

REPOS THERAPEUTICS INC.

Form 10-K

March 15, 2010

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

Form 10-K

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

For the fiscal year ended December 31, 2009

or

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

For the transition period from

to
Commission File No. 001-15281

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

Delaware
(State or other jurisdiction of
incorporation or organization)

76-0233274
(IRS Employer
Identification No.)

2408 Timberloch Place, Suite B-7
The Woodlands, Texas
(Address of principal executive offices)

77380
(Zip Code)

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

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

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

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

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

Yes ☐ No ☒

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

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

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

Large accelerated filer "

Accelerated filer x

Non-accelerated filer "

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

The aggregate market value of the voting stock held by non-affiliates of the registrant was approximately \$69,725,000 as of June 30, 2009, the last business day of the registrant's most recently completed second fiscal quarter, based on the closing sales price of the registrant's common stock on the Nasdaq Global Market on such date of \$7.19 per share. For purposes of the preceding sentence only, all directors, executive officers and beneficial owners of ten percent or more of the shares of the registrant's common stock are assumed to be affiliates.

As of March 6, 2010, there were 26,011,054 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 2010 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, 2009, are incorporated by reference into Part III of this Form 10-K.

REPROS THERAPEUTICS INC
2009 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

Repos Therapeutics Inc. ("the Company", "RPRX," "Repos", or "we," "us" or "our") was organized on August 20, 1987. We are a development stage biopharmaceutical company focused on the development of oral small molecule drugs for major unmet medical needs. As of December 31, 2009, we had accumulated losses of \$174.5 million, approximately \$1.9 million in cash and cash equivalents, and our accounts payable and accrued expenses were approximately \$2.4 million. The amount of cash on hand is not sufficient to fund our future clinical trials of Androxal®, complete all necessary activities relating to the suspension of our clinical trial program for Proellex®, and pay our accounts payable and accrued expenses as well as our normal corporate overhead and expenses. The foregoing and other matters raise substantial doubt about our ability to continue as a going concern. We continue to explore potential additional financing alternatives that may allow us to maintain our current reduced level of operations; however, there can be no assurance that we will be successful in raising any such additional funds on a timely basis or at all. Significant additional capital will be required for us to continue development of either of our product candidates.

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

Androxal® (male reproductive health):

- Completed Phase 2b proof-of-concept trial in men being treated for low testosterone levels who want to improve or maintain their fertility and/or sperm number and function; and
- Our Investigational New Drug Application, or IND, for the study of oral Androxal® in the treatment of hypogonadal men with type 2 diabetes was accepted by the FDA and, thus, we may initiate a Phase 2a trial.

Proellex® (female reproductive health): All ongoing clinical trial activities for Proellex® have been put on hold by the FDA.

Any further development efforts for either of our product candidates is dependent on our ability to raise additional capital. We also continue to maintain our patent portfolio of our phentolamine-based products for the treatment of sexual dysfunction and try to create value from these assets in various ways which includes product out-licensing.

Androxal®

Product Overview

Our primary product candidate, Androxal® (the trans isomer of clomiphene), is a single isomer of clomiphene citrate and is an orally active proprietary small molecule compound.

We are developing Androxal® for men of reproductive age with low testosterone levels who want to improve or maintain their fertility and/or sperm function while being treated for low testosterone. In addition, we submitted a new IND to the Division of Metabolic and Endocrine Products, or DMEP, for the investigation of Androxal® as a potential treatment for type 2 diabetes. On February 1, 2010, we received confirmation from the DMEP that our new IND was accepted and, as a result, we may initiate a Phase 2a trial. This new indication replaces our previously announced plan to develop Androxal® in men with adult-onset idiopathic hypogonadotropic hypogonadism, or

AIHH, with concomitant plasma glucose and lipid elevations, all of which are components of Metabolic Syndrome.

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

We believe Androxal® may have advantages over current therapies for the treatment of low testosterone due to secondary hypogonadism because it is designed as an oral therapy that acts centrally to restore testicular function and hence normal testosterone in the body, as compared to currently approved products that simply replace diminished testosterone either through injections, nasal spray or the application of a gel or cream containing testosterone over a percentage of body area.

We believe Androxal® will be superior to the existing administration of exogenous testosterone products used to normalize testosterone as only Androxal® has the property of restoring both LH and FSH levels. LH and FSH are the pituitary hormones that stimulate testicular testosterone and sperm production, respectively.

Testosterone is an important male hormone. Testosterone deficiency in men is linked to several negative physical and mental conditions, including loss of muscle tone, reduced sexual desire, and deterioration of memory and certain other cognitive functions. Testosterone production normally decreases as men age, sometimes leading to testosterone deficiency. According to the Urology Channel, recent estimates show that approximately 13 million men in the United States experience testosterone deficiency. The leading therapy is AndroGel®, a commercially available testosterone replacement cream marketed by Solvay Pharmaceuticals for the treatment of low testosterone, which 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, caused by failure of the pituitary to provide appropriate hormone signaling to the testes, which we believe causes testosterone levels to drop to the point where pituitary secretions fall under the influence of estrogen. In this state, we also believe that estrogen further suppresses the testicular stimulation from the pituitary. These men are readily distinguished from those that have primary testicular failure via assessment of the levels of secretions of pituitary hormones (i.e., men with primary testicular failure experience elevated secretions of pituitary hormones). Secondary hypogonadism is not relegated only to older men although the condition becomes more prevalent as men age.

Androxal® is considered a new chemical entity by the FDA which means that the compound will be required to undergo the full regulatory approval process. We must still meet additional clinical requirements including pre-clinical, Phase 1, Phase 2, pivotal Phase 3 trials and long-term Open Label Safety Studies as well as other requirements. Although Androxal® is considered a new chemical entity for purposes of requirements for approval, it is closely related chemically to the drug, Clomid®, which is approved for use in women to treat certain infertility disorders. The FDA has indicated that testicular tumors, gynecomastia and adverse ophthalmologic events, which have been reported in males taking Clomid®, are potential risks that should be included in informed consent forms for our Androxal® clinical trials. We do not believe that Androxal® will present with the same adverse events given its accelerated half-life in the human body as compared to Clomid®. In our preclinical studies and our clinical trials to date, we have observed no evidence of any of these events except for certain ophthalmologic events in our preclinical dog study at doses significantly higher than those administered in the clinical trials.

All clinical trial results are subject to review by the FDA, and the FDA may disagree with our conclusions about safety and efficacy. We caution that the results discussed herein are based on data from non-pivotal trials and that our Phase 2 trials, pivotal Phase 3 and long-term Open Label Safety Trial data may not agree with these results which will be based upon significantly larger and more diverse patient populations treated for longer periods of time.

Secondary Hypogonadism with Fertility Maintenance/Improvement

During the second quarter of 2008, we initiated a 24-patient Phase 2b proof-of-concept clinical trial (ZA-201) for a new indication in which we are monitoring the effects of Androxal® on male fertility and testicular function in patients being treated for low testosterone as compared to Testim®, a popular marketed topical testosterone medication. On October 6, 2009 we announced that Androxal® was able to maintain sperm counts in men being treated for their low testosterone levels. Testim® resulted in suppressed sperm levels while men were being treated with that topical gel. We requested a meeting with the FDA to discuss such results. In correspondence leading up to such meeting, the FDA stated that it could not agree with such proposed indication for Androxal® at that time because the patient population had not been adequately defined and that it was not aware of certain data to support our position. On January 25, 2010, we participated in a teleconference with the FDA relating to the future clinical path for Androxal®. During such teleconference, the FDA requested that we (i) propose a label that better defines the

population of individuals for whom we believe will benefit from the use of Androxal® and (ii) conduct a literature review of the incidence of infertility associated with the use of exogenous testosterone as supportive of our data. The FDA suggested that if it finds the submission appropriate, no additional clarifying meeting regarding this indication for Androxal® may be required. On February 8, 2010, we announced that we submitted the requested information to the FDA and we are currently awaiting the FDA's response to such submissions. Given that there is currently an acceptable treatment regimen for men with low testosterone, there is significant uncertainty as to whether or not an additional approach such as Androxal® would be approved by the FDA or accepted in the market. At this time it is too early in the clinical development process to estimate when or even if an NDA for Androxal® will be submitted for this indication.

Type 2 Diabetes

In April 2008, we submitted a White Paper, based on the results from a previously conducted non-pivotal Phase 2 clinical trial (ZA-003) with Androxal® for the treatment of testosterone deficiency due to secondary hypogonadism, to the Division of Reproductive and Urology Products. The data we believe demonstrated that in subjects with a serum glucose of greater than or equal to 105mg/dL, there was a statistically significant reduction in fasting serum glucose and a higher response rate to treatment in the Androxal®-group than the placebo or Androgel® groups. In November 2008, after the FDA reviewed this paper we received guidance from them suggesting that we open a new IND with the Division of Metabolic and Endocrine Products, or DMEP, for the investigation of Androxal® as a potential treatment for type 2 diabetes in mellitus. In December 2009, we submitted a new IND to the DMEP for the investigation of Androxal® for such purpose. On February 1, 2010, we received confirmation from the DMEP that our new IND was accepted and, as a result, we may initiate a Phase 2a trial. This new indication replaces our previously announced plan to develop Androxal® in men with adult-onset idiopathic hypogonadotropic hypogonadism, or AIHH, with concomitant plasma glucose and lipid elevations, all of which are components of Metabolic Syndrome.

