REPROS THERAPEUTICS INC.
Form 10-K
March 14, 2016

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

Form 10-K

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2015

or

.. TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to

Commission File No. 001-15281

Repros Therapeutics Inc.

(Exact name of registrant as specified in its charter)

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

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

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

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock, $.001 par value	The Nasdaq Stock Market LLC

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Securities Act. Yes ¨ No x

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

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

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

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

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

The aggregate market value of the common stock held by non-affiliates of the registrant was approximately $146,809,556 as of June 30, 2015, the last business day of the registrant's most recently completed second fiscal quarter, based on the closing sales price of the registrant's common stock on the Nasdaq Capital Market on such date of $7.15 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 February 26, 2016, there were 24,318,111 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 2016 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, 2015, are incorporated by reference into Part III of this Form 10-K.

REPROS THERAPEUTICS INC
2015 FORM 10-K ANNUAL REPORT

TABLE OF CONTENTS

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 1A. Risk Factors." Should one or more of these risks or uncertainties materialize, or should

underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, expected, estimated, projected, suggested or intended.

PART I

ITEM 1. Business

Overview

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

We are developing enclomiphene, a single isomer of clomiphene citrate which is an orally active proprietary small molecule compound. Enclomiphene is for the treatment of secondary hypogonadism in overweight men wishing to restore normal testicular function. Men with secondary hypogonadism exhibit low testosterone levels due to under stimulated testes but they are generally fertile. Enclomiphene is designed to treat the underlying mechanism, insufficient stimulation of the testes by the pituitary, which causes secondary hypogonadism. Secondary hypogonadism due to being overweight or obese is the single greatest cause of hypogonadism in general. Through 2014, sales of preparations for the treatment of low testosterone have exceeded $2 billion in the U.S. and first tier pharmaceutical companies are active participants in the low testosterone marketplace.

In December 2011, we completed a Phase 2B study of enclomiphene in men with secondary hypogonadism, but naïve to testosterone treatment, at the recommendation of the Food and Drug Administration (the "FDA"). Top line results of this study demonstrated that enclomiphene was generally well tolerated compared to placebo and that there were no drug related serious adverse events that led to discontinuation. We met with the FDA in May 2012 to discuss the design of pivotal Phase 3 efficacy studies for enclomiphene as well as the components of the overall drug development program required for a New Drug Application ("NDA") submission and agreed on registration requirements for enclomiphene oral therapy for the treatment of secondary hypogonadism. In July 2012, we announced that we reached an agreement with the FDA for the design of the pivotal efficacy studies for enclomiphene for the treatment of secondary hypogonadism. The pivotal studies were conducted under a Special Protocol Assessment ("SPA"). On March 27, 2013, we announced that the top-line results from our first pivotal Phase 3 study, ZA-301, met both co-primary endpoints mandated by the FDA, and we announced on September 16, 2013, that we met both co-primary endpoints in the second pivotal study, ZA-302. Additionally, on September 16, 2013, we announced the results from ZA-300, a six-month safety study. This study identified no new safety issues. On October 22, 2013, we announced that we received guidance from the FDA instructing the Company to request a meeting to discuss the adequacy of studies ZA-301 and ZA-302. In addition to this guidance, the FDA further noted that they would allow us to run head-to-head studies against approved testosterone replacement products. These head-to-head

studies, ZA-304 and ZA-305, were initiated in January 2014 and subsequently completed in September and August 2014, respectively. Both of these head-to-head studies achieved superiority for both co-primary endpoints and most secondary endpoints as compared to the approved testosterone replacement product. On October 21, 2014, we announced the results from ZA-303, a 52 week, single-blind, placebo-controlled Phase 3 study to evaluate the effects on bone mineral density. In this study, no new safety signals were identified, including no evidence of negative effects on bone mineral density. On February 2, 2015, we announced that we electronically submitted our NDA to the FDA for enclomiphene. The FDA accepted the NDA for review on April 1, 2015 and later assigned a Prescription Drug User Fee (PDUFA) goal date of November 30, 2015. In addition, the Division of Bone, Reproductive and Urologic Products (the Division) of the FDA scheduled an advisory committee meeting to review the NDA for November 3, 2015. However, the Division subsequently cancelled the scheduled advisory committee meeting due to questions that arose late in the review regarding the bioanalytical method validation that could affect interpretability of certain pivotal study data. On December 1, 2015, we announced that we had received a Complete Response Letter (CRL) from the FDA. A CRL informs companies that an NDA cannot be approved in its present form. In the CRL, the FDA stated that, based on recent scientific developments, the design of the enclomiphene Phase 3 studies is no longer adequate to demonstrate clinical benefit and recommended that Repros conduct an additional Phase 3 study or studies to support approval in the target population. The FDA also noted concerns regarding study entry criteria, titration and bioanalytical method validation in the Phase 3 program. Subsequently, on February 4, 2016, the Company attended a meeting with the FDA reviewers and senior leaders to discuss resolution of issues identified during the NDA review. The meeting covered a broad range of topics surrounding the NDA data as well as emerging agency and expert thinking regarding the treatment of hypogonadism. The Company believes based on the meeting that the FDA is not closed to considering secondary hypogonadism as an indication. Additionally, in January 2016, the Company initiated a Phase 2 double-blind, placebo controlled, proof of concept study, ZA-205, in obese secondary hypogonadal men to assess the impact of enclomiphene on metabolic parameters and quality of life under a diet and exercise regimen. This study was fully enrolled in February 2016 and six month data is expected in the third quarter of 2016.

