REPROS THERAPEUTICS INC.
Form 10-Q
August 10, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 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 number: 001-15281

REPROS THERAPEUTICS INC.

(Exact Name of Registrant as Specified in its Charter)

	2408 Timberloch Place, Suite B-7 The Woodlands, Texas 77380	
Delaware	(Address of principal executive offices	76-0233274
(State or other jurisdiction of incorporation or organization)	and zip code) (281) 719-3400 (Registrant's telephone number, including area code)	(IRS Employer Identification No.)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the 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 o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, 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 o

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

Large accelerated filer ¨ Accelerated filer x Non-accelerated filer ¨ 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 o No x

As of August 3, 2015, there were outstanding 24,281,018 shares of Common Stock, par value $.001 per share, of the Registrant.

REPROS THERAPEUTICS INC.

For the Quarter Ended June 30, 2015

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FACTORS AFFECTING FORWARD-LOOKING STATEMENTS

This quarterly report on Form 10-Q includes "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 are subject to certain risks, uncertainties and assumptions. 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. These risks and uncertainties include risks associated with the progress of the Company’s New Drug Application, or NDA, for its enclomiphene product candidate and the review of the NDA by the Food and Drug Administration, or FDA; the success of the clinical trials for Proellex®; uncertainty related to the Company's ability to obtain approval of the Company's products by the FDA and regulatory bodies in other jurisdictions; uncertainty relating to the Company's patent portfolio; and other risks and uncertainties described in the Company's filings with the Securities and Exchange Commission. For additional discussion of such risks, uncertainties and assumptions, see "Part I. Financial Information - Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources" included elsewhere in this quarterly report on Form 10-Q and “Item 1A. Risk Factors” to Part I of Form 10-K for the fiscal year ended December 31, 2014.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

The following unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. In the opinion of management, all adjustments (which include only normal recurring adjustments) considered necessary for a fair statement of the interim periods presented have been included. The year-end balance sheet data was derived from audited financial statements, but does not include all the disclosures required by accounting principles generally accepted in the United States of America. Operating results for the three and six month periods ended June 30, 2015 are not necessarily indicative of the results that may be expected for the year ending December 31, 2015. For further information, refer to the financial statements and footnotes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2014.

REPROS THERAPEUTICS INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED BALANCE SHEETS

(unaudited and in thousands except share and per share amounts)

	June 30, 2015	December 31, 2014
ASSETS		
Current Assets		
Cash and cash equivalents	$32,150	$ 46,620
Prepaid expenses and other current assets	438	289
Total current assets	32,588	46,909
Fixed assets, net	14	32
Total assets	$32,602	$ 46,941
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Accounts payable	$2,159	$ 2,090
Accrued expenses	699	834
Total current liabilities	2,858	2,924
Commitments and contingencies (note 6)		
Stockholders' Equity		
Undesignated Preferred Stock, $.001 par value, 5,000,000 shares authorized, none issued and outstanding	-	-
Common Stock, $.001 par value, 75,000,000 shares authorized, 24,393,368 and 24,388,523 shares issued, respectively and 24,281,018 and 24,276,173 shares outstanding, respectively	24	24
Additional paid-in capital	320,480	318,437
Cost of treasury stock, 112,350 shares	(1,380)	(1,380)
Accumulated deficit	(289,380)	(273,064)
Total stockholders' equity	29,744	44,017
Total liabilities and stockholders' equity	$32,602	$ 46,941

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

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REPROS THERAPEUTICS INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited and in thousands except per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Revenues				
Interest income	$ 1	$ 2	$ 2	$ 5
Total revenues and other income	1	2	2	5
Expenses				
Research and development	6,450	7,491	13,771	15,060
General and administrative	1,342	1,256	2,547	2,482
Total expenses	7,792	8,747	16,318	17,542
Net loss	$ (7,791)	$ (8,745)	$ (16,316)	$ (17,537)
Loss per share - basic and diluted:	$ (0.32)	$ (0.38)	$ (0.67)	$ (0.76)
Weighted average shares used in loss per share calculation:				
Basic	24,278	23,102	24,277	23,068
Diluted	24,278	23,102	24,277	23,068

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

REPROS THERAPEUTICS INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(unaudited and in thousands except share and per share amounts)

	Common Stock		Additional Paid-in	Treasury Stock		Deficit Accumulated During the	Total Stockholders'
	Shares	Amount	Capital	Shares	Amount	Development Stage	Equity
Balance at December 31, 2014	24,388,523	$ 24	$ 318,437	112,350	$ (1,380)	$ (273,064)	$ 44,017
Stock based compensation	-	-	2,043	-	-	-	2,043
Issuance of 4,845 shares of common stock for the cashless exercise of 15,000 stock options	4,845	-	-	-	-	-	-
Net loss	-	-	-	-	-	(16,316)	(16,316)
Balance at June 30, 2015	24,393,368	$ 24	$ 320,480	112,350	$ (1,380)	$ (289,380)	$ 29,744
Balance at December 31, 2013	23,125,565	$ 23	$ 314,405	112,350	$ (1,380)	$ (240,529)	$ 72,519
Stock based compensation	-	-	1,875	-	-	-	1,875
Issuance of 72,910 shares of common stock for the cashless exercise of 98,329 stock options	72,910	-	-	-	-	-	-
Exercise of stock options to purchase common stock stock for cash ($1.56 to $9.60 per share)	23,334	-	147	-	-	-	147
Net loss	-	-	-	-	-	(17,537)	(17,537)
Balance at June 30, 2014	23,221,809	$ 23	$ 316,427	112,350	$ (1,380)	$ (258,066)	$ 57,004

