REPROS THERAPEUTICS INC.
Form 10-Q
November 10, 2014

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 September 30, 2014

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)

Delaware	2408 Timberloch Place, Suite B-7	76-0233274
(State or other jurisdiction of incorporation or organization)	The Woodlands, Texas 77380 (Address of principal executive offices and zip code)	(IRS Employer Identification No.)

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

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 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 ¨

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 ¨ No **x**

As of November 3, 2014, there were outstanding 24,276,173 shares of Common Stock, par value $.001 per share, of the Registrant.

REPROS THERAPEUTICS INC.

(A development stage company)

For the Quarter Ended September 30, 2014

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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 Company's ability to continue as a going concern and to continue to be able to raise additional capital on acceptable terms or at all in order to have available funding for the continued development of Androxal® and Proellex®; the success of the clinical trials for Androxal® and Proellex®; uncertainty related to the Company's ability to obtain approval of the Company's products by the Food and Drug Administration, or 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, 2013.

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 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 nine month periods ended September 30, 2014 are not necessarily indicative of the results that may be expected for the year ending December 31, 2014. 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, 2013.

REPROS THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

CONDENSED CONSOLIDATED BALANCE SHEETS

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

	September 30, 2014	December 31, 2013
ASSETS		
Current Assets		
Cash and cash equivalents	$ 53,084	$ 75,807
Prepaid expenses and other current assets	264	189
Total current assets	53,348	75,996
Fixed assets, net	42	75
Other assets, net	3,360	2,906
Total assets	$ 56,750	$ 78,977
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Accounts payable	$ 2,574	$ 2,966
Accrued expenses	402	586
Total current liabilities	2,976	3,552
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, 24,113,784 and 23,125,565 shares issued, respectively and 24,001,434 and 23,013,215 shares outstanding, respectively	24	23
Additional paid-in capital	317,387	314,405
Cost of treasury stock, 112,350 shares	(1,380)	(1,380)
Deficit accumulated during the development stage	(262,257)	(237,623)
Total stockholders' equity	53,774	75,425
Total liabilities and stockholders' equity	$ 56,750	$ 78,977

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

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REPROS THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited and in thousands except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,		From Inception (August 20, 1987) through September 30,
	2014	2013	2014	2013	2014
Revenues					
Licensing fees	$ -	$ -	$ -	$ -	$ 28,755
Product royalties	-	-	-	-	627
Research and development grants	-	-	-	-	1,219
Interest income	2	3	7	6	16,318
Gain on disposal of fixed assets	-	-	-	-	102
Other Income	-	-	-	-	1,003
Total revenues and other income	2	3	7	6	48,024
Expenses					
Research and development	6,107	4,786	20,882	17,132	239,053
General and administrative	1,277	1,215	3,759	3,453	61,497
Other Expense	-	-	-	-	388
Total expenses	7,384	6,001	24,641	20,585	300,938
Loss from continuing operations	(7,382)	(5,998)	(24,634)	(20,579)	(252,914)
Loss from discontinued operations	-	-	-	-	(1,828)
Gain on disposal of discontinued operation	-	-	-	-	939
Net loss before cumulative effect of change in accounting principle	(7,382)	(5,998)	(24,634)	(20,579)	(253,803)
Cumulative effect of change in accounting principle	-	-	-	-	(8,454)
Net loss	$ (7,382)	$ (5,998)	$ (24,634)	$ (20,579)	$ (262,257)
Loss per share - basic and diluted:	$ (0.32)	$ (0.26)	$ (1.06)	$ (1.03)	

Weighted average shares used in loss per share calculation:				
Basic	23,347	23,006	23,162	20,066
Diluted	23,347	23,006	23,162	20,066

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

REPROS THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

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 Development	Total Stockholders'
	Shares	Amount	Capital	Shares	Amount	Stage	Equity
Balance at December 31, 2013	23,125,565	$ 23	$ 314,405	112,350	$ (1,380)	$ (237,623)	$ 75,425
Stock based compensation	-	-	2,836	-	-	-	2,836
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
Issuance of 562,222 shares of common stock for the cashless exercise of 562,523 Series A Warrants	562,222	1	(1)	-	-	-	-
Issuance of 329,753 shares of common stock for the cashless exercise of 380,101 Series B Warrants	329,753	-	-	-	-	-	-
Net loss	-	-	-	-	-	(24,634)	(24,634)
Balance at September 30, 2014	24,113,784	$ 24	$ 317,387	112,350	$ (1,380)	$ (262,257)	$ 53,774
Balance at December 31, 2012	17,272,505	$ 17	$ 234,299	112,350	$ (1,380)	$ (209,902)	$ 23,034
Stock based compensation	-	-	2,258	-	-	-	2,258
Issuance of 871,634 shares of common stock for the cashless exercise of 872,133 Series A Warrants	871,634	1	(1)	-	-	-	-
Issuance of 614,564 shares of common stock for the cashless exercise of 716,463 Series B Warrants	614,564	1	(1)	-	-	-	-
	42,849	-	107	-	-	-	107