We are also developing Proellex®, an orally administered selective blocker of the progesterone receptor in women, for the treatment of uterine fibroids and endometriosis. Uterine fibroids and endometriosis affect millions of women of reproductive age. Proellex® has shown statistically significant results in previous Phase 2 studies for endometriosis and uterine fibroids. We completed a low dose escalating study as permitted by the FDA in late 2011, to determine both signals of efficacy and safety for low oral doses of the drug. There was no evidence of elevations of liver enzymes over baseline, suggesting these lower doses avoid the type of adverse events seen at much higher doses in earlier studies. On October 8, 2012, we announced that the FDA has agreed to a reclassification of the full clinical hold to a partial clinical hold on low dose oral Proellex® to allow us to conduct a Phase 2 study in the treatment of endometriosis. We initiated this study in November 2012 and it was fully enrolled in January 2016.

On October 31, 2013, the Company held a meeting with the FDA to discuss the clinical development plan for low dose oral Proellex® in the treatment of uterine fibroids. During the meeting, the FDA provided guidance for endpoints it believed acceptable for the treatment of uterine fibroids in an efficacy study and instructed the Company to submit a request for lifting the full clinical hold. The Company has followed the FDA's recommendations and submitted the study protocol and the request for the full hold lift. Additionally, on March 17, 2014, we announced that the FDA indicated that we may proceed to conduct Phase 1 and Phase 2 studies of low dose oral Proellex® for endometriosis and uterine fibroids while remaining on partial clinical hold. This guidance indicated that the highest allowed dose will be 12 mg daily. On December 29, 2014, we announced that we have initiated a Phase 2B study for low dose oral Proellex® in the treatment of uterine fibroids. This study was fully enrolled in January 2016.

The Company has an active Investigational New Drug Application ("IND") for the vaginal delivery of Proellex® for the treatment of uterine fibroids. Since the clinical hold relates only to oral delivery of Proellex®, this IND has no clinical hold issues. In the first quarter of 2012, we initiated a Phase 2 vaginal administration study for the treatment of uterine fibroids and subsequently reported the final study results in January 2013. We held an end of Phase 2 meeting with the FDA in May 2013, to discuss a Phase 3 study design for vaginally delivered Proellex as a treatment for uterine fibroids. The FDA recommended that a Phase 2B study should be conducted prior to commencing a Phase 3 program. On December 29, 2014, we announced that we have initiated a Phase 2B study for vaginally delivered Proellex® in the treatment of uterine fibroids. This study was fully enrolled in January 2016.

As of December 31, 2015, we had accumulated losses of $302.3 million, approximately $21.4 million in cash and cash equivalents, and accounts payable and accrued expenses of approximately $2.9 million, in the aggregate. We anticipate that our current liquidity will be sufficient to continue the development of our product candidates into the first quarter of 2017. We continue to explore potential additional financing alternatives, including corporate partnering opportunities, that would provide sufficient funds to enable us to continue to develop our two product candidates through FDA approval; however, there can be no assurance that we will be successful in raising any such additional funds on a timely basis or at all. The foregoing matters raise substantial doubt about our ability to continue as a going concern.

Our Research and Development Program

Our product development pipeline, with milestone dates as expected as of the date of this report, is summarized in the table below:

Product Candidate (Indication)	**Status**	**Next Expected Milestone(s)**
Enclomiphene		
Secondary Hypogonadism	NDA submitted/Complete Response Letter Received	

Proellex®		
		Complete first course of treatment in a Phase 2B study (oral delivery) (H2 2016)
Uterine Fibroids	Phase 2	
		Complete first course of treatment in a Phase 2B study (vaginal delivery) (H2 2016)
Endometriosis	Phase 2	Topline data Phase 2 study (oral delivery) (H2 2016)

Enclomiphene

Product Overview

We are developing enclomiphene, a single isomer of clomiphene citrate which is an orally active proprietary small molecule compound. Enclomiphene is for the treatment of secondary hypogonadism in overweight men wishing to restore normal testicular function. Men with secondary hypogonadism exhibit low testosterone levels due to under stimulated testes but they are generally fertile. Enclomiphene is designed to treat the underlying mechanism, insufficient stimulation of the testes by the pituitary, which causes secondary hypogonadism. Secondary hypogonadism due to being overweight or obese is the single greatest cause of hypogonadism in general.