Proellex®

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. However, as a result of the recent liver toxicity exhibited by Proellex® in our previous Phase 2 and 3 clinical trials to endometriosis and uterine fibroids, respectively, all ongoing clinical trial activities have been put on hold by the FDA. There is currently no FDA-approved orally administered drug treatment for the long-term treatment of uterine fibroids or endometriosis.

Our estimates regarding the timing of our Proellex® clinical development program are completely on hold at this time in light of the FDA clinical hold and our recent discontinuation of ongoing clinical trials. In addition, any future development efforts are totally dependent on our ability to raise sufficient capital or find an appropriate partner to proceed and on decisions by the FDA regarding the current clinical hold on Proellex® clinical trials. If the FDA were to lift the clinical hold on Proellex®, and if the FDA requires a lower dosage of Proellex® to be used for future clinical trials, we would be required to commence Phase 2 studies again with the required lower dosage, thereby resulting in extensive additional costs and delays. The length of time required to complete Phase 1, Phase 2 and Phase 3 clinical trials and long-term Open Label Safety Trials may vary substantially according to factors relating to the particular trial, such as the type and intended use of the drug candidate, the clinical, trial design and the ability to enroll suitable patients. We have also, in the past, had difficulty recruiting patients into our Proellex® clinical trials primarily due to the various test procedures that are required, including multiple endometrial biopsies. Recruiting patients would likely be even more difficult due to the recent liver toxicity exhibited by Proellex®.

Other Products

We continue limited out-licensing efforts for our phentolamine-based product candidates, including VASOMAX®, which had previously been approved for marketing in several countries in Latin America for the treatment of male erectile dysfunction under the brand name, Z-Max. VASOMAX is currently on partial clinical hold in the U.S.

Business Strategy

Provided we are able to obtain sufficient funds to continue our business, we plan to focus our clinical program on Androxal®. Should the FDA permit the resumption of the Proellex® clinical trials, we will assess whether there are sufficient funds available to continue development ourselves of such product candidate or whether such program would be more appropriately funded by a corporate partner. Therefore, 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 a corporate partnering opportunity will be found.

Research and Development

We have limited resources and utilize consultants and outside entities to perform clinical development and limited research activities in connection with preclinical studies and clinical trials. Our primary research and development, or R&D, expenses for 2009 were for the payment of contract research organizations and consultants in connection with our clinical trials of Proellex® for the treatment of uterine fibroids, endometriosis and for Androxal® for testosterone deficiency. We believe that these expenses will continue to be our primary R&D expenses in the near future.

Proellex® License Agreement with National Institutes of Health

In 1999, we licensed rights to Proellex® from the National Institutes of Health, or NIH, under an exclusive, worldwide license in the field of treatment of human endocrinologic pathologies or conditions in steroid sensitive tissues which expires upon the expiration of the last licensed patent. Under the terms of the agreement, we are

obligated to meet developmental milestones as outlined in a commercial development plan, which has been amended and revised from time to time as circumstances warrant. In 2009, we finalized a Seventh Amendment with the NIH which establishes a new set of milestones for development. This set of milestones may need to be amended again depending on when or if the clinical hold is lifted. Should the FDA determine that the clinical hold on Proellex® shall not be lifted even at a lower dosage, the license with the NIH provides us with an opportunity to satisfy milestones under such license with a second generation drug.

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We provide annual updates to the NIH on the progress of our development of Proellex®. Based on our interaction with the NIH to date, we believe our license and relationship with NIH are in good standing. The NIH has the ability to terminate the agreement for lack of payment or if we are not meeting milestones as outlined in the commercial development plan and for other reasons as outlined in the agreement. Although we believe that we have a good working relationship with the NIH, there can be no assurance that all of the objectives and conditions in the commercial development plan will be met on a timely basis or at all, or that, if we fail to meet any of such objectives, the NIH will again agree to amend this agreement to our satisfaction. Failure to comply with the material terms contained in the license agreement could result in termination of such agreement, which would prohibit us from further development of Proellex® and severely harm our business prospects. The NIH retains, on behalf of the government, a nonexclusive, nontransferable, worldwide license to practice the inventions licensed under the licensed patents by or on behalf of the government. For the purpose of encouraging basic research, the NIH retains the right to grant nonexclusive research licenses to third parties. Due to the work that was done on Proellex® at the NIH prior to our license agreement, the government also has certain rights to use the product in the event of a national emergency pursuant to the Patent and Trademark Laws Amendments Act of 1980, as amended.

Manufacturing

Due to the clinical hold on Proellex®, we cancelled our development and supply contract with Gedeon Richter for the production of the active pharmaceutical ingredient, or API, for Proellex®. We remain in contact with Gedeon Richter and should the clinical hold be lifted, we believe we can reestablish our supply contract with Gedeon Richter.

We have a five year supply agreement with Diagnostic Chemical Limited, doing business as BioVectra, for the supply of the bulk active pharmaceutical ingredient used in Androxal®. We have obtained all of our supply of Androxal® to date from BioVectra. We have not faced any material problems with BioVectra in supplying us with our necessary quantities of Androxal® for our clinical trials and anticipate utilizing them for commercial production if we are able to raise sufficient additional capital to commence clinical trials. Though our relationship with BioVectra remains good we believe that alternate manufacturers capable of manufacturing Androxal® could be developed.

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 could result in the cancellation of shipments, loss of product in the manufacturing process or a shortfall in available product candidates.

Sales and Marketing

We have no experience in the sales, marketing and distribution of pharmaceutical products. We anticipate that we will outsource such activities, as well as possibly later stage pivotal trials of our product candidates, to larger pharmaceutical companies more capable of distributing the products to the market place. 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 National Institutes of Health, we have exclusive rights to three issued U.S. patents, which expire in 2017, two pending U.S. patent applications, and several foreign patents and pending applications made by the NIH regarding Proellex®. We also have five pending U.S. patent applications, four foreign PCT applications and 45 foreign pending patent applications that cover various formulations of Proellex® and methods for using Proellex®.

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Our Androxal® product candidate and its uses are covered in the United States by two issued U.S. patents and six pending patent applications. Foreign coverage of our Androxal® product candidate includes 35 issued foreign patents and 67 foreign pending patent applications. The issued patents and pending applications relate to methods and compositions for treating certain conditions including the treatment of testosterone deficiency in men, the treatment of metabolic syndrome and conditions associated therewith, and the treatment of infertility in hypogonadal men. Androxal® (the trans-isomer of clomiphene) is purified from clomiphene citrate. A third party individual holds two issued patents related to the use of an anti-estrogen such as clomiphene citrate and others for use in the treatment of androgen deficiency and disorders related thereto. In our prior filings with the SEC, we have described our request to the U.S. Patent and Trademark Office, or PTO, for re-examination of one of these patents based on prior art. The third party amended the claims in the re-examination proceedings, which led the PTO to determine that the amended claims are patentable in view of those publications under consideration and a re-examination certificate was issued. However, we believe that the amended claims are invalid based on additional prior art publications, and our request for re-examination by the PTO in light of a number of these additional publications and other publications cited by the PTO, has been granted. All of the claims have been finally rejected in the re-examination and the patent holder has appealed the rejections to the PTO Board of Patent Appeals and Interferences (“the Board”). A decision has been rendered by the Board affirming the rejection of all of the claims. The patent holder has filed a request for rehearing. If the Board maintains the rejections on rehearing or the request for rehearing is denied, the patent holder will have the opportunity to appeal the rejections to the United States Court of Appeals for the Federal Circuit. We also believe that the second of these two patents is invalid in view of published prior art not considered by the PTO. Nevertheless, there is no assurance that either patent will ultimately be found invalid over the prior art. If such patents are not invalidated by the PTO we may be required to obtain a license from the holder of such patents in order to develop Androxal® further or attempts may be made to undertake further legal action to invalidate such patents. If such licenses were not available on acceptable terms, or at all, we may not be able to successfully commercialize or out-license Androxal®.