Exercise of 42,849 Series B Warrants to purchase common stock for cash @ $2.49 per share							
Issuance of 5,407 shares of common stock for the cashless exercise of 8,332 stock options	5,407	-	-	-	-	-	-
Exercise of 2,500 stock options to purchase common stock for cash @ $18.74 per share	2,500	-	47	-	-	-	47
Issuance of 4,312,500 shares of common stock at $19.00 per share, net of offering costs of $5.2 million	4,312,500	4	76,760	-	-	-	76,764
Net loss	-	-	-	-	-	(20,579)	(20,579)
Balance at September 30, 2013	23,121,959	$ 23	$ 313,469	112,350	$ (1,380)	$ (230,481)	$ 81,631

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

REPROS THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited and in thousands)

	Nine Months Ended September 30,		From Inception (August 20, 1987) through September 30,
	2014	2013	2014
Cash Flows from Operating Activities			
Net loss	$ (24,634)	$ (20,579)	(262,257)
Gain on disposal of discontinued operations	-	-	(939)
Gain on disposal of fixed assets	-	-	(102)
Adjustments to reconcile net loss to net cash used in operating activities:			
Noncash financing costs	-	-	316
Noncash inventory impairment	-	-	4,417
Noncash patent impairment	-	-	2,614
Noncash other income	-	-	(709)
Noncash decrease in accounts payable	-	-	(1,308)
Depreciation and amortization	270	177	4,828
Noncash stock-based compensation	2,836	2,258	18,312
Common stock issued for agreement not to compete	-	-	200
Series B Preferred Stock issued for consulting services	-	-	18
Changes in operating assets and liabilities (net effects of purchase of businesses in 1988 and 1994):			
Increase in receivables	-	-	(199)
Increase in inventory	-	-	(4,447)
(Increase) decrease in prepaid expenses and other current assets	(75)	213	38
Increase (decrease) in accounts payable and accrued expenses	(439)	(532)	10,822
Net cash used in operating activities	(22,042)	(18,463)	(228,396)
Cash Flows from Investing Activities			
Change in trading marketable securities	-	-	(191)
Capital expenditures	-	(63)	(2,486)
Purchase of other assets	(828)	(776)	(7,210)
Proceeds from sale of PP&E	-	-	225

Cash acquired in purchase of FTI	-	-	3
Proceeds from sale of subsidiary, less $12,345 for operating losses during 1990 phase-out period	-	-	138
Proceeds from sale of the assets of FTI	-	-	2,250
Increase in net assets held for disposal	-	-	(213)
Net cash used in investing activities	(828)	(839)	(7,484)
Cash Flows from Financing Activities			
Proceeds from issuance of common stock, net of offering costs	-	76,764	284,195
Exercise of stock options & warrants	147	154	1,134
Proceeds from a shareholder transaction	-	-	327
Proceeds from issuance of preferred stock	-	-	23,688
Purchase of treasury stock	-	-	(21,487)
Proceeds from issuance of notes payable	-	-	2,839
Principal payments on notes payable	-	-	(1,732)
Net cash provided by financing activities	147	76,918	288,964
Net increase (decrease) in cash and cash equivalents	(22,723)	57,616	53,084
Cash and cash equivalents at beginning of period	75,807	24,212	-
Cash and cash equivalents at end of period	$ 53,084	$ 81,828	$ 53,084

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

REPROS THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2014

(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 development stage biopharmaceutical company focused on the development of new drugs to treat hormonal and reproductive system disorders.

Our primary product candidate, Androxal®, is a single isomer of clomiphene citrate and is an orally active proprietary small molecule compound. We are developing Androxal® for men of reproductive age with low testosterone levels. Androxal® treats the underlying mechanism that causes secondary hypogonadism and restores normal testicular function. We have completed all pivotal Phase 3 efficacy studies, including the recently completed, ZA-304 and ZA-305, against an approved testosterone replacement product.