Testosterone is an important male hormone. Testosterone deficiency in men is linked to several negative physical and mental conditions, including loss of muscle tone, reduced sexual desire and deterioration of memory and certain other cognitive functions. Testosterone production normally decreases as men age and this decline can be accelerated by obesity, sometimes leading to testosterone deficiency. The leading therapy for low testosterone is AndroGel®, a commercially available testosterone replacement cream marketed by Abbvie Inc. (“Abbvie”) for the treatment of low testosterone, which we believe has had and continues to have significant sales in North America.

Based on our own clinical trial screening data, we believe over 70% of men that have low testosterone suffer from secondary hypogonadism, a pituitary defect which is characterized by suboptimal levels of LH (luteinizing hormone) and FSH (follicle stimulating hormone). LH and FSH are the pituitary hormones that stimulate testicular testosterone and sperm production, respectively. Men with secondary hypogonadism can be readily distinguished from those that have primary testicular failure via assessment of the levels of secretions of pituitary hormones, as men with primary testicular failure experience elevated secretions of pituitary hormones. In secondary hypogonadism, the low levels of LH and FSH fail to provide adequate hormone signaling to the testes, causing testosterone levels to drop to a level where we believe pituitary secretions fall under the influence of estrogen, which is enhanced in obese men, thus further suppressing the testicular stimulation from the pituitary.

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

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

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

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

On July 9, 2012, we announced that we reached an agreement with the FDA for the design of the pivotal efficacy studies for enclomiphene for the treatment of secondary hypogonadism. The pivotal studies were conducted under an SPA. On March 27, 2013, we announced that the top-line results from our first pivotal Phase 3 study, ZA-301, met both co-primary endpoints mandated by the FDA and we announced on September 16, 2013, that we met both

co-primary endpoints in the second pivotal study, ZA-302.

The 500 subject, six month, open label safety study, ZA-300, completed enrollment in February 2013 at 28 U.S. clinical sites. On September 16, 2013, we reported top-line results of this study. Additionally, we completed enrollment into a one year, 150 subject DEXA study, ZA-303, in January 2013 at 10 U.S. clinical sites. On October 21, 2014, we announced that this study identified no new safety signals, including no evidence of negative effects on bone mineral density.

On October 22, 2013, we announced that we received guidance from the FDA instructing the Company to request a meeting to discuss the adequacy of studies ZA-301 and ZA-302. In addition to this guidance, the FDA further noted they would allow us to run head-to-head studies against approved testosterone replacement products. These head-to-head studies, ZA-304 and ZA-305, were initiated in January 2014 and subsequently completed in September and August 2014, respectively. Both of these head-to-head studies achieved superiority for both co-primary endpoints and most secondary endpoints as compared to the approved testosterone replacement product.

On February 2, 2015, we announced that we electronically submitted our NDA to the FDA for enclomiphene. The FDA accepted the NDA for review on April 1, 2015 and later assigned a Prescription Drug User Fee (PDUFA) goal date of November 30, 2015. In addition, the Division of Bone, Reproductive and Urologic Products (the Division) of the FDA scheduled an advisory committee meeting to review the NDA for November 3, 2015. However, the Division subsequently cancelled the scheduled advisory committee meeting due to questions that arose late in the review regarding the bioanalytical method validation that could affect interpretability of certain pivotal study data. On December 1, 2015, we announced that we had received a Complete Response Letter (CRL) from the FDA. A CRL informs companies that an NDA cannot be approved in its present form. In the CRL, the FDA stated that, based on recent scientific developments, the design of the enclomiphene Phase 3 studies is no longer adequate to demonstrate clinical benefit and recommended that Repros conduct an additional Phase 3 study or studies to support approval in the target population. The FDA also noted concerns regarding study entry criteria, titration and bioanalytical method validation in the Phase 3 program. Subsequently, on February 4, 2016, the Company attended a meeting with the FDA reviewers and senior leaders to discuss resolution of issues identified during the NDA review. The meeting covered a broad range of topics surrounding the NDA data as well as emerging agency and expert thinking regarding the treatment of hypogonadism. The Company believes based on the meeting that the FDA is not closed to considering secondary hypogonadism as an indication. Additionally, in January 2016, the Company initiated a Phase 2 double-blind, placebo controlled, proof of concept study, ZA-205, in obese secondary hypogonadal men to assess the impact of enclomiphene on metabolic parameters and quality of life under a diet and exercise regimen. This study was fully enrolled in February 2016 and six month data is expected in the third quarter of 2016.