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

Competition

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

Our main competitors for the treatment of testosterone deficiency are the testosterone replacement therapies currently being marketed. The current most common standard of care is AndroGel, a topical gel for the replacement of testosterone in North America. AndroGel is marketed by Solvay Pharmaceuticals, a considerably larger company than we are. There is another topical gel, Testim®, currently marketed by Auxilium Pharmaceuticals, and a transdermal patch, AndroDerm®, marketed by Watson Pharmaceuticals. In addition, other companies are developing other products that would compete with Androxal®. We believe we can compete with AndroGel and the other

replacement therapies because Androxal® would have the advantage of being orally administered. 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 most common therapeutic standard of care for uterine fibroids. In addition, surgical treatment of both uterine fibroids and endometriosis competes with Proellex® by removing uterine fibroids and by removing misplaced tissue in women with endometriosis. We believe we can potentially compete with Lupron and other GnRH agonists because we believe that Proellex® will not present the same side effect of a decrease in bone mineral density given its specific focus on progesterone inhibition, which differentiates it from GnRH agonists that create a low estrogen state. There are additional companies developing similar progesterone-blocking technology. Asoprisnil, an anti-progestin, formerly being developed by TAP Pharmaceuticals in partnership with Schering AG, has been tested and discontinued due to side effects up through Phase 3 clinical trials.

Governmental Regulation

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

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

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

Phase 3 clinical trials are undertaken to further evaluate clinical efficacy and to test further for safety within an expanded patient population at geographically dispersed clinical study sites. Phase 1, Phase 2 or Phase 3 testing may not be completed successfully within any specific time period, if at all, with respect to any products being tested by a sponsor. Furthermore, the FDA or the Investigational Review Board, or IRB may suspend clinical trials at any time on various grounds, including a finding that the healthy volunteers or patients are being exposed to an unacceptable health risk. 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 the Phase 3 clinical trials. There can be no assurance that the clinical 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, or GMP. In complying with current GMP, manufacturers must expend funds, time and effort in the area of production and quality control to ensure full technical compliance. We do not have any drug manufacturing capabilities and must rely on outside firms for this capability. The FDA stringently applies regulatory standards for manufacturing. Identification of previously unknown problems with respect to a product, manufacturer or facility may result in restrictions on the product, manufacturer or facility, including warning letters, suspensions of regulatory approvals, operating restrictions, delays in obtaining new product approvals, withdrawal of the product from the market, product recalls, fines, injunctions and criminal prosecution.

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

Our research and development involves the controlled use of hazardous materials and chemicals. Although we believe that our procedures for handling and disposing of those materials comply with state and federal regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. If such an accident occurs, we could be held liable for resulting damages, which could be material to our financial condition and business. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those

governing laboratory procedures, exposure to blood-borne pathogens, and the handling of biohazardous materials. Additional federal, state and local laws and regulations affecting us may be adopted in the future. Any violation of, and the cost of compliance with, these laws and regulations could materially and adversely affect us.

Third-Party Reimbursement and Pricing Controls

In the United States and elsewhere, sales of pharmaceutical products depend in significant part on the availability of reimbursement to the consumer from third-party payers, such as government and private insurance plans. Since we have no commercial products, we have not had to face this issue yet. However, third-party payers are increasingly challenging the prices charged for medical products and services. It will be time consuming and expensive for us to go through the process of seeking reimbursement from Medicaid, Medicare and private payers.

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Our products may not be considered cost effective, and coverage and reimbursement may not be available or sufficient to allow us to sell our products on a competitive and profitable basis. The passage of the Medicare Prescription Drug and Modernization Act of 2003 imposes new requirements for the distribution and pricing of prescription drugs which may affect the marketing of our products.

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

The Hatch-Waxman Act

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

The Hatch-Waxman Act also permits a patent extension term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent extension cannot extend the remaining term of a patent beyond a total of 14 years. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA, plus time of active FDA review between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and it must be applied for prior to expiration of the patent and within 60 days of the approval of the NDA. The PTO, in consultation with the FDA, reviews and approves or rejects the application for patent term extension.

Litigation

See Item 3 of Part I of this Annual Report on Form 10-K for our fiscal year ended December 31, 2009.

Employees and Consultants

Employees

As of March 15, 2010, we had 5 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.

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, or SEC, as soon as reasonably practicable after such material is electronically filed with or furnished to the SEC. Interested parties may also find reports, proxy and information statements and other information on issuers that file electronically with the SEC at the SEC's Internet site (<http://www.sec.gov>).

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 requires that we raise additional funds in the first half of 2010, without which we will need to cease our business operations and begin bankruptcy or liquidation proceedings.

Our ability to continue as a going concern is dependent upon our ability to obtain financing in the first half of 2010, our ability to control our operating expenses and our ability to achieve a level of revenues adequate to support our capital and operating requirements. In particular, we are exploring various financing alternatives to address our short term liquidity needs. No assurance can be given that we will be successful in obtaining financing on acceptable terms or at all. We anticipate that if we are able to secure financing, 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 current FDA clinical hold of our clinical trials for Proellex® will make it more difficult for us to obtain additional financing. In addition, the recently filed class action lawsuits will make our ability to raise funds even more difficult. As described above, 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 in the first half of 2010, we will need to cease our business operations and begin bankruptcy or liquidation proceedings.

We may need to seek protection under the provisions of the U.S. Bankruptcy Code, and in that event, it is unlikely that stockholders would receive any value for their shares.

We have not generated any significant revenues to date, and we have incurred losses in each year since our inception. As of December 31, 2009, we had approximately \$1.9 million in cash and cash equivalents and our accounts payable and accrued expenses were approximately \$2.4 million. The amount of cash on hand is not sufficient to fund future clinical trials of Androxal®, complete all necessary activities relating to the lifting of the hold associated with Proellex®, pay our accounts payable and accrued expenses as well as our normal corporate overhead and expenses. We cannot assure you that any actions that we take would raise or generate sufficient capital to fully address the uncertainties of our financial position. As a result, we may be unable to realize value from our assets and discharge our liabilities in the normal course of business and we may need to seek protection under the provisions of the U.S. Bankruptcy Code. In that event, we may seek to reorganize our business, or we or a trustee appointed by the court may be required to liquidate our assets. In either of these events, whether the stockholders receive any value for their shares is highly uncertain. If we needed 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 under the federal bankruptcy laws, it is highly unlikely that stockholders would receive any value for their shares.

Although we recently amended our exclusive license agreement with the National Institutes of Health, failure to meet our agreed upon milestones could result in a loss of our rights to Proellex®.

On October 28, 2009, the Company amended its exclusive license with the NIH dated April 16, 1999. This seventh amendment extends the time period by which the Company is required to obtain certain financing and/or licensing consideration. In addition, the seventh amendment allows the Company time to attempt to lift the clinical hold on Proellex® for purposes of proceeding with a lower dose program. If the clinical hold is lifted, the Company must reach certain developmental milestones for such lower dose program, such as commencing Phase II and III studies and obtaining U. S. FDA approval for treatment of uterine fibroids, each by a specified date. In the event the FDA does not approve Proellex® for further clinical trials, at a lower dosage, by a certain date, the Company is required to identify a second generation compound from those covered by the original Exclusive License Agreement, and the Company must reach certain developmental milestones for such second generation compound, such as completing Phases I, II and III studies of such second generation compound, each by a specified date. Even though such amendment allows the Company additional time to reach such benchmarks, there can be no assurance that the Company will be successful in obtaining such financing, that the FDA will agree to allow the Company to resume clinical trials at a lower dosage or that the Company will be successful in identifying a second generation drug. In addition, the license may be terminated by the NIH immediately upon notice to the Company following a filing of a petition in bankruptcy or a letter from the Company to the NIH stating that it is insolvent. In the event that any of the conditions contained in the license agreement for termination by the NIH are triggered, the Company's license agreement may be terminated and the Company would lose its exclusive rights to Proellex®. Any such termination of the license agreement could have a material adverse effect on the Company's financial position and results of operations, and in such event, the value of the Company's common stock may be materially adversely affected.

We believe we have identified a dose-related increase in liver enzymes in Proellex® clinical trial patients, leading to the suspension of Proellex® studies and the FDA's notice of clinical hold on all Proellex® clinical trials.

In our clinical trials program for Proellex®, we believe we have identified a dose-related increase in liver enzymes in a limited number of patients that resulted in our decision to suspend all clinical trials relating to Proellex®. In August 2009, the FDA placed all Proellex® clinical studies on hold. There can be no assurance whether and when the FDA will remove the clinical hold; whether Proellex® can be further developed, financed or commercialized in a timely manner without significant additional studies or patient data or significant expense; and whether any future development will be sufficient to support product approval. If we are unable to resolve the FDA's concerns, we will not be able to proceed further to obtain regulatory approval for Proellex®.

We have no clear clinical path for Androxal® at this time.

We are developing Androxal® for men of reproductive age with low testosterone levels who want to maintain their fertility while being treated for their low testosterone condition. During the second quarter of 2008, we initiated a Phase 2b proof-of-concept clinical trial in which we are monitoring the effects of Androxal® on male fertility and testicular function in patients being treated for low testosterone as compared to Testim®, a popular marketed topical testosterone medication. Given that there is already an acceptable treatment regimen for men with low testosterone, there is significant uncertainty as to whether or not an additional approach such as Androxal® would be approved by the FDA or accepted in the market. At this time it is too early in the clinical development process to estimate when or even if an NDA for Androxal® will be submitted for this indication.

