the first quarter of 2014. 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, we anticipate that such financing will result in significant dilution of the ownership interests of our current stockholders and may provide certain rights to the new investors senior to the rights of our current stockholders, including but not limited to voting rights and rights to proceeds in the event of a sale or liquidation of the Company. The uncertainties relating to the foregoing matters raise substantial doubt about our ability to continue

as a going concern.

Contractual Obligations and Commercial Commitments

The Company leases laboratory and office space pursuant to leases accounted for as operating leases. The lease for the Company's laboratory and office space expires in June 2015. Rental expense for the years ended December 31, 2012, 2011 and 2010, was approximately $76,000, $68,000 and $63,000, respectively. Future minimum lease payments under non-cancelable leases with original terms in excess of one year as of December 31, 2012, are as follows (in thousands):

2013	52
2014	53
2015	27
Total	$132

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk. We had cash and cash equivalents of approximately $24.2 million as of December 31, 2012 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 SEC, pursuant to the Securities Exchange Act of 1934 (the "Exchange Act") is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC and that such information is accumulated and communicated to our management, including our Chief Executive Officer (CEO) and Principal Financial Officer (PFO), as appropriate, to allow timely decisions regarding required disclosures.

Management, with the participation of our CEO and PFO, 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 PFO 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 PFO, as appropriate, to allow timely decisions regarding required disclosures.

Management's Report on Internal Control Over Financial Reporting

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

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

Based on management's evaluation, management has concluded that internal control over financial reporting was effective as of December 31, 2012.

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, 2012, 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, 2012 that have materially affected, or is reasonable likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

Not applicable.

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 2013 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, 2012.

ITEM 11. Executive Compensation

The information required by this item is hereby incorporated by reference from the information in our proxy statement for our 2013 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, 2012.

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 2013 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, 2012.

ITEM 13. Certain Relationships 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 2013 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, 2012.

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 2013 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, 2012.

PART IV

ITEM 15. Exhibits and Financial Statement Schedules

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

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 SEC. Upon request to the Company and payment of a reasonable fee, copies of the individual exhibits will be furnished.

Exhibit Number	Identification Of Exhibit
3.1(a)	Restated Certificate of Incorporation. Exhibit 3.3 to the Company's Registration Statement on Form SB-2 (No. 33-57728-FW), as amended ("Registration Statement"), is incorporated herein by reference.
3.1(b)	Certificate of Amendment to the Company's Restated Certificate of Incorporation, dated as of May 2, 2006. Exhibit 3.1 to the Company's Current Report on Form 8-K as filed with the Commission on May 2, 2006 is incorporated herein by reference.
3.1(c)	