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

In addition, the Company continues to consider the potential for use of enclomiphene as an adjuvant therapy in hypogonadal men with Type 2 diabetes. The Company has an active IND open with the Division of Endocrine and Metabolic Products at the FDA for this indication. We believe there may be an association between the restoration of normal pituitary function and improvement of metabolic conditions such as Type 2 diabetes. Research has been published which demonstrates that increased insulin resistance, a characteristic implicated in Type 2 diabetes, is associated with the onset of secondary hypogonadism. Based on our own clinical trial screening data from our previously conducted Phase 2 study, we have found hypogonadism, obesity and Type 2 diabetes to be co-morbid conditions in a significant number of men. The results from this Phase 2 study indicated that the enclomiphene treated subjects showed statistically significant improvement in HbA1c and insulin, as well as HOMA-IR compared to placebo in men less than 65 years of age.

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

Proellex®

Product Overview

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

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

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

Up until the summer of 2009, all side effects exhibited in the studies were considered manageable and the benefit of Proellex® far outweighed the risk. However, in Phase 3 efficacy and larger Phase 3 safety studies in diverse populations, a small number of subjects exhibited serious adverse effects associated with elevated liver enzymes. As a result of these findings, we elected to stop the trials and the FDA subsequently placed Proellex® on full clinical hold. All women that experienced elevated liver enzymes and returned for follow-up visits returned to baseline conditions with no overnight hospitalization necessary. An analysis of all the subjects that experienced such serious adverse effects showed that the effect only occurred in a small percentage of subjects that were exposed to the 50 mg dose of the drug for any period of time. Based on these findings, we petitioned the FDA to allow us to conduct a low dose study to demonstrate both safety and signals of efficacy in low oral doses of Proellex®, up to 12 mg administered per day. The FDA upgraded the full clinical hold to a partial hold to allow the low dose study to be conducted. In addition, we are exploring vaginal delivery as an alternative administrative route to bypass first-pass liver effects and reduce systemic exposure, which is currently in a Phase 2 study.

Low Dose Oral Study

Pursuant to the terms of the partial clinical hold currently in place as a result of the liver toxicity exhibited by Proellex®, the FDA allowed us to run a single study to test low oral doses of Proellex® for signals of safety and efficacy. The study tested five different doses of Proellex® (1, 3, 6, 9 and 12 mg), with 1 mg being the first dose tested. Each dose was then compared to placebo with weekly assessments of liver function during both the placebo and drug period. Subjects were dosed with the active drug for 10 weeks, which allowed for adequate time to determine the impact of a given dose on trends in liver function. Each dose was tested in up to 12 different subjects and assessment of pharmacokinetic parameters was obtained at the start of dosing and the end of the dosing period to determine overall and maximum drug exposure for a given dose. We also monitored changes in menstrual bleeding patterns and ovulation as well as changes in endometrial thickness. The FDA required that an independent Drug Safety Monitoring Board be established and that the informed consent clearly state the liver toxicity previously experienced with Proellex®. We have completed this study and have announced that there was no evidence of elevations of liver enzymes over baseline, suggesting these lower doses avoid the type of adverse events seen at much higher doses in earlier studies.

On July 16, 2012, we announced that we held a teleconference with the FDA to discuss the development of low dose oral Proellex® as a treatment for endometriosis. Subsequently, on October 8, 2012, we announced that the FDA has agreed to reclassify the full clinical hold to a partial clinical hold on low dose oral Proellex® to allow us to conduct a Phase 2 study in the treatment of endometriosis. We initiated this 60 subject, four month active dosing study in November 2012 and it was fully enrolled in January 2016.

On October 31, 2013, the Company held a meeting with the FDA to discuss the clinical development plan for low dose oral Proellex® in the treatment of uterine fibroids. During the meeting, the FDA provided guidance for endpoints it believed acceptable for the treatment of uterine fibroids in an efficacy study and instructed the Company to submit a request for lifting the full clinical hold. The Company has followed the FDA’s recommendations and submitted the study protocol and the request for the full hold lift. Additionally, on March 17, 2014, we announced that the FDA indicated that we may proceed to conduct Phase 1 and Phase 2 studies of low dose oral Proellex® for endometriosis and uterine fibroids while remaining on partial clinical hold. This guidance indicated that the highest allowed dose will be 12 mg daily. On December 29, 2014, we announced that we have initiated a Phase 2B study for low dose oral Proellex® in the treatment of uterine fibroids. This study was fully enrolled in January 2016.

Vaginal Administration

We are assessing vaginal administration of Proellex® to avoid first pass liver effects and achieve higher reproductive tract concentrations of the drug while minimizing systemic exposure. We reported results from two in vivo animal studies which confirmed reduced maximum circulating concentrations of the drug when administered vaginally, as well as efficacy signals at substantially lower doses than oral administration. The Company has an active IND for the

vaginal delivery of Proellex® for the treatment of uterine fibroids. Since the clinical hold relates only to the oral delivery of Proellex®, this IND has no clinical hold issues. In the first quarter of 2012, we initiated a Phase 2 vaginal administration study for the treatment of uterine fibroids. In January 2013, we reported the final study results which indicated the 12 mg dose achieved statistically significant improvement in menstrual bleeding, uterine fibroid symptoms and reduction in fibroid volume even with the low number of subjects enrolled into the study (n=12 @ 12 mg). Based on these findings, the Company believes the 12 mg dose is appropriate for further development. We held an end of Phase 2 meeting with the FDA in May 2013, to discuss a Phase 3 study design for the vaginally delivered Proellex as a treatment for uterine fibroids. The FDA recommended that a Phase 2B study should be conducted prior to commencing a Phase 3 program. On December 29, 2014, we announced that we have initiated a Phase 2B study for vaginally delivered Proellex® in the treatment of uterine fibroids. This study was fully enrolled in January 2016.