Proellex®, our product candidate for female reproductive health, is a new chemical entity that acts as a selective blocker of the progesterone receptor and is being developed for the treatment of symptoms associated with uterine fibroids and endometriosis. We completed a dose escalating study to demonstrate both safety and efficacy signals in low oral doses of Proellex® and we are conducting a Phase 2 study in the treatment of endometriosis. Additionally, the Food and Drug Administration has accepted an Investigational New Drug Application for vaginally delivered Proellex®. As a result, we completed a Phase 1/2 vaginal administration study for uterine fibroids.

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)

Androxal®		
Secondary Hypogonadism	Phase 3	Submit New Drug Application (NDA) (submission timeline to be reassessed based on analysis of November 2014 interactions with FDA)
Proellex®		
Uterine Fibroids	Phase 2	Initiate a Phase 2B study (vaginal delivery) (Q4 2014) Initiate a Phase 2 study (oral delivery) (Q4 2014)
Endometriosis	Phase 2	Fully enroll Phase 2 study (oral delivery) (H1 2015)

As of September 30, 2014, we had accumulated losses of $262.3 million, approximately $53.1 million in cash and cash equivalents, and accounts payable and accrued expenses of approximately $3.0 million, in the aggregate. We anticipate that our current liquidity will be sufficient to continue the development of our product candidates through at least the first 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.

NOTE 2 — Patents and Patent Applications

As of September 30, 2014, we had approximately $3.4 million in capitalized patent and patent application costs reflected on our balance sheet. Of this amount, $2.0 million relates to Androxal® and $1.4 million relates to Proellex®.

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

NOTE 3 — Accrued Expenses

Accrued expenses consist of the following (in thousands):

	September 30, 2014	December 31, 2013
Research and development costs	$ 193	$ 89
Personnel related costs	48	196
Patent costs	28	188
Other	133	113
Total	$ 402	$ 586

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 loss per share is computed using the average share price for the period and applying the treasury stock method to potentially dilutive outstanding options. In all applicable periods, all potential common stock equivalents were anti-dilutive and, accordingly, were not included in the computation of diluted loss per share.

The following table presents information necessary to calculate loss per share for the three and nine month periods ended September 30, 2014 and 2013 (in thousands, except per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Net loss	$ (7,382)	$ (5,998)	$ (24,634)	$ (20,579)
Average common shares outstanding	23,347	23,006	23,162	20,066
Basic and diluted loss per share	$ (0.32)	$ (0.26)	$ (1.06)	$ (1.03)

Potential common stock of 3,191,426 and 3,975,430 common shares underlying stock options and warrants for the periods ended September 30, 2014 and 2013, respectively, were excluded from the above calculation of diluted loss per share because they were anti-dilutive. Other potential common stock at September 30, 2014 includes Series A Warrants to purchase 314,614 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 September 30, 2013 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 810,109 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 September 30, 2014, the Compensation Committee of the Company's Board of Directors approved grants of options to purchase 50,000 shares of our common stock to employees and directors under the 2011 Equity Incentive Plan. All of the options granted during the three month period ended September 30, 2014 vest over a three year period. During the nine month period ended September 30, 2014, the Compensation Committee of the Company's Board of Directors approved grants of options to purchase 351,000 shares of our common stock to employees under the 2011 Equity Incentive Plan. Of the options granted, 326,000 options vest over a three year period and 25,000 vest over a one year period. Additionally, during the nine month period ended September 30, 2014, 127,080 options either expired or were forfeited.

NOTE 6 — Commitments and Contingencies

Therapeutic uses of our Androxal® product candidate are covered in the United States by nine issued U.S. patents and six pending patent applications. Foreign coverage of therapeutic uses of our Androxal® product candidate includes 68 issued foreign patents and 78 foreign pending patent applications. The issued patents and pending applications relate to methods for treating certain conditions including the treatment of testosterone deficiency in men, the treatment of diabetes mellitus Type 2, the treatment of metabolic syndrome and conditions associated therewith, and the treatment of infertility in hypogonadal men. Androxal® (the trans-isomer of clomiphene) is purified from clomiphene citrate. A third party individual holds two issued patents related to the use of anti-estrogen such as clomiphene citrate and others for use in the treatment of disorders related to androgen deficiency. 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 Androxal® 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 Androxal® further. Adverse determinations in litigation proceedings could require us to seek licenses which may not be available on commercially reasonable terms, or at all, or subject us to significant liabilities, in which case we may not be able to successfully commercialize or out-license Androxal® until such patents expire or are otherwise no longer in force.