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

REPROS THERAPEUTICS INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited and in thousands)

	Six Months Ended June 30,	
	2015	2014
Cash Flows from Operating Activities		
Net loss	$ (16,316)	$ (17,537)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	18	23
Noncash stock-based compensation	2,043	1,875
(Increase) decrease in prepaid expenses and other current assets	(251)	(194)
Increase (decrease) in accounts payable and accrued expenses	(66)	532
Net cash used in operating activities	(14,572)	(15,301)
Cash Flows from Investing Activities		
Capital expenditures	-	-
Net cash used in investing activities	-	-
Cash Flows from Financing Activities		
Exercise of stock options & warrants	-	147
Proceeds from a shareholder transaction	102	-
Net cash provided by financing activities	102	147
Net decrease in cash and cash equivalents	(14,470)	(15,154)
Cash and cash equivalents at beginning of period	46,620	75,807
Cash and cash equivalents at end of period	$ 32,150	$ 60,653

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

REPROS THERAPEUTICS INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

June 30, 2015

(Unaudited)

NOTE 1 — Organization, Operations and Liquidity

Repros Therapeutics Inc. (the "Company," "RPRX," "Repros," or "we," "us" or "our") was organized on August 20, 1987. We a biopharmaceutical company focused on the development of new drugs to treat hormonal and reproductive system disorders.

Our enclomiphene product candidate, formerly known as Androxal®, is a single isomer of clomiphene citrate and is an orally active proprietary small molecule compound. We expect to rename this product candidate in the near future. We are developing enclomiphene 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. The Company believes that secondary hypogonadism due to being overweight or obese is the single greatest cause of hypogonadism in general. On February 2, 2015, we announced that we electronically submitted our New Drug Application ("NDA") to the Food and Drug Administration ("FDA") for enclomiphene. Subsequently, we announced that the NDA was accepted by the FDA and the FDA assigned a Prescription Drug User Fee Act ("PDUFA") goal date of November 30, 2015. In addition, we have announced the FDA has scheduled the advisory committee to review the Company's NDA on November 3, 2015.

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. On December 29, 2014, we announced that we have initiated two Phase 2B studies for low dose Proellex® in the treatment of uterine fibroids and are currently conducting a Phase 2 study in the treatment of endometriosis.

Our product development pipeline, with 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 accepted and under review	PDUFA date of November 30, 2015
Proellex®		
Uterine Fibroids	Phase 2	Complete first course of treatment in a Phase 2B study (oral delivery) (Q2 2016) Complete first course of treatment in a Phase 2B study (vaginal delivery) (Q2 2016)
Endometriosis	Phase 2	Fully enroll Phase 2 study (oral delivery) (Q1 2016)

As of June 30, 2015, we had accumulated losses of $289.4 million, approximately $32.2 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 second half of 2016. 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.

Recent Accounting Pronouncements

In August 2014, the FASB issued Accounting Standards Update No. 2014-15, “Presentation of Financial Statements - Going Concern.” The new standard requires management to evaluate whether there are conditions or events that raise substantial doubt about an entity's ability to continue as a going concern for both annual and interim reporting periods. This guidance is effective for us for the fiscal year beginning January 1, 2016 and interim periods thereafter. The guidance is not expected to have a material impact on our consolidated financial statements.

In June 2014, the FASB issued Accounting Standards Update 2014-10, “Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation.” The guidance eliminates the definition of a development stage entity thereby removing the incremental financial reporting requirements from U.S. Generally Accepted Accounting Principles for development stage entities, primarily presentation of inception to date financial information. The provisions of the amendment is effective for annual reporting periods beginning after December 15, 2015. We elected to adopt ASU 2014-10 early and as an early adopter, we are no longer providing inception-to-date financial information in our consolidated financial statements.

In May 2014, the FASB issued Accounting Standards Update 2014-09, “Revenue from Contracts with Customers” (“ASU 2014-09”). ASU 2014-09 is a comprehensive new revenue recognition model requiring a company to recognize revenue to depict the transfer of goods or services to a customer at an amount reflecting the consideration it expects to receive in exchange for those goods or services. In adopting ASU 2014-09, companies may use either a full retrospective or a modified retrospective approach. Additionally, this guidance requires improved disclosures regarding the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. On July 9, 2015, the FASB voted to delay the effective date of this standard by one year. This deferral resulted in ASU 2014-09 being effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2017. The Company is currently assessing the impact of the new standard on our consolidated financial statements.