Other Products

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

Business Strategy

We plan to focus our clinical program on (i) conducting a Phase 2B study for low dose oral Proellex® in the treatment of uterine fibroids, (ii) conducting a Phase 2B vaginal administration study for Proellex® in the treatment of uterine fibroids, (iii) conducting a Phase 2 study for low dose oral Proellex® for the treatment of endometriosis and (iv) conducting a Phase 2 proof of concept study for enclomiphene for the treatment of secondary hypogonadism. We anticipate that our current liquidity will be sufficient to continue the development of our product candidates into the first quarter of 2017. In the normal course of business we continue to explore potential corporate partnering opportunities for assistance in the clinical development funding and commercialization of our products, as appropriate; however, there can be no assurance that an acceptable corporate partnering opportunity will be successfully completed or that our current liquidity will be sufficient to fund all of our product development needs.

Research and Development

We have limited resources and utilize consultants and outside entities to perform clinical development and limited research activities in connection with preclinical studies and clinical trials. Our primary research and development (“R&D”) expenses for 2015 were for the payment for salaries and related employee expenses, contracted regulatory affairs activities, insurance coverage for clinical trials and prior product sales, contracted research and consulting fees, facility costs, fees associated with our patent portfolio and internal research and development supplies. We believe that these expenses will continue to be our primary R&D expenses in 2016.

-6-

Proellex® License Agreement with the National Institutes of Health

In 1999, we licensed rights to Proellex® from the National Institutes of Health ("NIH"), under an exclusive, worldwide license in the field of treatment of human endocrinologic pathologies or conditions in steroid-sensitive tissues which expires upon the expiration of the last licensed patent, currently 2017. This license agreement contains numerous detailed performance obligations, with time sensitive dates for compliance, relating to clinical development and commercialization activities required by us or our designated third-party providers, as well as additional financial milestones and royalties. If we fail to achieve the benchmarks specified in the commercial development plan attached to the license agreement or meet payment obligations, the NIH can terminate the license agreement and we lose our rights to develop and commercialize Proellex®. We and the NIH periodically update the commercial development plan. There can be no assurance that we will be able to meet any or all of the performance objectives in the future on a timely basis or at all, or that, if we fail to meet any of such objectives, the NIH will agree to revised objectives. The NIH also has the ability to terminate the agreement for an uncured material breach of the agreement, if we do not keep Proellex® reasonably available to the public after commercial launch or if we cannot reasonably satisfy unmet health and safety needs, among other reasons.

We provide annual updates to the NIH on the progress of our development of Proellex®. Based on our interaction with the NIH to date, we believe our license and relationship with the NIH are in good standing.

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

Manufacturing

We have identified multiple potential suppliers for the bulk active pharmaceutical ingredient ("API") used in enclomiphene, though we have not yet contracted with one. We have not faced any material problems obtaining the necessary quantities of enclomiphene for our clinical trials and, therefore, do not anticipate any material problems obtaining the API necessary for commercial production if enclomiphene is approved for sale. Additionally, we have contracted with Gregory Pharmaceutical Holdings, Inc., doing business as UPM Pharmaceuticals, for the finished drug product and packaging of enclomiphene for commercial production, if approved by the FDA for sale.

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

For the foreseeable future, we expect to continue to rely on third-party manufacturers and other third parties to produce, package and store sufficient quantities of enclomiphene and Proellex®. These product candidates are complicated and expensive to manufacture. If our third-party manufacturers fail to deliver our product candidates for clinical use on a timely basis, with sufficient quality, and at commercially reasonable prices, we may be required to delay or suspend clinical trials or otherwise discontinue development and production of our product candidates. While we may be able to identify replacement third-party manufacturers or develop our own manufacturing capabilities for these product candidates, this process would likely cause a delay in the availability of our product candidates and an increase in costs. In addition, third-party manufacturers may have a limited number of facilities in which our product candidates can be produced, and any interruption of the operation of those facilities due to events such as equipment malfunction or failure or damage to the facility could result in the cancellation of shipments, loss of product in the manufacturing process or a shortfall in available product candidates.