We are currently not in compliance with Nasdaq rules for continued listing on the Nasdaq Capital Market and are at risk of being delisted, which may subject us to the SEC's penny stock rules and decrease the liquidity of our common stock.

On January 12, 2010, we received a letter from the Nasdaq Hearings Panel (the "Panel") stating that our shares would be transferred from the Nasdaq Global Market to the Nasdaq Capital Market, effective at the open of the trading session on Thursday, January 14, 2010. As previously announced, we have not been in compliance with Marketplace Rules 5450(a)(1) and 5450(b)(2)(A) and (C), requiring (i) a minimum \$1.00 bid price per share, (ii) a minimum \$50 million market value of listed securities and (iii) a minimum market value of publicly held shares of \$15 million, respectively, for continued inclusion on the Nasdaq Global Market. The Panel's determination to transfer our shares to the Nasdaq Capital Market follows our hearing before the Panel on December 3, 2009. If we cannot demonstrate compliance with all the requirements for continued listing on the Nasdaq Capital Market, including the requirement to maintain a minimum bid price of \$1.00 per share by June 14, 2010 and maintain either stockholders' equity of at least \$2.5 million or a market value of listed securities of \$35 million, by May 5, 2010, our shares will be subject to immediate delisting.

If we are delisted from The Nasdaq Capital Market, our common stock may be traded over-the-counter on the OTC Bulletin Board or in the "pink sheets." These alternative markets, however, are generally considered to be less efficient than The Nasdaq Capital Market. Many over-the-counter stocks trade less frequently and in smaller volumes than securities traded on the Nasdaq markets, which would likely have a material adverse effect on the liquidity of our common stock.

If our common stock is delisted from The Nasdaq Capital Market, there may be a limited market for our stock, trading in our stock may become more difficult and our share price could decrease even further. In addition, if our common stock is delisted, our ability to raise additional capital may be impaired.

In addition, our common stock may become subject to penny stock rules. The SEC generally defines "penny stock" as an equity security that has a market price of less than \$5.00 per share, subject to certain exceptions. We are not currently subject to the penny stock rules because our common stock qualifies for an exception to the SEC's penny

stock rules for companies that have an equity security that is quoted on The Nasdaq Stock Market. However, if we were delisted, our common stock would become subject to the penny stock rules, which impose additional sales practice requirements on broker-dealers who sell our common stock. If our common stock were considered penny stock, the ability of broker-dealers to sell our common stock and the ability of our stockholders to sell their shares in the secondary market would be limited and, as a result, the market liquidity for our common stock would be adversely affected. We cannot assure that trading in our securities will not be subject to these or other regulations in the future.

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The Company and certain of its officers and directors were named as a party in several class action lawsuits which could result in a material adverse affect on our business and financial condition.

The Company and certain of its officers were named as parties in several shareholder class action lawsuits alleging, among other things, that the Company and such officers violated certain provisions of the Exchange Act by issuing materially false and misleading press releases regarding the results of clinical trials for its drug Proellex®. Our bylaws require us to indemnify our officers in certain proceedings, subject to certain limited exceptions. In addition, each of our directors has an indemnification agreement with the Company providing for certain additional indemnification benefits for such persons in the event of a lawsuit. As a result of the class action lawsuits, we are obligated to pay for certain costs and expenses of our officers and directors and may be liable for substantial damages, costs and expenses if such class action is successful. Such litigation could also divert the attention of our management and our resources in general from day-to-day operations. Further, it is possible that additional claims beyond those that have already been filed will be brought by the current plaintiffs or by others in an effort to seek monetary relief from us.

Additionally, such class action lawsuits are covered by the Company's director and officer insurance policy. In the event there are adverse judgments against the Company in such lawsuits, the Company's insurance coverage may not be adequate to cover such judgments and the Company's cash position may not be sufficient to satisfy such judgment. Such adverse judgments could have a material and adverse affect on the Company.

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

We expect to make additional capital outlays and to increase operating expenditures over the next several years to support our preclinical development and clinical trial activities, particularly with respect to pivotal clinical trials for Androxal® and, if and when the clinical hold on Proellex® is lifted, for Proellex®. Based on our current planned clinical programs, we will need to raise additional capital in the first half of 2010. Thereafter we will need to seek additional funding through public or private financings, including equity or debt financings, and/or through other means, including collaborations and license agreements. We do not know whether additional financing will be available when needed, or that, if available, we will obtain financing on terms favorable to our stockholders or us. If adequate funds are not available to us, we may be required to:

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

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

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

- competing technological and market developments.

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

The current economic downturn may affect our ability to raise capital, as well as our suppliers and contractors, and could materially affect our ability to continue our business.

The current economic downturn has reduced the availability of liquidity and credit to fund or support the continuation and expansion of business operations worldwide. Recent financial market conditions have resulted in significant write-downs of asset values by financial institutions, and have caused many financial institutions to seek additional capital, to merge with larger and stronger institutions and, in some cases, to fail. Many lenders and institutional investors have reduced and, in some cases, ceased to provide funding to borrowers. Continued disruption of the credit markets could adversely affect the credit capacity of our suppliers, contractors and insurance providers and could result in cancellations, suspensions or project delays. If one or more of our suppliers or contractors experiences difficulties that result in a reduction or interruption in supplies or services to us, or they fail to meet any of our manufacturing requirements, our business could be adversely impacted until we are able to secure alternative sources, if any. The equity capital markets have also been impacted, in that there are fewer private equity, venture capital and hedge funds in existence today than in previous years that are willing to invest in early stage biotechnology companies. Investment banks and major pharmaceutical companies are also not pursuing as many new financings and deals as in the past due to the lack of available capital and investors. In addition to these factors, please refer to the risk factor titled, "We rely on third parties to conduct clinical trials for our product candidates, and their failure to timely and properly perform their obligations may result in costs and delays that prevent us from obtaining regulatory approval or successfully commercializing our product candidates" for a discussion of additional adverse events that could arise from the failure of our independent contractors.

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

Before we can obtain regulatory approval for the commercial sale of any product candidate that we develop, we are required to complete preclinical development and extensive clinical trials in humans to demonstrate its safety and efficacy. Positive data from preclinical studies or early clinical trials should not be relied upon as evidence that those studies or trials will produce positive results, or that later or larger-scale clinical trials will succeed. Previous clinical trials for 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 type 2 diabetes. Furthermore, the only data that we obtained to date relating to Androxal® is to treat testosterone deficiency. We will be required to demonstrate through larger-scale clinical trials that these product candidates are safe and effective for use in a diverse population before we can seek regulatory approvals for their commercial sale. There is typically an extremely high rate of attrition from the failure of drug candidates proceeding through clinical trials. We are also required to complete our two-year rat carcinogenicity studies as well as other preclinical studies before we are permitted to file a new drug application, or NDA, for Androxal® and Proellex®. If 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 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, 2009, we had a deficit of approximately \$174.5 million. We expect to continue incurring net losses and we may not achieve or maintain profitability for some time if at all. As we increase expenditures for the clinical development of 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. The uncertainties relating to the foregoing matters raise substantial doubt about our ability to continue as a going concern.

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

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

property that enables licensees to develop competing products.

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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 failure of the FDA to lift the clinical hold for lower doses of Proellex® or any of our other current or future product candidates, or unfavorable results or decisions or negative perceptions regarding any of such clinical trials, could cause our stock price to decline significantly.

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

Our product candidates will require continued preclinical studies and extensive clinical trials prior to the submission of a regulatory application for commercial sales. Because of the nature of clinical trials 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, such as those we recently changed in our Androxal® clinical trials after our meeting with the FDA;
- reaching agreements on acceptable terms with prospective contract manufacturers for manufacturing sufficient quantities of a product candidate; and
 - obtaining institutional review board approval to conduct a clinical trial at a prospective site.