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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 Androxal®. 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 an inventor to any of these patents. On October 2, 2013, Dr. Fisch filed his answer and counterclaims to our complaint. Dr. Fisch asserted counterclaims seeking correction of inventorship of the three patents at issue to name Dr. Fisch as a co-inventor of the applications leading these patents. Dr. Fisch subsequently stipulated that he does not claim to be a co-inventor of U.S. Patent No. 7,173,064. Dr. Fisch also seeks reasonable attorney's fees. Discovery closed on September 19, 2014 and summary judgment motions filed by both parties are pending. No hearing date for the motions has been set. We believe there is no merit to Dr. Fisch's counterclaims and we intend to continue to vigorously defend against them. However, there can be no assurance that we will ultimately be successful in this matter.

NOTE 7 — Subsequent Events

On October 15, 2014, 274,739 shares of our common stock were issued for the cashless exercise of 275,019 Series A Warrants.

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.

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

We are developing Androxal®, an oral therapy that normalizes testicular function, for the treatment of low testosterone due to secondary hypogonadism. Secondary hypogonadism is associated with obesity and we believe it is among the most common causes of low testosterone in men. It is estimated that 13 million men in the U.S. experience low levels of testosterone, and the condition is becoming recognized with more frequency. As of 2013, sales of preparations for the treatment of low testosterone have exceeded $1 billion in the U.S. and first tier pharmaceutical companies have entered the low testosterone marketplace.

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

In December 2011, we completed a Phase 2B study of Androxal® in men with secondary hypogonadism, but naïve to testosterone treatment, at the recommendation of the Food and Drug Administration (the “FDA”). Top line results of this study demonstrated that Androxal® was generally well tolerated compared to placebo and that there were no drug related serious adverse events that led to discontinuation. We met with the FDA in May 2012 to discuss the design of

pivotal Phase 3 efficacy studies for Androxal® as well as the components of the overall drug development program required for a New Drug Application ("NDA") submission and agreed on registration requirements for Androxal® 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 Androxal® 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. 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 both studies were completed in the third quarter of 2014. On August 27, 2014 and September 25, 2014, we announced the top line results from studies ZA-305 and ZA-304, respectively. These studies achieved superiority for both co-primary endpoints versus the leading topical testosterone gel in the treatment of secondary hypogonadism. On October 21, 2014, we announced the completion and top line results from our one year dual-energy X-ray absorptiometry ("DEXA") study. The DEXA study showed no evidence of negative effects on bone mineral density and no new safety signals were identified. On November 6, 2014, the Company reported the outcome of a meeting with the FDA to discuss the anticipated NDA submission. Based on the data compiled to date, the FDA did not identify any additional clinical studies that would be required for filing the NDA. Although no specific request was made, the FDA stated that as a result of its recent Advisory Committee Meeting, cardiovascular risk is of particular interest and that additional safety studies could be required in the future. In addition, the FDA advised that the environmental assessment of Androxal® should be discussed with the appropriate FDA personnel prior to NDA submission due to their evolving interest in this class of chemicals to avoid late cycle approval delays. The Company will reassess NDA submission timelines once it has had this discussion with the appropriate FDA personnel, however, we are confident that we will be able to address all concerns noted in the meeting and believe the discussions provided constructive guidance for the NDA filing. We expect the NDA submission to include the study reports from the completed efficacy studies ZA-301 and ZA-302, as well as studies ZA-304 and ZA-305. Additionally, we completed a 500 subject open label safety study in the third quarter of 2013.

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 full enrolled in the first half of 2015.

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. The Company believes it may be able to initiate this study in the fourth quarter of 2014. 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.

The FDA has accepted an Investigational New Drug Application ("IND") for vaginally delivered Proellex® and, as a result, we commenced a Phase 2 vaginal administration study for uterine fibroids in the first quarter of 2012 and reported final study results in January 2013. We 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. The Company believes it may be able to initiate the Phase 2B study in the fourth quarter of 2014.

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)**
Androxal®		
Secondary Hypogonadism	Phase 3	Submit NDA (submission timeline to be reassessed based on analysis of November 2014 interactions with FDA)

Proellex®		
Uterine Fibroids	Phase 2	Initiate a Phase 2B study (vaginal delivery) (Q4 2014) Initiate a Phase 2 study (oral delivery) (Q4 2014)
Endometriosis	Phase 2	Fully enroll Phase 2 study (oral delivery) (H1 2015)

As of September 30, 2014, we had accumulated losses of $262.3 million, approximately $53.1 million in cash and cash equivalents, and accounts payable and accrued expenses of approximately $3.0 million, in the aggregate. We anticipate that our current liquidity will be sufficient to continue the development of our product candidates through at least the first 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.