NOTE 2 — Revision of Prior Years' Financial Statements

While preparing its financial statements for the year ended December 31, 2014, the Company identified a prior period error related to the accounting for patent costs. As disclosed in its prior filings, historically the Company had capitalized patent related costs associated with its drug candidates, enclomiphene and Proellex®. However, the Company has now concluded that these costs should have been expensed as research and development costs since the related products were, at the time the costs were incurred, in the development phase and had not been approved by the FDA. The Company concluded this error was not material individually or in the aggregate to any of the prior reporting periods, and therefore, no restatements of previously issued financial statements were necessary. However, if the entire correction had been recorded in the fourth quarter of 2014, the cumulative impact would have been material to the fourth quarter of 2014, and would have impacted the comparability to prior periods. As such, revisions for the prior periods are reflected in the financial statements herein. The quarter ended June 30, 2015 was not affected.

At December 31, 2013, accumulated deficit and shareholders' equity were reported as ($237,623) and $75,425, respectively, and were revised to ($240,529) and $72,519, respectively.

The effects of the error correction on the consolidated statements of operations for the three and six month periods ended June 30, 2014 are as follows (in thousands):

	Three months ended June 30, 2014			Six months ended June 30, 2014		
	As previously reported	Correction	As revised	As previously reported	Correction	As revised
Research and development	$ 7,450	$ 41	$ 7,491	$ 14,775	$ 285	$ 15,060
Total expenses	8,706	41	8,747	17,257	285	17,542
Net loss	(8,704)	(41)	(8,745)	(17,252)	(285)	(17,537)
Loss per share – basic and diluted	(0.38)	(0.00)	(0.38)	(0.75)	(0.01)	(0.76)

The effects of the error correction on the consolidated statements of cash flows for the six month period ended June 30, 2014 are as follows (in thousands):

	Six months ended June 30, 2014 Correction

	As previously reported		As revised
Net cash used in operating activities	$(14,773)	$ (528)	$(15,301)
Net cash used in investing activities	(528)	528	(0)

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NOTE 3 — Accrued Expenses

Accrued expenses consist of the following (in thousands):

	June 30, 2015	December 31, 2014
Research and development costs	$ 556	$ 284
Personnel related costs	56	458
Other	87	92
Total	$ 699	$ 834

NOTE 4 — Loss Per Share

Basic loss per share is computed by dividing net loss by the weighted average number of shares of common stock outstanding during the period. Diluted net loss per share is computed by dividing net loss by the weighted average number of shares of common stock and dilutive common stock equivalents outstanding. Given that the Company is in a loss position for each of the periods presented, there is no difference between basic and diluted net loss per share since the effect of common stock equivalents would be anti-dilutive and, therefore, they are excluded from the diluted net loss per share calculation.

The following table presents information necessary to calculate loss per share for the three and six month periods ended June 30, 2015 and 2014 (in thousands, except per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Net loss	$ (7,791)	$ (8,745)	$ (16,316)	$ (17,537)
Average common shares outstanding	24,278	23,102	24,277	23,068
Basic and diluted loss per share	$ (0.32)	$ (0.38)	$ (0.67)	$ (0.76)

Potential common stock of 3,237,907 and 4,086,553 common shares underlying stock options and warrants for the periods ended June 30, 2015 and 2014, respectively, were excluded from the above calculation of diluted loss per share because they were anti-dilutive. Other potential common stock at June 30, 2015 includes Series A Warrants to purchase 39,595 shares of our common stock at an exercise price of $0.01 and Series B Warrants to purchase 429,704 shares of our common stock at an exercise price of $2.49 issued in our February 8, 2011 public offering. Other potential common stock at June 30, 2014 includes Series A Warrants to purchase 877,137 shares of our common stock

at an exercise price of $0.01 and Series B Warrants to purchase 809,805 shares of our common stock at an exercise price of $2.49 issued in our February 8, 2011 public offering.

NOTE 5 – Stock-Based Compensation

During the three month period ended June 30, 2015, the Compensation Committee of the Company's Board of Directors approved grants of options to purchase 30,000 shares of our common stock to employees and directors under the 2011 Equity Incentive Plan. Of the options granted during the three month period ended June 30, 2015, 25,000 options vest over a one year period and 5,000 options vest over a three year period. During the six month period ended June 30, 2015, the Compensation Committee of the Company's Board of Directors approved grants of options to purchase 399,000 shares of our common stock to employees under the 2011 Equity Incentive Plan. Of the options granted, 374,000 options vest over a three year period and 25,000 vest over a one year period. Additionally, during the six month period ended June 30, 2015, 56,250 options either expired or were forfeited.

NOTE 6 — Commitments and Contingencies

Therapeutic uses of our enclomiphene product candidate are covered in the United States by nine issued U.S. patents and nine pending patent applications. Foreign coverage of therapeutic uses of our enclomiphene product candidate includes 76 issued foreign patents and 100 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.