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

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

Once a clinical trial has begun, it may be delayed, suspended or terminated by us or the FDA, such as we are experiencing with Proellex®, or other regulatory authorities due to a number of factors, including:

- lack of effectiveness of any product candidate during clinical trials;
- side effects experienced by trial participants or other safety issues;
- slower than expected rates of patient recruitment and enrollment or lower than expected patient retention rates;
- delays or inability to manufacture or obtain sufficient quantities of materials for use in clinical trials;
- inadequacy of or changes in our manufacturing process or compound formulation;
- delays in obtaining regulatory approvals to commence a trial, or “clinical holds” or delays requiring suspension or termination of a trial by a regulatory agency, such as the FDA, after a trial is commenced;
- changes in applicable regulatory policies and regulations;

- delays in identifying and reaching agreement on acceptable terms with prospective clinical trial sites;
- uncertainty regarding proper dosing;
- unfavorable results from on-going clinical trials and preclinical studies;
- failure of our clinical research organizations to comply with all regulatory and contractual requirements or otherwise fail to perform their services in a timely or acceptable manner;
- scheduling conflicts with participating clinicians and clinical institutions;
- failure to construct appropriate clinical trial protocols;
- insufficient data to support regulatory approval;
- inability or unwillingness of medical investigators to follow our clinical protocols;
- difficulty in maintaining contact with subjects during or after treatment, which may result in incomplete data;
- ongoing discussions with the FDA or other regulatory authorities regarding the scope or design of our clinical trials; as was the case with our development for the initial indication of Androxal® that we are no longer pursuing;
- acceptability to the FDA of data obtained from clinical studies conducted in Europe or other non-United States jurisdictions; and
- lack of adequate funding to continue clinical trials.

Many of these factors that may lead to a delay, suspension or termination of clinical testing of a current or potential product candidate may also ultimately lead to denial of regulatory approval of a current or potential product candidate.

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

Even if we successfully complete clinical trials for 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 a new drug application, or NDA, to the FDA or that any NDA we submit will be approved by the FDA in a timely manner, if at all. After completing clinical trials for a product candidate in humans, a drug dossier is prepared and submitted to the FDA as an NDA, and includes all preclinical studies and clinical trial data relevant to the safety and effectiveness of the product at the suggested dose and duration of use for the proposed indication, in order to allow the FDA to review such drug dossier and to consider a product candidate for approval for commercialization in the United States. If we are unable to submit an NDA with respect to 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 will be unable to generate sufficient revenues to continue operations or attain profitability and our reputation in the industry and in the investment community would likely be damaged.

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

Preclinical studies and Phase 1 and Phase 2 clinical trials are not primarily designed to test the efficacy of a drug candidate, but rather to test safety, to study pharmacokinetics and pharmacodynamics, and to understand the drug candidate's side effects at various doses and schedules. To date, long-term safety and efficacy have not yet been demonstrated in clinical trials for any of our product candidates and in fact, our product candidate Proellex® is currently on clinical hold with the FDA due to safety issues experienced in our Phase 2 and Phase 3 clinical trials for endometriosis and uterine fibroids, respectively. Favorable results in our early studies or trials may not be repeated in later studies or trials, including continuing preclinical studies and large-scale clinical trials analyzed with more rigorous statistical methods, and our drug candidates in later-stage trials may fail to show desired safety and efficacy despite having progressed through earlier-stage trials. Unfavorable results from ongoing preclinical studies or clinical trials could result in delays, modifications or abandonment of ongoing or future clinical trials. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Negative or inconclusive results or adverse medical events during a clinical trial could cause a clinical trial to be delayed, repeated or terminated. In addition, we may report top-line data from time to time, which is based on a preliminary analysis of key efficacy and safety data; such data may be subject to change following a more comprehensive review of the data related to the applicable clinical trial.

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

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

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

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

- relative convenience and ease of administration;
- the prevalence and severity of any adverse side effects;
- availability, effectiveness and cost of alternative treatments;
- pricing and cost effectiveness of our drugs;
- effectiveness of our or collaborators' sales and marketing strategies; and
- our ability to obtain sufficient third-party insurance coverage or reimbursement.

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

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

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

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

Currently, we do not have the ability internally to manufacture the product candidates that we need to conduct our clinical trials. We recently terminated our supply agreement with Gedeon Richter for the manufacturing of Proellex® due to the clinical hold imposed by the FDA in August 2009. We have not sought an alternate manufacturer at this time, although we believe that other manufacturers are available.

We have a five year supply agreement with Diagnostic Chemical Limited, doing business as BioVectra, for the supply of the bulk active pharmaceutical ingredient used in Androxal®. We have obtained all of our supply of Androxal® to date from BioVectra. We have not faced any material problems with BioVectra in supplying us with our necessary quantities of Androxal® for our clinical trials and anticipate utilizing them for commercial production if Androxal® is approved. The Company believes that should an issue with BioVectra arise an alternative supplier could be identified.

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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.

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 sale in the event that such product candidates are approved by the FDA or foreign regulatory bodies. Significant scale-up of manufacturing requires certain additional developmental work, which the FDA must review and approve to assure product comparability. If we or our third-party manufacturers are unable to successfully increase the manufacturing capacity for a product candidate, the regulatory approval or commercial launch of that product candidate may be delayed or there may be a shortage in supply of that product candidate.

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

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.

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

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

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

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

Neither 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 with many companies with substantially greater resources than we have and other possible advantages.

We are engaged in biopharmaceutical product development, an industry that is characterized by extensive research efforts and rapid technological progress. The biopharmaceutical industry is also highly competitive. Our success will depend on our ability to acquire, develop and commercialize products and our ability to establish and maintain markets for any products for which we receive marketing approval. Potential competitors in North America, Europe and elsewhere include major pharmaceutical companies, specialty pharmaceutical companies and biotechnology

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

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

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

The main therapeutic products competitive with Proellex® for the treatment of uterine fibroids and endometriosis are GnRH agonists, including Lupron and the use of approved progestin-based contraceptives for the treatment of endometriosis. In addition, surgical treatment of both uterine fibroids and endometriosis would compete with Proellex®, if approved, by removing uterine fibroids and by removing misplaced tissue in women with endometriosis. Furthermore, Neurocrine Biosciences Inc. is developing a GnRH antagonist for the treatment of endometriosis.

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

The competition for qualified personnel in the biopharmaceutical field is intense, and our future success depends upon our ability to attract, retain and motivate highly skilled scientific, technical and managerial employees. We have only 5 full-time employees at the present time, including Joseph S. Podolski. We are highly dependent on 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. We do not maintain key person life insurance on any of our directors, officers or employees. The loss of the services of any of our 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 intend to enter into collaboration arrangements with strategic partners to develop and commercialize our product candidates. For our collaboration efforts to be successful, we must identify partners whose competencies complement ours. We must also successfully enter into collaboration agreements with them on terms attractive to us and integrate and coordinate their resources and capabilities with our own. We may be unsuccessful in entering into collaboration agreements with acceptable partners or negotiating favorable terms in these agreements. In addition, we may face a disadvantage in seeking to enter into or negotiating collaborations with potential partners because other potential collaborators may have greater management and financial resources than we do. Also, we may be unsuccessful in integrating the resources or capabilities of these collaborators. In addition, our collaborators may prove difficult to work with or less skilled than we originally expected. If we are unsuccessful in our collaborative efforts, our ability to develop and market product candidates could be severely limited.

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 Intellectual Property

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

Our rights to Proellex® are licensed exclusively to us from NIH under a license agreement. This license agreement contains numerous detailed performance obligations, with time sensitive dates for compliance, relating to clinical development and commercialization activities required by us or our designated third-party providers, as well as additional financial milestones and royalties. Failure to achieve the benchmarks specified in the commercial development plan attached to the license agreement or meet payment obligations could result in termination of the license agreement and the loss of our rights to develop and commercialize Proellex®. We periodically update the commercial development plan as such plans evolve. There can be no assurance that we will be able to meet any or all of the performance objectives in the future on a timely basis or at all, or that, if we fail to meet any of such objectives, NIH will agree to revised objectives. NIH has the ability to terminate the agreement for an uncured material breach of the agreement, if we made a false statement or willful omission in our license application, if we do not keep Proellex® reasonably available to the public after commercial launch, if we cannot reasonably satisfy unmet health and safety needs, or if we cannot reasonably justify a failure to comply with the domestic production requirement unless such requirement has been waived.

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

A third party individual holds two issued patents related to the use of an anti-estrogen such as clomiphene citrate and others for use in the treatment of androgen deficiency and disorders related thereto. In our prior filings with the SEC, we have described our request to the U.S. Patent and Trademark Office, or PTO, for re-examination of one of these patents based on prior art. The third party amended the claims in the re-examination proceedings, which led the PTO to determine that the amended claims are patentable in view of those publications under consideration and a re-examination certificate was issued. However, we believe that the amended claims are invalid based on additional prior art publications, and our request for re-examination by the PTO in light of a number of these additional publications and other publications cited by the PTO, has been granted. All of the claims have been finally rejected in the re-examination and the patent holder has appealed the rejections to the PTO Board of Patent Appeals and Interferences (“the Board”). A decision has been rendered by the Board affirming the rejection of all of the claims. The patent holder has filed a request for rehearing. If the Board maintains the rejections on rehearing or the request for rehearing is denied, the patent holder will have the opportunity to appeal the rejections to the United States Court of Appeals for the Federal Circuit. We also believe that the second of these two patents is invalid in view of published prior art not considered by the PTO. Nevertheless, there is no assurance that either patent will ultimately be found invalid over the prior art. If such patents are not invalidated by the PTO we may be required to obtain a license from the holder of such patents in order to develop Androxal® further or attempts may be made to undertake further legal action to invalidate such patents. If such licenses were not available on acceptable terms, or at all, we may not be able to successfully commercialize or out-license Androxal®.