Sales and Marketing

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

Patents and Proprietary Information

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

Under a license agreement with the NIH, we have exclusive rights to four issued U.S. patents, which expire in 2017, two pending U.S. patent applications, and several foreign patents and pending applications made by the NIH regarding Proellex®. We also have two issued U.S. patents and seven pending U.S. patent applications, 112 foreign pending patent applications and 63 granted foreign patents that cover various formulations of Proellex® and methods for using Proellex®.

Therapeutic uses of our enclomiphene product candidate are covered in the United States by nine issued U.S. patents and eight pending patent applications. Foreign coverage of therapeutic uses of our enclomiphene product candidate includes 79 issued foreign patents and 111 foreign pending patent applications. The issued patents and pending applications relate to methods for treating certain conditions including the treatment of testosterone deficiency in men, the treatment of diabetes mellitus Type 2, the treatment of metabolic syndrome and conditions associated therewith, and the treatment of infertility in hypogonadal men. Enclomiphene (the trans-isomer of clomiphene) is purified from clomiphene citrate. A third party individual holds two issued patents related to the use of anti-estrogen such as clomiphene citrate and others for use in the treatment of androgen deficiency and disorders related thereto. We requested re-examination of one of these patents by the U.S. Patent and Trademark Office (“PTO”) based on prior art. The patent holder amended the claims in the re-examination proceedings, which led the PTO to determine that the amended claims were patentable in view of those publications under consideration and a re-examination certificate was issued. We subsequently filed a second request for re-examination by the PTO in light of a number of additional publications. The request was granted and all of the claims were finally rejected by the PTO in the re-examination. The patent holder appealed the rejections to the PTO Board of Patent Appeals and Interferences (the “PTO Board”) which ultimately reversed the rejections of several dependent claims in view of those publications under consideration. The patent holder filed a Notice of Appeal to the Federal Circuit on September 28, 2010 contesting the rejections maintained by the PTO Board. A decision was rendered by the Court of Appeals for the Federal Circuit on December 12, 2011, affirming the rejection of the appealed claims. The PTO issued an Ex Parte Reexamination Certificate on April 29, 2013, canceling the rejected claims and confirming the patentability of the remaining claims. Nevertheless, we believe that our development of enclomiphene does not infringe any of the remaining claims and that all of the remaining claims are invalid on various grounds including additional prior art publications. We also believe that the second of these two patents is invalid in view of published prior art not considered by the PTO. If necessary, we intend to vigorously defend any and all claims that may be brought by the holder of such patents in a court of competent jurisdiction in order to develop enclomiphene further. Adverse determinations in litigation proceedings could require us to seek licenses which may not be available on commercially reasonable terms, or at all, or subject us to significant liabilities, in which case we may not be able to successfully commercialize or out-license enclomiphene until such patents expire or are otherwise no longer in force.

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

Competition

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

Our main competitors for the treatment of testosterone deficiency are the testosterone replacement therapies currently being marketed. The current standard of care is AndroGel®, a topical gel for the replacement of testosterone. AndroGel® is marketed by Abbvie. There is another topical gel, Testim®, currently marketed by Endo International PLC, and a transdermal patch, AndroDerm®, marketed by Watson Pharmaceuticals. Eli Lilly and Company also entered into a licensing agreement with a third party for a topical testosterone treatment called Axiron®, which has become available in pharmacies. In addition, other companies such as Apricus Biosciences, Inc. and Clarus Therapeutics, Inc. are developing other products that would compete with enclomiphene. We believe we can compete with AndroGel® and the other replacement therapies because we believe that enclomiphene is the only drug with an NDA submitted that normalizes testicular function and may provide additional metabolic benefits. Based on our clinical trial supply cost to date, we currently expect that enclomiphene, if approved, can compete favorably on a cost basis with current testosterone replacement therapies.

Our main competitors for the treatment of uterine fibroids and endometriosis are GnRH agonists, especially Lupron®, the current therapeutic standard of care for uterine fibroids. Lupron® is marketed by Abbvie, which has far greater resources and marketing capabilities than we have. Recently Abbvie has licensed a Phase 3-ready molecule from Neurocrine Biosciences for the treatment of endometriosis. Gedeon Richter and Watson Pharmaceuticals have also entered into an exclusive license agreement to develop and market Esmya™ (an orally active selective progesterone receptor modulator) in the U.S. and Canada. In addition, surgical treatment of both uterine fibroids and endometriosis competes with Proellex® by removing uterine fibroids and by removing misplaced tissue in women with endometriosis. We believe we can potentially compete with Lupron® and other GnRH agonists because we believe that Proellex® will not present the same side effect of a decrease in bone mineral density given its specific focus on progesterone inhibition, which differentiates it from GnRH agonists that create a low estrogen state. There are additional companies developing similar progesterone-blocking technology.