On July 19, 2013, we received a letter from Dr. Harry Fisch threatening to file a lawsuit against us and two of our executive officers (Joseph S. Podolski, President and Chief Executive Officer and Ron Wiehle, Executive Vice President), seeking addition of Dr. Harry Fisch as an inventor on three of our patents, U.S. Patent Nos. 7,173,064, 7,737,185 and 7,759,360, covering therapeutic uses of enclomiphene. We believe that these allegations are without merit and on August 2, 2013, we commenced a lawsuit against Dr. Fisch in the U.S. District Court for the Southern District of Texas seeking a declaratory judgment that he should not be added as inventor to any of these patents. On October 2, 2013, Dr. Fisch filed counterclaims to our complaint seeking correction of inventorship of the three patents at issue to name Dr. Fisch as a co-inventor of the applications leading to these patents. Dr. Fisch subsequently stipulated that he does not claim to be a co-inventor of U.S. Patent No. 7,173,064. The court granted summary judgment in favor of the Company on separate equitable and legal grounds, and entered judgment on December 23, 2014. Our request for attorney's fees was denied. On February 9, 2015, Dr. Fisch filed a notice of appeal of the summary judgment rulings to the United States Court of Appeals for the Federal Circuit. Dr. Fisch filed his opening appeal brief on May 20, 2015. Our opposition brief was filed on August 6, 2015. Oral argument on appeal remains to be scheduled.

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Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion contains forward-looking statements, within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act") that involve risk and uncertainties. Any statements contained in this quarterly report that are not statements of historical fact may be forward-looking statements. When we use the words "may," "anticipates," "believes," "plans," "expects" and similar expressions, we are identifying forward-looking statements. Forward-looking statements involve risks and uncertainties which may cause our actual results, performance or achievements to be materially different from those expressed or implied by forward-looking statements. The following discussion of financial condition should be read in conjunction with the accompanying consolidated financial statements and related notes.

Repros Therapeutics Inc.

The Company 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.

We are developing enclomiphene, formerly known as Androxal®, a single isomer of clomiphene citrate which is an orally active proprietary small molecule compound. The Food and Drug Administration (the “FDA”) rejected the proprietary name of Androxal® because it evokes the word “androgen”, which is a male sex hormone, and enclomiphene is not an androgen. The Company expects to rename this product candidate in the near future. 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. The Company believes that secondary hypogonadism due to being overweight or obese is the single greatest cause of hypogonadism in general. As of 2013, sales of preparations for the treatment of low testosterone have exceeded $2 billion in the U.S. and first tier pharmaceutical companies have entered 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 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”). We have completed both Phase 3 pivotal efficacy

studies. 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. Subsequently, we announced that the NDA was accepted by the FDA and the FDA assigned a Prescription Drug User Fee Act (“PDUFA”) goal date of November 30, 2015. In addition, we have announced the FDA has scheduled the advisory committee to review the Company’s NDA on November 3, 2015. In conjunction with the review process and the advisory committee meeting, we plan to respond to any questions or issues raised by the FDA. The NDA includes a collection of data on safety and efficacy from over 20 studies, including four Phase 3 efficacy studies. Regardless of the outcome of the advisory committee meeting, there can be no assurance that the FDA will approve our enclomiphene product candidate. Additionally, we have announced the European Medicines Agency (“EMA”) has informed the Company that its enclomiphene citrate capsules are eligible for submission for a centralized marketing authorization application (“MAA”) as a New Active Substance. Granting New Active Substance status will allow an application to be made for a supplementary protection certificate which, if granted, can extend the exclusivity period of the product. Confirmation of eligibility for submission is not predictive of the EMA’s ultimate approval of an MAA.

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. To date, we have experienced difficulty enrolling subjects into this study due to changes in the current treatment of this disorder. We believe we can have this study fully enrolled in the first quarter of 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.

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 reported 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 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.

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 accepted and under review	PDUFA date of November 30, 2015
Proellex®		
Uterine Fibroids	Phase 2	Complete first course of treatment in a Phase 2B study (oral delivery) (Q2 2016) Complete first course of treatment in a Phase 2B study (vaginal delivery) (Q2 2016)
Endometriosis	Phase 2	Fully enroll Phase 2 study (oral delivery) (Q1 2016)

As of June 30, 2015, we had accumulated losses of $289.4 million, approximately $32.2 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 second half of 2016. 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.

Enclomiphene

Product Overview

We are developing enclomiphene, formerly known as Androxal®, a single isomer of clomiphene citrate which is an orally active proprietary small molecule compound. The FDA rejected the proprietary name of Androxal® because it evokes the word “androgen”, which is a male sex hormone, and enclomiphene is not an androgen. The Company expects to rename this product candidate in the near future. 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. The Company believes that 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 Abbott Laboratories (“Abbott”) 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.