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

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

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

Our commercial success also depends upon our ability to develop and manufacture our product candidates and market and sell drugs, if any, and conduct our research and development activities without infringing or misappropriating the proprietary rights of others. We may be exposed to future litigation by others based on claims that our product candidates, technologies or activities infringe the intellectual property rights of others. Numerous United States and foreign issued patents and pending patent applications owned by others also exist in the therapeutic areas in, and for the therapeutic targets for, which we are developing drugs. These could materially affect our ability to develop our product candidates or sell drugs, and our activities, or those of our licensor or future collaborators, could be determined to infringe these patents. Because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that our drug candidates or technologies may infringe. There also may be existing patents, of which we are not aware, that our product candidates or technologies may infringe. Further, there may be issued patents and pending patent applications in fields relevant to

our business, of which we are or may become aware, that we believe we do not infringe or that we believe are invalid or relate to immaterial portions of our overall drug discovery and development efforts. We cannot assure you that others holding any of these patents or patent applications will not assert infringement claims against us for damages or seeking to enjoin our activities. We also cannot assure you that, in the event of litigation, we will be able to successfully assert any belief we may have as to non-infringement, invalidity or immateriality, or that any infringement claims will be resolved in our favor.

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

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- require us, or potential collaborators, to obtain a license to continue to use, manufacture or market the affected drugs, methods or processes, which may not be available on commercially reasonable terms, if at all;
- prevent us from importing, making, using, selling or offering to sell the subject matter claimed in patents held by others and subject to potential liability for damages; or
- consume a substantial portion of our managerial, scientific and financial resources; or be costly, regardless of the outcome.

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

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 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.

ITEM 1B.

UNRESOLVED STAFF COMMENTS

None.

ITEM 2.

PROPERTIES

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

ITEM 3.

LEGAL PROCEEDINGS

On August 7, 2009, R.M. Berry filed a putative class action lawsuit naming the Company, Joseph Podolski, Paul Lammers, and Louis Ploth, Jr. as defendants. The lawsuit is pending in the United States District Court for the Southern District of Texas, Houston Division. The lawsuit, styled R.M. Berry, on Behalf of Himself and all Others Similarly Situated v. Repros Therapeutics, Inc., Joseph Podolski, Paul Lammers, and Louis Ploth, Jr., alleges that the defendants made certain misleading statements related to the Company’s Proellex® drug. Among other claims, the lawsuit contends that the defendants misrepresented the side effects of the drug related to liver function, and the risk that these side effects could cause a suspension of clinical trials of Proellex®. The lawsuit seeks to establish a class of shareholders allegedly harmed by the misleading statements, and asserts causes of action under the Securities Exchange Act of 1934. On August 14, 2009, a lawsuit making similar allegations and naming the same defendants was also filed in the United States District Court for the Southern District of Texas. This suit is styled Josephine Medina, Individually and On Behalf of all Others Similarly Situated v. Repros Therapeutics, Inc., Joseph Podolski, Paul Lammers, and Louis Ploth, Jr. On September 25, 2009, a lawsuit also making allegations similar to those in the Berry action, and naming the same defendants, was filed in the United States District Court for the Southern District of Texas. That lawsuit is styled Shane Simpson, Paul Frank and Clayton Scobie, on Behalf of Themselves and all Others Similarly Situated v. Repros Therapeutics, Inc., Joseph Podolski, Paul Lammers, and Louis Ploth, Jr. The lawsuits have now been consolidated, and lead plaintiffs appointed. On January 27, 2010, the lead plaintiffs filed a Consolidated Class Action Complaint styled In re Repros Therapeutics, Inc. Securities Litigation, Civil Action No. 09

Civ. 2530 (VDG). The lawsuit names Repros Therapeutics, Inc., Joseph Podolski, Paul Lammers, and Louis Ploth, Jr. as defendants. The allegations in the Consolidated Class Action Complaint are substantially the same as those contained in the prior complaints, and focus on the claim that the defendants deliberately withheld information concerning the negative side-effects of Proellex® related to liver function. Plaintiffs seek to establish a class action for all persons who “purchased or otherwise acquired Repros common stock between July 1, 2009, and August 2, 2009.” No discovery has yet occurred in the matter, and defendants intend to file a motion to dismiss the Consolidated Class Action Complaint. An estimate of the possible loss or range of losses in connection with the lawsuits cannot be made at this time.

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On August 10, 2009, a vendor of the Company filed a lawsuit naming the Company as a defendant. The lawsuit claimed the Company owed it \$147,000 in accordance with the terms of its agreement with the Company. On August 20, 2009, another vendor of the Company filed a lawsuit naming the Company as a defendant. The lawsuit claimed the Company owed it \$443,600 in accordance with the terms of its agreement with the Company. On October 29, 2009, the Company entered into a Master Settlement Agreement and Releases with certain trade creditors, pursuant to which we issued 5,361,194 shares of our common stock, at \$1.10 per share, and paid approximately \$2.77 million in cash to such creditors as payment in full for our then outstanding liabilities and for the release of these claims held by and the dismissal of the litigation commenced by these creditors against the Company as described above.

On October 2, 2009, a vendor of the Company filed a lawsuit naming the Company as a defendant. The lawsuit claimed the Company owed it \$294,718 in accordance with the terms of its agreement with the Company. On December 1, 2009, the Company entered into a confidential settlement agreement with this vendor which resolved the lawsuit.

On November 13, 2009, a vendor filed a lawsuit naming the company as a defendant. The lawsuit claimed the Company owed it \$93,698 in accordance with the terms of its agreement with the Company. On February 1, 2010, the Company entered into a confidential settlement agreement with this vendor which resolved the lawsuit.

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. The amount claimed is approximately \$175,000. 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. Pursuant to the October Settlement Agreement, 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.

ITEM 4.

(REMOVED AND RESERVED)

PART II

ITEM MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS 5. 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 common stock, as reported by the Nasdaq Stock Market, during the periods presented.

	Price Range	
	High	Low
2008		
First Quarter	\$ 10.20	\$ 8.11
Second Quarter	11.09	8.21
Third Quarter	10.00	5.31
Fourth Quarter	11.25	5.68
2009		
First Quarter	\$ 13.94	\$ 5.84
Second Quarter	8.30	5.70

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Third Quarter	6.01	0.65
Fourth Quarter	2.48	0.64

2010

First Quarter (January 2nd through March 5th)	\$ 1.22	\$ 0.68
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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 5, 2010, the last sale price of our common stock, as reported by the Nasdaq Capital Market, was \$0.80 per share. On March 5, 2010, there were approximately 177 holders of record and approximately 3,750 beneficial holders of our common stock.

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On January 12, 2010, we received a letter from the Nasdaq Hearings Panel (the "Panel") stating that our shares would be transferred from the Nasdaq Global Market to the Nasdaq Capital Market, effective at the open of the trading session on Thursday, January 14, 2010. As previously announced, we have not been in compliance with Marketplace Rules 5450(a)(1) and 5450(b)(2)(A) and (C), requiring (i) a minimum \$1.00 bid price per share, (ii) a minimum \$50 million market value of listed securities and (iii) a minimum market value of publicly held shares of \$15 million, respectively, for continued inclusion on the Nasdaq Global Market. The Panel's determination to transfer our shares to the Nasdaq Capital Market follows our hearing before the Panel on December 3, 2009. If we cannot demonstrate compliance with all the requirements for continued listing on the Nasdaq Capital Market, including the requirement to maintain a minimum bid price of \$1.00 per share by June 14, 2010 and maintain either stockholders' equity of at least \$2.5 million or a market value of listed securities of \$35 million, by May 5, 2010, our shares will be subject to immediate delisting.

Dividends

General

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

Rights Plan

We are party to a rights agreement, as amended, pursuant to which a dividend consisting of one preferred stock purchase right was distributed for each share of our common stock held as of the close of business on September 13, 1999, and to each share of common stock issued thereafter until the earlier of (i) the distribution date which is defined in the rights plan, (ii) the redemption date which is defined in the rights plan or (iii) September 13, 2010. The rights plan is designed to deter coercive takeover tactics and to prevent an acquirer from gaining control of us without offering fair value to our stockholders. The rights will expire on September 13, 2010, subject to earlier redemption or exchange as provided in the rights plan. Each right entitles its holder to purchase from us one one-hundredth of a share of a new series of Series One Junior Participating Preferred Stock at a price of \$20.00 per one one-hundredth of a share, subject to adjustment. The rights are generally exercisable only if a person acquires beneficial ownership of 20% or more of our outstanding common stock.