	Certificate of Designation of Series One Junior Participating Preferred Stock dated September 2, 1999. Exhibit A to Exhibit 4.1 to the Company's Registration Statement on Form 8-A as filed with the Commission on September 3, 1999 (the "Rights Plan Registration Statement"), is incorporated herein by reference.
3.1(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.
3.1(e)	Certificate of Amendment to Restated Certificate of Incorporation, dated as of November 18, 2009. Exhibit 3.1(e) to the Company's Current Report on Form 8-K dated November 19, 2009 is incorporated herein by reference.
3.1(f)	Certificate of Amendment to Restated Certificate of Incorporation, dated October 14, 2010. Exhibit 3.1(f) to the Company's Current Report on Form 8-K dated October 14, 2010 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, 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	Sixth Amendment to Rights Agreement, dated as of September 9, 2010, between the Company and Computershare Trust Company, Inc. (as successor in interest to Computershare Investor Services, LLC). Exhibit 4.7 to the Company’s Current Report on Form 8-K as filed with the Commission on September 10, 2010 is incorporated herein by reference.
4.9	Form of Rights Certificate. Exhibit B to Exhibit 4.1 to the Rights Plan Registration Statement is incorporated herein by reference.
4.10	Form of Series A Warrant Certificate. Exhibit 4.10 to the Company’s Registration Statement on Form S-1/A (No. 333-171196) as filed with the Commission on February 2, 2011 is incorporated herein by reference.
4.11	Form of Series B Warrant Certificate. Exhibit 4.11 to the Company’s Registration Statement on Form S-1/A (No. 333-171196) as filed with the Commission on February 2, 2011 is incorporated herein by reference
4.12	Series A Warrant Agreement dated February 8, 2011 by and among the Company and Computershare Inc. and its wholly-owned subsidiary, Computershare Trust Company, N.A. Exhibit 4.1 to the Company’s Current Report on Form 8-K as filed with the Commission on February 9, 2011 is incorporated herein by reference.
4.13	Series B Warrant Agreement dated February 8, 2011 by and among the Company and Computershare Inc. and its wholly-owned subsidiary, Computershare Trust Company, N.A. Exhibit 4.2 to the Company’s Current Report on Form 8-K as filed with the Commission on February 9, 2011 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 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+	Third Amendment to Employment Agreement dated effective March 11, 2009, between the Company and Joseph S. Podolski. Exhibit 10.1 to the Company’s Current Report on Form 8-K as filed with the Commission on March 17, 2009 is incorporated herein by reference.
10.12+	Fourth Amendment to Employment Agreement effective March 10, 2010 between the Company and Joseph S. Podolski. Exhibit 10.1 to the Company’s Current Report on Form 8-K as filed with the Commission on March 11, 2010 is incorporated herein by reference.
10.13	Lease Agreement dated May 11, 2004 between the Company and Sealy Woodlands, L.P. Exhibit 10.14 to the Company's Annual Report on Form 10-K for the year ended December 31, 2004 is incorporated herein by reference.
10.14	Amendment to Lease Agreement between the Company and Sealy Woodlands, L.P., dated May 17, 2006. Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2006 is incorporated herein by reference.
10.15	Second Amendment to Lease, effective as of July 1, 2010, between the Company and Columbia Texas 2408 Timberloch Industrial, L.P. Exhibit 10.1 to the Company’s Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2010 is incorporated herein by reference.
10.16++	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.
10.17++	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.
10.18	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++	Sixth Amendment to PHS Patent License Agreement, as amended, dated July 7, 2009 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/A as filed with the Commission on December 22, 2009 is incorporated herein by reference.
10.20++	Seventh Amendment to PHS Patent License Agreement, as amended, dated October 28, 2009 between the Company and certain agencies of the United States Public Health Service within the Department of Health and Human Services. Exhibit 10.21 to the Company’s Annual Report on Form 10-K as filed with the Commission on March 15, 2010 is incorporated herein by reference.
10.21	Form of Indemnification Agreement entered into between the Company and each of its directors. Exhibit 10.1 to the Company’s Current Report on Form 8-K as filed with the Commission on May 20, 2009 is incorporated herein by reference.

10.22	Equity Distribution Agreement dated February 12, 2010 between the Company and Ladenburg Thalmann & Co. Inc. Exhibit 10.1 to the Company's Current Report on Form 8-K as filed with the Commission on February 19, 2010 is incorporated herein by reference.
10.23+	Employment Agreement dated August 1, 2011 by and between the Company and Katherine A. Anderson. Exhibit 10.1 to the Company's Current Report on Form 8-K as filed with the Commission on August 4, 2011 is incorporated herein by reference.
10.24+	2011 Equity Incentive Plan (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-8 (No. 333-175641) as filed with the Commission on July 18, 2011).
10.25+	Fifth Amendment to Employment Agreement dated effective December 30, 2011 by and between the Company and Joseph S. Podolski. Exhibit 10.1 to the Company's Current Report on Form 8-K as filed with the Commission on January 4, 2012 is incorporated herein by reference.
10.26	Placement Agency Agreement dated January 26, 2012 by and between the Company and Ladenburg Thalmann & Co. Inc. Exhibit 1.1 to the Company's Current Report on Form 8-K as filed with the Commission on January 27, 2012 is incorporated herein by reference.
10.27	Form of Subscription Agreement between the Company and the investors identified on the signature pages thereto. Exhibit 10.1 to the Company's Current Report on Form 8-K as filed with the Commission on January 27, 2012 is incorporated herein by reference.
10.28	Securities Purchase Agreement dated August 31, 2012 by and among the Company and certain institutional investors. Exhibit 10.1 to the Company's Current Report on Form 8-K as filed with the Commission on September 12, 2012 is incorporated herein by reference.
10.29	Registration Rights Agreement dated August 31, 2012 by and among the Company and certain institutional investors. Exhibit 10.2 to the Company's Current Report on Form 8-K as filed with the Commission on September 12, 2012 is incorporated herein by reference.
10.30	Agreement dated September 4, 2012 by and between the Company and Trout Capital LLC. Exhibit 10.3 to the Company's Current Report on Form 8-K as filed with the Commission on September 12, 2012 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 (Principal Financial Officer)
32.1*	Certification Furnished Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Chief Executive Officer)
32.2*	Certification Furnished Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Principal Financial Officer)

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*Filed herewith.