Government Regulation

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

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

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

Phase 3 clinical trials are undertaken to further evaluate clinical efficacy and to test further for safety within an expanded patient population at geographically dispersed clinical study sites. Phase 1, Phase 2 or Phase 3 testing may not be completed successfully within any specific time period, if at all, with respect to any products being tested by a sponsor. Furthermore, the FDA or the Investigational Review Board may suspend clinical trials at any time on various grounds, including a finding that the healthy volunteers or patients are being exposed to an unacceptable health risk. This was evidenced when Proellex®, our product candidate for uterine fibroids and endometriosis, was placed on clinical hold by the FDA in summer 2009 due to liver toxicity data resulting from our clinical trials. Though the full clinical hold has been upgraded to a partial clinical hold, there can be no assurance that the partial hold will be lifted at any time.

Even if regulatory approvals for any products we may develop are obtained, we, our potential collaborators, our products, and the facilities manufacturing our products would be subject to continual review and periodic inspection. The FDA will require post-marketing reporting to monitor the safety of our products. Each drug-manufacturing establishment supplying the United States must be registered with the FDA. Manufacturing establishments are subject to periodic inspections by the FDA and must comply with the FDA's requirements regarding current Good Manufacturing Practices ("GMP"). In complying with current GMP, manufacturers must expend funds, time and effort in the area of production and quality control to ensure full technical compliance. We do not have any drug manufacturing capabilities and must rely on outside firms for this capability. The FDA stringently applies regulatory standards for manufacturing. Identification of previously unknown problems with respect to a product, manufacturer or facility may result in restrictions on the product, manufacturer or facility, including warning letters, suspensions of regulatory approvals, operating restrictions, delays in obtaining new product approvals, withdrawal of the product from the market, product recalls, fines, injunctions and criminal prosecution.

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

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

Third-Party Reimbursement and Pricing Controls

In the United States and elsewhere, sales of pharmaceutical products depend in significant part on the availability of reimbursement to the consumer from third-party payers, such as government and private insurance plans. Third-party payers are increasingly challenging the prices charged for medical products and services. Should any of our product candidates be approved for any commercial sales, it will be time consuming and expensive for us to go through the process of seeking reimbursement from Medicaid, Medicare and private payers.

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

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

The Hatch-Waxman Act

Under the U.S. Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act, newly approved drugs and indications benefit from a statutory period of non-patent marketing exclusivity. The Hatch-Waxman Act provides five year marketing exclusivity to the first applicant to gain approval of an NDA for a new chemical entity (“NCE”), meaning that the FDA has not previously approved any other new drug containing the same active ingredient. Both of our current product candidates are considered NCEs. The Hatch-Waxman Act prohibits approval of an abbreviated new drug application (“ANDA”), for a generic version of the drug during the

five-year exclusivity period. Protection under the Hatch-Waxman Act will not prevent the filing or approval of another full NDA, however, the applicant would be required to conduct its own adequate and well-controlled clinical trials to demonstrate safety and effectiveness. The Hatch-Waxman Act also provides three years of marketing exclusivity for the approval of new NDAs with new clinical trials for previously approved drugs and supplemental NDAs, for example, for new indications, dosages, or strengths of an existing drug, if new clinical investigations are essential to the approval. This three year exclusivity covers only the new changes associated with the supplemental NDA and does not prohibit the FDA from approving ANDAs for drugs containing the original active ingredient or indications.

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

Litigation

See Item 3 of Part I of this Form 10-K.

Employees and Consultants

Employees

At December 31, 2015, we had 26 full-time employees. We also utilize consultants as well as contract research organizations and other outside specialty firms for various services such as preclinical and clinical trial support, manufacturing, regulatory approval advice and accounting and human resource management. We believe our relationship with our employees is good.

Scientific Advisors and Consultants

We benefit from consultation with prominent scientists active in fields related to our technology. For this purpose, we have part-time consulting relationships with a number of scientific advisors. At our request, these advisors review the

feasibility of product development programs under consideration, provide advice about advances in areas related to our technology and aid in recruiting personnel. All of the advisors are employed by academic institutions or other entities and may have commitments to or advisory agreements with other entities that limit their availability to us. Our advisors are required to sign an agreement providing that, if appropriate, they are to disclose and assign to us any ideas, discoveries and inventions they develop in the course of providing consulting services. We also use consultants for various administrative needs. None of our advisors are otherwise affiliated with us.

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

Available Information

Our Internet site (www.reprosrx.com) makes available free of charge to all interested parties our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to those reports, as well as all other reports and schedules filed electronically with the Securities and Exchange Commission (the “SEC” or “Commission”), as soon as reasonably practicable after such material is electronically filed with or furnished to the SEC. Interested parties may also find reports, proxy and information statements and other information on issuers that file electronically with the SEC at the SEC's Internet site (http://www.sec.gov). In addition, we have made available on our Internet website under the heading “Corporate Governance” our Code of Business Conduct and Ethics and Code of Ethics for Senior Financial Officers. We intend to make available on our website any future amendments or waivers to our Code of Business Conduct and Ethics and Code of Ethics for Senior Financial Officers within four business days after any such amendments or waivers. The information on our Internet website is not part of this Form 10-K.