Enclomiphene is in the midst of a full regulatory approval process, including pivotal Phase 3 trials, long-term open label safety studies and a dual-energy X-ray absorptiometry (DEXA) study, as well as other requirements. Enclomiphene is closely related chemically to the drug, Clomid®, which is approved for use in women to treat certain infertility disorders. Clomid® contains both the trans and cis isomers of clomiphene citrate; enclomiphene contains only the trans isomer. The FDA has indicated that testicular tumors, gynecomastia and adverse ophthalmologic events, which have been reported in males taking Clomid®, are potential risks that should be included in informed consent forms for our enclomiphene clinical trials. We do not believe that enclomiphene will present with the same adverse events given its reduced half-life and lack of cis isomer as compared to Clomid®. In our preclinical studies and our clinical trials to date, we have observed no evidence of any of these events except for certain ophthalmologic events in our preclinical dog study at doses significantly higher than those administered in the clinical trials. All clinical trial results are subject to review by the FDA and the FDA may disagree with our conclusions about safety and efficacy.

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. Subsequently, we announced that the NDA was accepted by the FDA and the FDA assigned a PDUFA goal date of November 30, 2015. In addition, we have announced the FDA has scheduled the advisory committee to review the Company's NDA on November 3, 2015. In conjunction with the review process and the advisory committee meeting, we plan to respond to any questions or issues raised by the FDA. The NDA includes a collection of data on safety and efficacy from over 20 studies, including four Phase 3 efficacy studies. Regardless of the outcome of the advisory committee meeting, there can be no assurance that the FDA will approve our enclomiphene product candidate. Additionally, the EMA has informed the Company that its enclomiphene citrate capsules are eligible for submission for a centralized MAA as a New Active Substance. Granting New Active Substance status will allow an application to be made for a supplementary protection certificate which, if granted, can extend the exclusivity period of the product. Confirmation of eligibility for submission is not predictive of the EMA's ultimate approval of an MAA.

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, as an adjunct therapy to a program of diet and exercise, 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

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. To date, we have experienced difficulty enrolling subjects into this study due to changes in the current treatment of this disorder. We believe we can have this study fully enrolled in the first quarter of 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.

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.

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 and (iii) conducting a Phase 2 study for low dose oral Proellex® for the treatment of endometriosis. With respect to enclomiphene, on February 2, 2015, we reported that the NDA was electronically submitted to the FDA. Subsequently, we announced that the NDA was accepted by the FDA, that the FDA assigned a PDUFA goal date of November 30, 2015 and that the FDA has scheduled the advisory committee meeting to review the Company's NDA on November 3, 2015. We anticipate that our current liquidity will be sufficient to continue the development of our product candidates into the second half of 2016. Should we undertake additional strategies, such as commercialization, we will require additional capital prior to the time anticipated. 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.

Corporate Information

We were organized as a Delaware corporation in August 1987. Our principal executive offices are located at 2408 Timberloch Place, Suite B-7, The Woodlands, Texas, 77380, and our telephone number is (281) 719-3400. We maintain an internet website at www.reprosrx.com. The information on our website or any other website is not incorporated by reference into this quarterly report and does not constitute a part of this quarterly report. Our Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K and all amendments to such reports are made available free of charge through the Investor Relations section of our website as soon as reasonably practicable after they have been filed or furnished with the Securities and Exchange Commission.

General

We have 26 full-time employees. We utilize the services of contract research organizations, contract manufacturers and various consultants to assist us in performing clinical and regulatory services for the clinical development of our products. We are substantially dependent on our various contract groups to adequately perform the activities required to obtain regulatory approval of our products.

We have accumulated net operating losses through June 30, 2015 and the value of the tax asset associated with these accumulated net operating losses may be substantially diminished in value due to various tax regulations, including change in control provisions in the tax code. Additionally, during 2013, the Company completed an analysis of its section 382 limit. Based on this analysis, the Company concluded that the amount of net operating loss (“NOL”) carryforwards and the credits available to offset taxable income is limited under section 382. See “Critical Accounting Policies and the Use of Estimates – Income Taxes,” below.

Losses have resulted principally from costs incurred in conducting clinical trials for our product candidates, in research and development activities related to efforts to develop our products and from the associated administrative costs required to support those efforts. There can be no assurance that we will be able to successfully complete the transition from a development stage company to the successful introduction of commercially viable products. Our ability to achieve profitability will depend on, among other things, successfully completing the clinical development of our products in a reasonable time frame and at a reasonable cost, obtaining regulatory approvals, establishing marketing, sales and manufacturing capabilities or collaborative arrangements with others that possess such capabilities, and, if applicable, continuing to raise sufficient funds to finance our activities. There can be no assurance that we will be able to achieve profitability.

Critical Accounting Policies and the Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Accrued Expenses

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

Research and Development Expenses

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

Stock-Based Compensation

We had one stock-based compensation plan at June 30, 2015, the 2011 Equity Incentive Plan. Accounting for stock-based compensation generally requires the recognition of the cost of employee services for stock-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

Our losses from inception to date have resulted principally from costs incurred in conducting clinical trials and in research and development activities related to efforts to develop our products and from the associated administrative costs required to support those efforts. We have recorded a deferred tax asset for our NOLs; however, as the Company has incurred losses since inception, and since there is no certainty of future profits, a valuation allowance has been provided in full on our deferred tax assets in the accompanying consolidated financial statements. Additionally, during 2013, the Company completed an analysis of its section 382 limit. Based on this analysis, the Company concluded that the amount of NOL carryforwards and the credits available to offset taxable income is limited under section 382. Accordingly, if the Company generates taxable income in any year in excess of its then annual limitation, the Company may be required to pay federal income taxes even though it has unexpired NOL carryforwards. Additionally, because U.S. tax laws limit the time during which NOLs and tax credit carryforwards may be applied against future taxable income and tax liabilities, the Company may not be able to take full advantage of its NOLs and tax credit carryforwards for federal income tax purposes. Future public and private stock placements may create additional limitations on the Company’s NOLs, credits and other tax attributes.