A complete description of the rights, the rights plan with Computershare Trust Company, N.A., as rights agent, and the Series One Junior Participating Preferred Stock is hereby incorporated by reference from the information appearing under the caption "Item 1. Description of the Registrant's Securities to be Registered" contained in the Registration Statement on Form 8-A filed on September 3, 1999, and as amended by amendments to such Registration Statement on Form 8-A/A filed on September 11, 2002, October 31, 2002, June 30, 2005, January 10, 2008 and October 10, 2008.

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.

	12/04	12/05	12/06	12/07	12/08	12/09
Repros Therapeutics Inc.	100.00	118.01	291.22	215.24	242.96	18.40
NASDAQ Composite	100.00	101.41	114.05	123.94	73.43	105.89
NASDAQ Pharmaceutical	100.00	102.39	105.36	100.01	92.37	98.60

ITEM 6.

SELECTED CONSOLIDATED FINANCIAL DATA

The statement of operations data for the years ended December 31, 2009, 2008 and 2007, and the balance sheet data as of December 31, 2009 and 2008, 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, 2006 and 2005, and the balance sheet data as of December 31, 2007, 2006 and 2005 have been derived from our financial statements not included in this annual report on Form 10-K. Our historical results are not necessarily indicative of results to be expected for any future period. The data presented below have been derived from financial statements that have been prepared in accordance with accounting principles generally accepted in the United States and should be read with our financial statements, including notes, and with "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this annual report on Form 10-K.

STATEMENTS OF OPERATIONS DATA:

	2009	2008	2007	2006	2005
Revenues and Other Income:					
Interest income	\$ 4	\$ 433	\$ 1,508	\$ 596	\$ 630
Research and development grants	—	—	—	—	4
Other income	547	—	—	—	—
Total revenues	551	433	1,508	596	634
Expenses:					
Research and development	23,062	22,575	12,420	11,912	6,101
General and administrative	4,723	3,060	2,788	2,879	1,924
Total expenses	27,785	25,635	15,208	14,791	8,025
Net loss	\$ (27,234)	\$ (25,202)	\$ (13,700)	\$ (14,195)	\$ (7,391)
Net loss per share – basic and diluted (1)	\$ (1.57)	\$ (1.88)	\$ (1.09)	\$ (1.40)	\$ (0.77)
Shares used in loss per share calculation	17,344	13,372	12,524	10,147	9,647

BALANCE SHEET DATA:

Cash, cash equivalents and marketable securities	\$ 1,886	\$ 19,470	\$ 25,903	\$ 6,736	\$ 16,832
Total assets	2,960	22,603	27,599	7,849	17,682
Deficit accumulated during the development stage	(174,476)	(147,242)	(122,040)	(108,340)	(94,145)
Total stockholders' equity	\$ 562	\$ 15,614	\$ 24,060	\$ 3,790	\$ 16,955

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

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following management's discussion and analysis should be read in conjunction with our historical consolidated financial statements and their notes included elsewhere in this Form 10-K. This discussion contains forward-looking statements that reflect our current views with respect to future events and financial performance. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors, such as those set forth under "Risk Factors" and elsewhere in this Form 10-K.

Overview

Repros Therapeutics Inc. ("the Company", "RPRX," "Repros", or "we," "us" or "our") was organized on August 20, 1987. We are a development stage biopharmaceutical company focused on the development of oral small molecule drugs for major unmet medical needs.

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

Androxal® (male reproductive health):

- Completed Phase 2b proof-of-concept trial in men being treated for low testosterone levels who want to improve or maintain their fertility and/or sperm number and function; and
- Our Investigational New Drug Application, or IND, for the study of oral Androxal® in the treatment of hypogonadal men with type 2 diabetes was accepted by the FDA and, thus, we may initiate a Phase 2a trial.

Proellex® (female reproductive health): All ongoing clinical trial activities for Proellex® have been put on hold by the FDA.

Any further development efforts for either of our product candidates is dependent on our ability to raise additional capital. We also continue to maintain our patent portfolio of our phentolamine-based products for the treatment of sexual dysfunction and try to create value from these assets in various ways which includes product out-licensing.

Our primary product candidate, Androxal® (the trans isomer of clomiphene), is a single isomer of clomiphene citrate and is an orally active proprietary small molecule compound. We are developing Androxal® for men of reproductive age with low testosterone levels who want to improve or maintain their fertility and/or sperm function while being treated for low testosterone. In addition, we submitted a new IND to the Division of Metabolic and Endocrine Products, or DMEP, for the investigation of Androxal® as a potential treatment for type 2 diabetes. On February 1, 2010, we received confirmation from the DMEP that our new IND was accepted and, as a result, we may initiate a Phase 2a trial. This new indication replaces our previously announced plan to develop Androxal® in men with adult-onset idiopathic hypogonadotrophic hypogonadism, or AIHH, with concomitant plasma glucose and lipid elevations, all of which are components of Metabolic Syndrome.

During the second quarter of 2008, we initiated a 24-patient Phase 2b proof-of-concept clinical trial (ZA-201) for a new indication in which we are monitoring the effects of Androxal® on male fertility and testicular function in patients being treated for low testosterone as compared to Testim®, a popular marketed topical testosterone medication. On October 6, 2009 we announced that Androxal® was able to maintain sperm counts in men being treated for their low testosterone levels. Testim® resulted in suppressed sperm levels while men were being treated with that topical gel. We requested a meeting with the FDA to discuss such results. In correspondence leading up to such meeting, the FDA stated that it could not agree with such proposed indication for Androxal® at that time because

the patient population had not been adequately defined and that it was not aware of certain data to support our position. On January 25, 2010, we participated in a teleconference with the FDA relating to the future clinical path for Androxal®. During such teleconference, the FDA requested that we (i) propose a label that better defines the population of individuals for whom we believe will benefit from the use of Androxal® and (ii) conduct a literature review of the incidence of infertility associated with the use of exogenous testosterone as supportive of our data. The FDA suggested that if it finds the submission appropriate, no additional clarifying meeting regarding this indication for Androxal® may be required. On February 8, 2010, we announced that we submitted the requested information to the FDA and we are currently awaiting the FDA's response to such submissions. Given that there is currently an acceptable treatment regimen for men with low testosterone, there is significant uncertainty as to whether or not an additional approach such as Androxal® would be approved by the FDA or accepted in the market. At this time it is too early in the clinical development process to estimate when or even if an NDA for Androxal® will be submitted for this indication.

In April 2008, we submitted a White Paper, based on the results from a previously conducted non-pivotal Phase 2 clinical trial (ZA-003) with Androxal® for the treatment of testosterone deficiency due to secondary hypogonadism, to the Division of Reproductive and Urology Products. The data we believe demonstrated that in subjects with a serum glucose of greater than or equal to 105mg/dL, there was a statistically significant reduction in fasting serum glucose and a higher response rate to treatment in the Androxal®-group than the placebo or Androgel® groups. In November 2008, after the FDA reviewed this paper we received guidance from them suggesting that we open a new IND with the Division of Metabolic and Endocrine Products, or DMEP, for the investigation of Androxal® as a potential treatment for type 2 diabetes in mellitus. In December 2009, we submitted a new IND to the DMEP for the investigation of Androxal® for such purpose. On February 1, 2010, we received confirmation from the DMEP that our new IND was accepted and, as a result, we may initiate a Phase 2a trial. This new indication replaces our previously announced plan to develop Androxal® in men with adult-onset idiopathic hypogonadotropic hypogonadism, or AIHH, with concomitant plasma glucose and lipid elevations, all of which are components of Metabolic Syndrome.

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. However, as a result of the recent liver toxicity exhibited by Proellex® in our previous Phase 2 and 3 clinical trials to endometriosis and uterine fibroids, respectively, all ongoing clinical trial activities have been put on hold by the FDA. There is currently no FDA-approved orally administered drug treatment for the long-term treatment of uterine fibroids or endometriosis.

Our estimates regarding the timing of our Proellex® clinical development program are completely on hold at this time in light of the FDA clinical hold and our recent discontinuation of ongoing clinical trials. In addition, any future development efforts are totally dependent on our ability to raise sufficient capital or find an appropriate partner to proceed and on decisions by the FDA regarding the current clinical hold on Proellex® clinical trials. If the FDA were to lift the clinical hold on Proellex®, and if the FDA requires a lower dosage of Proellex® to be used for future clinical trials, we would be required to commence Phase 2 studies again with the required lower dosage, thereby resulting in extensive additional costs and delays. The length of time required to complete Phase 1, Phase 2 and Phase 3 clinical trials and long-term Open Label Safety Trials may vary substantially according to factors relating to the particular trial, such as the type and intended use of the drug candidate, the clinical, trial design and the ability to enroll suitable patients. We have also, in the past, had difficulty recruiting patients into our Proellex® clinical trials primarily due to the various test procedures that are required, including multiple endometrial biopsies. Recruiting patients would likely be even more difficult due to the recent liver toxicity exhibited by Proellex®.