+Management contract or compensatory plan.

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

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.

Dated: March 18, 2013 By: /s/ Joseph S. Podolski
Joseph S. Podolski
President and Chief Executive Officer

Signature	Title	Date
/s/ Joseph S. Podolski Joseph S. Podolski	President, Chief Executive Officer and Director (Principal Executive Officer)	March 18, 2013
/s/ Katherine A. Anderson Katherine A. Anderson	Chief Financial Officer and Secretary (Principal Financial Officer and Principal Accounting Officer)	March 18, 2013
/s/ Nola Masterson Nola Masterson	Chair of the Board	March 18, 2013
/s/ Daniel F. Cain Daniel F. Cain	Director	March 18, 2013
/s/ Jaye Thompson Jaye Thompson, Ph.D.	Director	March 18, 2013

/s/ Michael Wyllie	Director	March 18, 2013
Michael Wyllie, Ph.D.		

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 as of December 31, 2012 and 2011, the related consolidated statements of operations and cash flows for each of the three years in the period ended December 31, 2012, and the statements of stockholders' equity for each of the ten years in the period ended December 31, 2012 present fairly, in all material respects, the financial position of Repros Therapeutics Inc. and subsidiary, a development stage company, at December 31, 2012 and 2011, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2012, and cumulatively for the period January 1, 2002 through December 31, 2012 (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, 2012, 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 (which was an integrated audit in 2012). 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, projects it will need to raise additional capital and there can be no assurance that the Company will be successful in raising additional funds on a timely basis or at all. The foregoing 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 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 18, 2013

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

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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

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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

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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

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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

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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

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REPROS THERAPEUTICS INC. AND SUBSIDIARY
(A development stage company)

CONSOLIDATED BALANCE SHEETS
(in thousands except share and per share amounts)

	December 31, 2012	December 31, 2011
ASSETS		
Current Assets		
Cash and cash equivalents	$24,212	$4,565
Prepaid expenses and other current assets	406	99
Total current assets	24,618	4,664
Fixed Assets, net	53	15
Other Assets, net	2,161	1,385
Total assets	$26,832	$6,064
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Accounts payable	$3,240	$1,145
Accrued expenses	558	253
Total current liabilities	3,798	1,398
Commitments and Contingencies (note 10)		
Stockholders' Equity		
Preferred Stock, $.001 par value, 5,000,000 shares authorized, none issued and outstanding	-	-
Common Stock, $.001 par value, 75,000,000 shares authorized, 17,272,505 and 12,470,694 shares issued, respectively; 17,160,155 and 12,358,344 shares outstanding, respectively	17	12
Additional paid-in capital	234,299	197,769
Cost of treasury stock, 112,350 shares	(1,380)	(1,380)
Deficit accumulated during the development stage	(209,902)	(191,735)
Total stockholders' equity	23,034	4,666
Total liabilities and stockholders' equity	$26,832	$6,064

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

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REPROS THERAPEUTICS INC. AND SUBSIDIARY
(A development stage company)

CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands except per share amounts)

	For the Year Ended December 31,			From Inception (August 20, 1987) through December 31,
	2012	2011	2010	2012 (unaudited)
Revenues and other income				
Licensing fees	$-	$-	$-	$28,755
Product royalties	-	-	-	627
Research and development grants	-	-	-	1,219
Interest income	3	2	-	16,302
Gain on disposal of fixed assets	-	-	-	102
Other income	-	-	421	1,003
Total revenues and other income	3	2	421	48,008
Expenses				
Research and development	13,343	8,682	2,904	195,259
General and administrative	4,827	3,811	2,285	52,920
Other expense	-	-	-	388
Total expenses	18,170	12,493	5,189	248,567
Loss from continuing operations	(18,167)	(12,491)	(4,768)	(200,559)
Loss from discontinued operations	-	-	-	(1,828)
Gain on disposal of discontinued operations	-	-	-	939
Net loss before cumulative effect of changes in accounting principles	(18,167)	(12,491)	(4,768)	(201,448)
Cumulative effect of changes in accounting principles	-	-	-	(8,454)
Net loss	$(18,167)	$(12,491)	$(4,768)	$(209,902)
Loss per share - basic and diluted	$(1.18)	$(1.04)	$(0.59)	
Shares used in loss per share calculation:				
Basic	15,346	11,961	8,057	
Diluted	15,346	11,961	8,057	