Recent Accounting Pronouncements

In August 2014, the FASB issued Accounting Standards Update No. 2014-15, “Presentation of Financial Statements - Going Concern.” The new standard requires management to evaluate whether there are conditions or events that raise substantial doubt about an entity's ability to continue as a going concern for both annual and interim reporting periods. This guidance is effective for us for the fiscal year beginning January 1, 2016 and interim periods thereafter. The guidance is not expected to have a material impact on our consolidated financial statements.

In June 2014, the FASB issued Accounting Standards Update 2014-10, “Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation.” The guidance eliminates the definition of a development stage entity thereby removing the incremental financial reporting requirements from U.S. Generally Accepted Accounting Principles for development stage entities, primarily presentation of inception to date financial information. The provisions of the amendment is effective for annual reporting periods beginning after December 15, 2015. We elected to adopt ASU 2014-10 early and as an early adopter, we are no longer providing inception-to-date financial information in our consolidated financial statements.

In May 2014, the FASB issued Accounting Standards Update 2014-09, “Revenue from Contracts with Customers” (“ASU 2014-09”). ASU 2014-09 is a comprehensive new revenue recognition model requiring a company to recognize revenue to depict the transfer of goods or services to a customer at an amount reflecting the consideration it expects to receive in exchange for those goods or services. In adopting ASU 2014-09, companies may use either a full retrospective or a modified retrospective approach. Additionally, this guidance requires improved disclosures regarding the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. On July 9, 2015, the FASB voted to delay the effective date of this standard by one year. This deferral resulted in ASU 2014-09 being effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2017. The Company is currently assessing the impact of the new standard on our consolidated financial statements.

Results of Operations

Comparison of the three and six month periods ended June 30, 2015 and 2014

Revenues and Other Income

Total revenues and other income decreased to $1,000 for the three month period ended June 30, 2015 as compared to $2,000 for the same period in the prior year. Total revenue and other income decreased to $2,000 for the six month period ended June 30, 2015 as compared to $5,000 for the same period in the prior year. The decrease for the three and six month periods ended June 30, 2015 as compared to the same periods in the prior year was primarily due to decreased cash balances resulting in decreased interest income.

Research and Development Expenses

R&D expenses include contracted services relating to our clinical product development activities which include preclinical studies, clinical trials, expenses associated with our patent portfolio, regulatory affairs, including FDA filing fees, 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 enclomiphene and Proellex®. R&D expenses also include internal operating expenses relating to our general research and development activities. R&D expenses decreased 14%, or $1.0 million, to $6.5 million for the three month period ended June 30, 2015, as compared to $7.5 million for the same period in the prior year. Our primary R&D expenses for the three month periods ended June 30, 2015 and 2014 are shown in the following table (in thousands):

	Three months ended June 30,			
Research and Development	2015	2014	Variance	Change (%)
Enclomiphene clinical development	$ 2,365	$ 5,106	$ (2,741)	(54)%
Proellex® clinical development	1,359	587	772	132 %
Payroll and benefits	1,565	1,069	496	46 %
Operating and occupancy	1,161	729	432	59 %
Total	$ 6,450	$ 7,491	$ (1,041)	(14)%

Operating and occupancy expense for the three and six month periods ended June 30, 2014 has been revised. For a further description of the revisions, see Note 2 – "Revision of Prior Years' Financial Statements" of the Notes to Condensed Consolidated Financial Statements.

For the three month period ended June 30, 2015, as compared to the same period in 2014, R&D expenses related to the clinical development of enclomiphene decreased 54%, or approximately $2.7 million, primarily due to the completion of all Phase 3 clinical trials. R&D expenses related to the clinical development of Proellex® increased 132%, or approximately $772,000, due to increased expenses associated with our Phase 2B clinical trials for the treatment of uterine fibroids.

Payroll and benefits expenses increased 46%, or approximately $496,000, to $1.6 million for the three month period ended June 30, 2015, as compared to $1.1 million for the same period in the prior year. Included in payroll and benefits expense is a charge for non-cash stock-based compensation of $546,000 for the three month period ended June 30, 2015, as compared to $451,000 for the same period in the prior year. Additionally, salaries for the three month period ended June 30, 2015 were $886,000, as compared to $482,000 for the same period in the prior year. Salary expense for the three month period ended June 30, 2015 included a bonus awarded to the R&D personnel in the amount of $338,000 upon the FDA's acceptance of the NDA for enclomiphene.