Item 1A. Risk Factors

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

Risks Relating to Our Business

Our ability to continue as a going concern may require that we raise additional funds no later than the first quarter of 2017, without which we may need to cease our business operations and begin liquidation proceedings.

Based upon our current expense and revenue assumptions, we anticipate that we will need to obtain additional financing no later than the first quarter of 2017. If our expenses are greater than expected or our clinical trials take longer than expected, we may be required to raise additional funds prior to that time. We will continue to explore various financing alternatives to address our liquidity needs. No assurance can be given that we will be successful in obtaining additional financing on acceptable terms or at all. We anticipate that if we are able to secure additional financing, that such financing could result in significant dilution of the ownership interests of our stockholders and may provide certain rights to the new investors senior to the rights of our current stockholders, including but not limited to, voting rights and rights to proceeds in the event of a sale or liquidation of the Company. We expect to continue to incur significant losses for the foreseeable future, and we may never achieve or sustain profitability. In the event that we are unable to obtain adequate financing to conduct operations, we may need to cease our business operations and begin liquidation proceedings. If we need to liquidate our assets, we would likely realize significantly less from them than the values at which they are carried on our financial statements.

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

We expect to make additional capital outlays and to increase operating expenditures over the next several years to support our preclinical development and clinical trial activities, particularly with respect to ongoing Phase 2 clinical trials for Proellex®. On February 2, 2015, we announced that we submitted the NDA for our enclomiphene product candidate to the FDA. The FDA accepted the NDA for review on April 1, 2015 and later assigned a Prescription Drug

User Fee Act (PDUFA) goal date of November 30, 2015. In addition, the Division of Bone, Reproductive and Urologic Products (the Division) of the FDA scheduled an advisory committee meeting to review the NDA for November 3, 2015. However, the Division subsequently cancelled the scheduled advisory committee meeting due to questions that arose late in the review regarding the bioanalytical method validation that could affect interpretability of certain pivotal study data. On December 1, 2015, we announced that we had received a Complete Response Letter (CRL) from the FDA. A CRL informs companies that an NDA cannot be approved in its present form. In the CRL, the FDA stated that, based on recent scientific developments, the design of the enclomiphene Phase 3 studies is no longer adequate to demonstrate clinical benefit and recommended that Repros conduct an additional Phase 3 study or studies to support approval in the target population. The FDA also noted concerns regarding study entry criteria, titration and bioanalytical method validation in the Phase 3 program. Subsequently, on February 4, 2016, the Company attended a meeting with the FDA reviewers and senior leaders to discuss resolution of issues identified during the NDA review. The meeting covered a broad range of topics surrounding the NDA data as well as emerging agency and expert thinking regarding the treatment of hypogonadism.

As a result of these events, the Company plans to focus its resources on the Phase 2B studies for Proellex® for the treatment of uterine fibroids, the Phase 2 study for Proellex® for the treatment of endometriosis and the Phase 2 study for enclomiphene for the treatment of secondary hypogonadism. Based on our current and planned clinical programs, we anticipate that our current liquidity will be sufficient to continue the development of our product candidates into the first quarter of 2017. However, it is possible that our clinical trial activities will be more costly and take longer than we anticipate; accordingly, there can be no assurance that additional capital will not be necessary prior to the time anticipated. 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 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. We may continue to seek additional funding through public or private financings, including equity or debt financings, and/or through other means, including collaborations and license agreements, as appropriate. 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. We anticipate that if we are able to secure additional financing, that such financing will result in significant dilution of the ownership interests of our stockholders and may provide certain rights to the new investors senior to the rights of our current stockholders, including but not limited to, voting rights and rights to proceeds in the event of a sale or liquidation of the Company. We expect to continue to incur significant losses for the foreseeable future, and we may never achieve or sustain profitability. In the event that we are unable to obtain adequate financing to conduct operations, we may need to cease our business operations and begin liquidation proceedings. If we need to liquidate our assets, we would likely realize significantly less from them than the values at which they are carried on our financial statements. The funds resulting from the liquidation of our assets would be used first to pay off the debt owed to any secured and unsecured creditors before any funds would be available to pay our stockholders, and any shortfall in the proceeds would directly reduce the amounts available for distribution, if any, to our creditors and to our stockholders. In the event we were required to liquidate, it is highly unlikely that stockholders would receive any value for their shares.

In recent years, the general economic and capital market conditions in the United States have varied significantly and have increased the cost of capital in many circumstances, and there is no certainty that economic conditions will permit us to raise capital in an amount to sufficiently fund our long-term plans, in 2016 or beyond. If economic conditions become worse, our future cost of equity or debt capital and access to the capital markets could be adversely affected. If we cannot raise adequate funds, we may be required to:

- delay, reduce the scope of or eliminate one or more of our development programs;
- relinquish, license or otherwise dispose of rights to technologies, product candidate or products that we would otherwise