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

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	Deferred	Treasury Stock		Deficit Accumulated During the Development	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Compensation	Shares	Amount	Stage	Equity
Exchange of common stock ($.016 per share) for technology rights and services from founding stockholders	-	$ -	61,342	$ -	$ 1	$ -	-	$ -	$ -	$ 1
Net Loss	-	-	-	-	-	-	-	-	(28)	(28)
BALANCE AT DECEMBER 31, 1987 (unaudited)	-	-	61,342	-	1	-	-	-	(28)	(27)
Net Loss	-	-	-	-	-	-	-	-	(327)	(327)
BALANCE AT DECEMBER 31, 1988 (unaudited)	-	-	61,342	-	1	-	-	-	(355)	(354)
Proceeds from issuance of common stock	-	-	16,358	-	3	-	-	-	-	3
Net Loss	-	-	-	-	-	-	-	-	(967)	(967)
BALANCE AT DECEMBER 31, 1989 (unaudited)	-	-	77,700	-	4	-	-	-	(1,322)	(1,318)
Proceeds from issuance of common stock	-	-	117	-	-	-	-	-	-	-
Net Loss	-	-	-	-	-	-	-	-	(1,426)	(1,426)
BALANCE AT DECEMBER 31, 1990 (unaudited)	-	-	77,816	-	4	-	-	-	(2,748)	(2,744)
Net Loss	-	-	-	-	-	-	-	-	(1,820)	(1,820)
BALANCE AT DECEMBER 31, 1991 (unaudited)	-	-	77,816	-	4	-	-	-	(4,568)	(4,564)
Conversion of 391,305 shares of Series C preferred stock into common stock	-	-	22,861	-	360	-	-	-	-	360
Purchase of retirement of common stock	-	-	(5,889)	-	(1)	-	-	-	-	(1)
Proceeds from issuance of common stock	-	-	4,236	-	7	-	-	-	-	7
Net Loss	-	-	-	-	-	-	-	-	(1,583)	(1,583)
	-	-	99,024	-	370	-	-	-	(6,151)	(5,781)

BALANCE AT DECEMBER 31, 1992 (unaudited)										
Issuance of common stock for cash, April 1, 1993, and May 12, 1993 ($22.00 per share), net of offering costs of $1,403	-	-	383,749	-	7,039	-	-	-	-	7,039
Issuance of common stock for cash and license agreement, December 9, 1993 ($41.68 per share), net of offering costs of $47	-	-	59,983	-	2,453	-	-	-	-	2,453
Conversion of Series A preferred stock to common stock	-	-	44,984	-	600	-	-	-	-	600
Conversion of Series B preferred stock to common stock	-	-	24,003	-	378	-	-	-	-	378
Conversion of Series C preferred stock to common stock	-	-	219,078	-	3,444	-	-	-	-	3,444
Conversion of Series D preferred stock to common stock	-	-	70,062	-	600	-	-	-	-	600
Conversion of bridge loan to common stock	-	-	16,000	-	256	-	-	-	-	256
Net Loss	-	-	-	-	-	-	-	-	(2,532)	(2,532)

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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	Deferred	Treasury Stock		Deficit Accumulated During the Development	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Compensation	Shares	Amount	Stage	Equity
BALANCE AT DECEMBER 31, 1993 (unaudited)	-	$ -	916,884	$ -	$ 15,140	$ -	-	$ -	$ (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 ($15.76 per share)	-	-	9,906	-	156	-	-	-	-	156
Issuance of common stock for purchase of FTI, October 13, 1994	-	-	27,778	-	1,567	-	-	-	-	1,567
Net loss	-	-	-	-	-	-	-	-	(3,970)	(3,970)
BALANCE AT DECEMBER 31, 1994	-	-	954,567	-	17,051	(150)	-	-	(12,653)	4,248
Amortization of deferred compensation	-	-	-	-	-	37	-	-	-	37
Exercise of options to purchase common stock for cash, January and April 1995 ($.40 to $24.52 per share)	-	-	1,136	-	14	-	-	-	-	14
Issuance of common stock for cash and a financing										