Operating and occupancy expenses increased 59%, or approximately $432,000, to $1.2 million for the three month period ended June 30, 2015, as compared to $729,000 for the same period in the prior year, primarily due to increased legal expenses.

R&D expenses decreased 9%, or approximately $1.3 million, to $13.8 million for the six month period ended June 30, 2015, as compared to $15.1 million for the same period in the prior year. Our primary R&D expenses for the six month periods ended June 30, 2015 and 2014 are shown in the following table (in thousands):

	Six months ended June 30,			
Research and Development	2015	2014	Variance	Change (%)
Enclomiphene clinical development	$ 6,434	$ 10,105	$ (3,671)	(36)%
Proellex® clinical development	2,180	1,064	1,116	105 %
Payroll and benefits	2,856	2,134	722	34 %
Operating and occupancy	2,301	1,757	544	31 %
Total	$ 13,771	$ 15,060	$ (1,289)	(9)%

For the six month period ended June 30, 2015, as compared to the same period in 2014, R&D expenses related to the clinical development of enclomiphene decreased 36%, or approximately $3.7 million, primarily due to the completion of all Phase 3 clinical trials, partially offset by the payment of $2.3 million to the FDA associated with the submission

of our NDA for the product candidate. R&D expenses related to the clinical development of Proellex® increased 105%, or approximately $1.1 million, due to increased expenses associated with our Phase 2B clinical trials for the treatment of uterine fibroids.

Payroll and benefits expenses increased 34%, or approximately $722,000, to $2.9 million for the six month period ended June 30, 2015, as compared to $2.1 million for the same period in the prior year. Included in payroll and benefits expense is a charge for non-cash stock-based compensation of $1.1 million for the six month period ended June 30, 2015, as compared to $929,000 for the same period in the prior year. Additionally, salaries for the six month period ended June 30, 2015 were $1.5 million, as compared to $963,000 for the same period in the prior year. Salary expense for the six month period ended June 30, 2015 included a bonus awarded to the R&D personnel in the amount of $338,000 upon the FDA’s acceptance of the NDA for enclomiphene.

Operating and occupancy expenses increased 31%, or approximately $544,000, to $2.3 million for the three month period ended June 30, 2015, as compared to $1.8 million for the same period in the prior year, primarily due to increased legal expenses.

Through June 30, 2015 we have incurred approximately $66.7 million for the development of enclomiphene and approximately $65.0 million for the development of Proellex®. These accumulated costs exclude any internal operating expenses.

General and Administrative Expenses

General and administrative ("G&A") expenses increased 7%, or approximately $86,000, to $1.34 million for the three month period ended June 30, 2015, as compared to $1.26 million for the same period in the prior year. Our primary G&A expenses for the three month periods ended June 30, 2015 and 2014 are shown in the following table (in thousands):

	Three months ended June 30,			
General and Administrative	2015	2014	Variance	Change (%)
Payroll and benefits	$ 846	$ 779	$ 67	9 %
Operating and occupancy	496	477	19	4 %
Total	$ 1,342	$ 1,256	$ 86	7 %

G&A payroll and benefits expenses include salaries, bonuses, non-cash stock-based compensation expense and fringe benefits. Included in payroll and benefits expense is a charge for non-cash stock-based compensation of $474,000 for the three month period ended June 30, 2015, as compared to $504,000 for the same period in the prior year. Additionally, salaries for the three month period ended June 30, 2015 were $336,000, as compared to $244,000 for the same period in the prior year. Salary expense for the three month period ended June 30, 2015 included a bonus awarded to the G&A personnel in the amount of $80,000 upon the FDA's acceptance of the NDA for enclomiphene.

G&A operating and occupancy expenses, which include expenses to operate as a public company, increased 4%, or approximately $19,000, to $496,000 for the three month period ended June 30, 2015 as compared to $477,000 for the same period in the prior year primarily due to increases in professional services and travel expenses, partially offset by a decrease in Delaware franchise tax.

G&A expenses increased 3%, or approximately $65,000, to $2.55 million for the six month period ended June 30, 2015, as compared to $2.48 million for the same period in the prior year. Our primary G&A expenses for the six month periods ended June 30, 2015 and 2014 are shown in the following table (in thousands):

	Six months ended June 30,			
General and Administrative	2015	2014	Variance	Change (%)

Payroll and benefits	$ 1,589	$ 1,514	$ 75	5 %
Operating and occupancy	958	968	(10)	(1)%
Total	$ 2,547	$ 2,482	$ 65	3 %

G&A payroll and benefits expenses include salaries, bonuses, non-cash stock-based compensation expense and fringe benefits. Included in payroll and benefits expense is a charge for non-cash stock-based compensation of $922,000 for the six month period ended June 30, 2015, as compared to $946,000 for the same period in the prior year. Additionally, salaries for the six month period ended June 30, 2015 were $590,000, as compared to $490,000 for the same period in the prior year. Salary expense for the six month period ended June 30, 2015 included a bonus awarded to the G&A personnel in the amount of $80,000 upon the FDA's acceptance of the NDA for enclomiphene.