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

The clinical development of pharmaceutical products is a complex undertaking, and many products that begin the clinical development process do not obtain regulatory approval. The costs associated with our clinical trials may be impacted by a number of internal and external factors, including the number and complexity of clinical trials necessary to obtain regulatory approval, the number of eligible patients necessary to complete our clinical trials and any difficulty in enrolling these patients, and the length of time to complete our clinical trials. Given the uncertainty of these potential costs, we recognize that the total costs we will incur for the clinical development of our product candidates may exceed our current estimates. We do, however, expect these costs to decrease in year 2010 as compared to year 2009 due to the clinical hold on Proellex®. Continued development of either of our programs is contingent on raising additional capital.

As with most biotechnology companies with drug candidates in development, the path to marketing approval by the U.S. Food and Drug Administration, or the FDA, and comparable foreign agencies for each such candidate is long and uncertain. The regulatory process, both domestically and abroad, is a multi-year process with no certainty when and if a drug candidate will be approved for commercial use. The development path for a particular drug candidate typically includes a variety of clinical trials. While we have a general estimate of the timeframe for our clinical trials, the actual anticipated completion dates for each of our drug candidates are uncertain due to a wide variety of risks, including those described in the risk factors in this 2009 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, among other factors, on our ability to be successful in our clinical trials, the regulatory approval process in the United States and other foreign jurisdictions and the ability to complete new licenses and product development agreements. The timing of our revenues may not match the timing of our associated product development expenses. To date, research and development expenses have generally exceeded revenue in any particular period and/or fiscal year.

As of December 31, 2009, the Company had an accumulated deficit of \$174.5 million and had cash and cash equivalents of \$1.9 million. We have experienced negative cash flows from operations since inception and have funded our activities to date primarily from equity financings and corporate collaborations. Based on our current planned clinical programs, we will need to raise additional capital during the first half of 2010. We believe we can secure 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. Failure to raise sufficient funds will likely result in either bankruptcy or the dissolution of the Company. The uncertainties relating to the foregoing matters raise substantial doubt about our ability to continue as a going concern.

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Our common stock is traded on the Nasdaq Capital Market under our ticker symbol, RPRX.

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

We have 5 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, 2009 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, among other things, on successfully completing the clinical development of our products in a reasonable time frame and at a reasonable cost, obtaining regulatory approvals, establishing marketing, sales and manufacturing capabilities or collaborative arrangements with others that possess such capabilities, our and our partners' ability to realize value from our research and development programs through the commercialization of those products and raising sufficient funds to finance our activities. There can be no assurance that we will be able to achieve profitability or that profitability, if achieved, can be sustained. See "Item 1. Business — Risk Factors" and "Note 1. Organization and Operations" of Notes to Consolidated Financial Statements.

Critical Accounting Policies and the Use of Estimates

The preparation of our financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in our financial statements and accompanying notes. Please see Note 2, "Summary of Significant Accounting Policies", for a detailed discussion of our critical accounting policies. A brief summary of our accounting policies is provided below.

Investments

Management determines the appropriate classification of investments in debt and equity securities at the time of purchase and re-evaluates such designation as of each subsequent balance sheet date. Debt securities for which we have the ability and intent to hold to maturity are classified as "held to maturity". Securities we designate as "trading securities" are recorded at fair value. Gains and losses on trading securities, realized and unrealized, are included in earnings and are calculated using the specific identification method. Any other securities are classified as "available for sale." Due to the volatility of the financial markets at December 31, 2009, we had no marketable securities and held our cash in either an insured bank account or a money market mutual fund backed by U.S. government issued securities.

Prior to the disruption of the financial markets, our investments typically included corporate bonds and notes, Euro-dollar bonds, taxable auction securities and asset-backed securities. Our policy is to require minimum credit ratings of A2/A and A1/P1 with maturities of up to three years, excluding taxable auction securities. These securities were classified as trading securities and were valued in our financial statements at their fair value. Our policy required

that the average life of the investment portfolio, excluding taxable auction securities, may not exceed 24 months.

Capitalized Patent Costs

The Company capitalizes the cost associated with building its patent library for its Androxal® and Proellex® products. As of December 31, 2009 and 2008, other assets consist of capitalized patent costs in the amount of \$885,000 and \$1,713,000 respectively. Patent costs, which include legal and application costs related to the patent portfolio, are being amortized over the lesser of 20 years or the estimated economic life of the patent. Amortization of patent cost expense was \$54,000, \$27,000 and \$10,350 in 2009, 2008 and 2007, respectively. All of the \$885,000 in capitalized patent costs as of December 31, 2009 related to Androxal® patent and patent application costs.

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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.

Due to the clinical hold on Proellex® and the uncertainty of future cash flows related to the Proellex® patent applications, the Company recorded an impairment charge of approximately \$957,000 in 2009 related to these patent applications. Additionally, the Company concluded that it will no longer seek to protect the specific matter covered in certain Androxal® patent applications and recorded an impairment charge of approximately \$318,000 to abandon these patent applications. These charges were recorded in Research and Development expenses on the consolidated statement of operations. The remaining capitalized patent and patent application costs relating to Androxal® can continue to be used, outlicensed or sold to third parties for at least an amount management believes is sufficient to recover the carrying value of the capitalized patent costs.

Should the Company not continue development of Androxal® or should the Company not continue as a going concern, the remaining capitalized patent and patent application 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. Due to the clinical hold on Proellex® and our current financial condition, any further development of our product candidates is dependent on our ability to raise additional capital. As a result, we anticipate that our estimated accruals for clinical services will be significantly reduced in future periods. 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.

R&D Expense

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

Share-Based Compensation

We have two stock-based compensation plans at December 31, 2009, the 2000 Non-Employee Directors' Stock Option Plan, or 2000 Director Plan and the 2004 Stock Option Plan, or 2004 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 losses since inception and, therefore, have not been subject to federal income taxes. We have accumulated approximately \$2.5 million of research and development tax credits. As of December 31, 2009, we had approximately \$152 million of net operating loss, or NOL, carry-forwards for federal income tax purposes. Additionally, approximately \$3.4 million of NOLs, and approximately \$120,000 of research and development tax credits, expired in 2009. 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 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, and the issuances of unregistered shares as part of the October 29, 2009 Settlement Agreement and Subsequent Settlement Agreements may have created a change of ownership for Federal Income tax purposes. The Company has not undertaken a study to determine if this has occurred. A change in ownership for Federal Income tax purposes may result in a limitation on the use of net operating loss and tax credit carryforwards in future periods.

RECENT ACCOUNTING PRONOUNCEMENTS

In September 2006, FASB issued new accounting guidance which defines fair value, established a framework for measuring fair value in generally accepted accounting principles and expanded disclosures about fair value measurements. This guidance is effective for financial statements issued for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. In February 2008, the FASB deferred the effective date of this new guidance for all nonfinancial assets and nonfinancial liabilities to fiscal years beginning after November 15, 2008. The implementation of this guidance for financial assets and financial liabilities, effective January 1, 2008, did not have a material impact on Repros' consolidated financial position and results of operations. The implementation of this guidance for nonfinancial assets, effective January 1, 2009, and nonfinancial liabilities did not have a material impact on the Company's consolidated financial position and results of operations.

In May 2009, the FASB issued new accounting guidance on management's assessment of subsequent events and incorporates this guidance into accounting literature. This guidance is effective prospectively for interim and annual period ending after June 15, 2009. The implementation of this standard did not have a material impact on our consolidated financial position and results of operations.

Results of Operations

Comparison of Years Ended December 31, 2009 and 2008

Revenues and Other Income

Total revenues and other income increased 27% to \$551,000 in 2009 as compared to \$433,000 for 2008. This increase was primarily due to an increase of \$547,000 in other income, offset by a decrease in interest income of \$429,000. The Company recognized \$547,000 in non-cash other income related to debt relief from settlements with certain vendors in the fourth quarter of 2009. The decrease in interest income is due to lower combined cash, cash equivalents and marketable securities balances and reduced interest rate yields that have occurred as we moved our cash investments solely into money market mutual fund.

Research and Development Expenses

Research and development, or R&D, expenses include contracted services relating to our clinical product development activities which include preclinical studies, clinical trials, regulatory affairs and bulk manufacturing scale-up activities and bulk active ingredient purchases for preclinical and clinical trials primarily relating to our two products in clinical development, which are Proellex® and Androxal®. Research and development expenses also include internal operating expenses relating to our general research and development activities. R&D expenses increased 2% or approximately \$487,000 to \$23.1 million for the year ended 2009 as compared to \$22.6 million in 2008. Our primary R&D expenses for 2009 and 2008 are shown in the following table (in thousands):

Research and Development	December 31, 2009	December 31, 2008	Variance	Change (%)
Androxal® clinical development	\$ 786	\$ 2,370	\$ (1,584)	(67)%
Proellex® clinical development	18,376	17,788	588	3%
Payroll and benefits	1,384			