G&A operating and occupancy expenses, which include expenses to operate as a public company, decreased 1%, or approximately $10,000, to $958,000 for the six month period ended June 30, 2015, as compared to $968,000 for the same period in the prior year primarily due to a decrease in Delaware franchise tax, partially offset by an increase in professional services expense.

Off-Balance Sheet Arrangements

As of June 30, 2015, we did not have any off-balance sheet arrangements.

Liquidity and Capital Resources

Since our inception, we have financed our operations primarily with proceeds from private placements and public offerings of equity securities and with funds received under collaborative agreements.

Our primary use of cash to date has been in operating activities to fund research and development, including preclinical studies and clinical trials, and general and administrative expenses. We had cash and cash equivalents of approximately $32.2 million as of June 30, 2015 as compared to $46.6 million as of December 31, 2014. All cash and cash equivalents as of June 30, 2015 and December 31, 2014 were held in an account backed by U.S. government securities.

Net cash of approximately $14.6 million and $15.3 million was used in operating activities during the six month periods ended June 30, 2015 and 2014, respectively. The major use of cash for operating activities for the six month period ended June 30, 2015 was to fund our clinical development programs and associated administrative costs. No cash was used in investing activities during the six month period ended June 30, 2015. Cash provided by financing activities during the six month period ended June 30, 2015 was approximately $102,000 due to the receipt of that amount from a former 10% shareholder of the Company in accordance with Section 16(a) under the Securities Exchange Act of 1934, as amended.

We have experienced negative cash flows from operations since inception. We will require substantial funds for R&D, including preclinical studies and clinical trials of our product candidates, and to commence sales and marketing efforts, if appropriate, if the FDA or other regulatory approvals are obtained. Based on our current and planned clinical activities, we believe that our current liquidity will be sufficient to continue the development of our product candidates into the second half of 2016. 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. Our capital requirements will depend on many factors, which are discussed in detail in “Item 1A. Risk Factors” to Part I of Form 10-K for the fiscal year ended December 31, 2014. Additionally, as discussed in Note 6 to the financial statements included in this report, there is a third party individual patent holder that claims priority over our patent application for enclomiphene.

Our results of operations may vary significantly from quarter to quarter and year to year, and depend on, among other factors, our ability to raise additional capital on acceptable terms or at all, 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 strategic licenses and product development agreements. The timing of our revenues may not match the timing of our associated product development expenses. To date, R&D expenses have usually exceeded revenue in any particular period and/or fiscal year.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk. We had cash and cash equivalents of approximately $32.2 million at June 30, 2015 which is held in an account backed by U.S. government securities. Although this cash account is subject to fluctuations in interest rates and market conditions, no significant gain or loss on this account is expected to be recognized in earnings. We do not invest in derivative securities.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

Based on their evaluation as of the end of the period covered by this Quarterly Report on Form 10-Q, our Principal Executive Officer and Principal Financial Officer have concluded that our disclosure controls and procedures (as defined in Rule 13a-15(e)) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), were effective as of June 30, 2015.

Changes in Internal Control over Financial Reporting

In connection with the evaluation described above, we identified no change in internal control over financial reporting that occurred during the quarter ended June 30, 2015 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

See Note 6 of the Notes to the Condensed Consolidated Financial Statements.

Item 1A. Risk Factors

There were no material changes from the risk factors previously disclosed in the registrant's Form 10-K for the fiscal year ended December 31, 2014 in response to "Item 1A. Risk Factors" to Part I of Form 10-K.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None

Item 3. Defaults Upon Senior Securities.

None

Item 4. Mine Safety Disclosures.

None

Item 5. Other Information

None

Item 6. Exhibits

10.1*	Third Amendment to Lease Agreement, dated as of April 23, 2015, between the Company and Columbia Texas 2408 Timberloch Industrial, L.P.
31.1*	Certification Pursuant to Rule 13(a)-14(a) or 15(d)-14(a) of the Exchange Act, As Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (Principal Executive Officer).
31.2*	Certification Pursuant to Rule 13(a)-14(a) or 15(d)-14(a) of the Exchange Act, As Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (Principal Financial Officer).
32.1**	Certification Furnished Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Principal Executive Officer) (This exhibit shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section. Further, this exhibit shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended.)
32.2**	Certification Furnished Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Principal Financial Officer) (This exhibit shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section. Further, this exhibit shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended.)
101.INS*	XBRL Instance Document

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101.SCH* XBRL Taxonomy Extension Schema Document

101.CAL* XBRL Taxonomy Extension Calculation Linkbase Document

101.DEF* XBRL Taxonomy Extension Definition Linkbase Document

101.LAB* XBRL Taxonomy Extension Label Linkbase Document

101.PRE* XBRL Taxonomy Extension Presentation Linkbase Document

*	Filed herewith.
**	Furnished herewith.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

REPROS THERAPEUTICS INC.

Date: August 10, 2015 By: /s/ Joseph S. Podolski
Joseph S. Podolski
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 10, 2015 By: /s/ Katherine A. Anderson
Katherine A. Anderson
Chief Financial Officer
(Principal Financial Officer)