Androxal®

Product Overview

Our primary product candidate, Androxal®, is a single isomer of clomiphene citrate and is an orally active proprietary small molecule compound. We are developing Androxal® for men of reproductive age with low testosterone levels. Androxal® treats the underlying mechanism that causes secondary hypogonadism and restores normal testicular function. 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. Unlike testosterone replacement which suppresses testicular function, Androxal® does not impair testicular function, including fertility.

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

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

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

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

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

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

On July 9, 2012, we announced that we reached an agreement with the FDA for the design of the pivotal efficacy studies for Androxal® for the treatment of secondary hypogonadism. The pivotal studies 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 have completed a one year, 300 subject DEXA study. On October 21, 2014, we announced the completion and top line results from our one year DEXA study. The DEXA study showed no evidence of negative effects on bone mineral density and no new safety signals were identified.

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 both studies were completed in the third quarter of 2014. On August 27, 2014 and September 25, 2014, we announced the top line results from studies ZA-305 and ZA-304, respectively. These studies achieved superiority for both co-primary endpoints versus the leading topical testosterone gel in the treat of secondary hypogonadism. On November 6, 2014, the Company reported

the outcome of a meeting with the FDA to discuss the anticipated NDA submission. Based on the data compiled to date, the FDA did not identify any additional clinical studies that would be required for filing the NDA. Although no specific request was made, the FDA stated that as a result of its recent Advisory Committee Meeting, cardiovascular risk is of particular interest and that additional safety studies could be required in the future. In addition, the FDA advised that the environmental assessment of Androxal® should be discussed with the appropriate FDA personnel prior to NDA submission due to their evolving interest in this class of chemicals to avoid late cycle approval delays. The Company will reassess NDA submission timelines once it has had this discussion with the appropriate FDA personnel, however, we are confident that we will be able to address all concerns noted in the meeting and believe the discussions provided constructive guidance for the NDA filing. We expect the NDA submission to include the study reports from the completed efficacy studies ZA-301 and ZA-302, as well as studies ZA-304 and ZA-305. Additionally, we completed a 500 subject open label safety study in the third quarter of 2013.

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

In addition, the Company continues to consider the potential for use of Androxal® 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 Androxal® 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 Androxal®, should it be approved. There can be no assurance, however, that we will be successful in implementing this strategy or that the FDA will approve our drug for commercial use.

Proellex®

Product Overview

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

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

We have conducted numerous studies with Proellex® dosing approximately 700 women with the drug. All Proellex® studies completed to date exhibited strong efficacy signals, whether in uterine fibroids or endometriosis. In a 120 patient study of Proellex® as a treatment of uterine fibroids conducted in the United States (roughly 40 subjects per arm), both a 12.5 and 25 mg dose of Proellex® were compared to placebo. In this study each of the 12.5 and 25 mg doses achieved highly statistically significant results when compared to placebo when menstrual bleeding was

assessed ($p<0.0001$). The two doses also achieved highly statistically significant improvement in quality of life measures using the Uterine Fibroid Symptom Quality of Life questionnaire developed and validated by Georgetown University and used in the development of device like treatments of uterine fibroids such as uterine artery embolization. There was no statistical difference in efficacy measures between the two doses. Importantly, in the Phase 2 U.S. trial a significant percentage of women stopped menstruating. Proellex® resulted in the induction of amenorrhea (cessation of menses), which we believe is a strong surrogate signal of efficacy. Over 80% of women on both the 12.5 and 25 mg doses exhibited no menses during the three month trial, whereas all women on placebo exhibited at least one menses.

Up until the summer of 2009, all side effects exhibited in the studies were considered manageable and the benefit of Proellex® far outweighed the risk. However, in Phase 3 efficacy and larger Phase 3 safety studies in diverse populations, a small number of subjects exhibited serious adverse effects associated with elevated liver enzymes. As a result of these findings, we elected to stop the trials and the FDA subsequently placed Proellex® on full clinical hold. All women that experienced elevated liver enzymes and returned for follow-up visits returned to baseline conditions with no overnight hospitalization necessary. An analysis of all the subjects that experienced such serious adverse effects showed that the effect only occurred in a small percentage of subjects that were exposed to the 50 mg dose of the drug for any period of time. Based on these findings, we petitioned the FDA to allow us to conduct a low dose study to demonstrate both safety and signals of efficacy in low oral doses of Proellex®, up to 12 mg administered per day. The FDA upgraded the full clinical hold to a partial hold to allow the low dose study to be conducted. In addition, we are exploring vaginal delivery as an alternative administrative route to bypass first-pass liver effects and reduce systemic exposure. The Company believes it may be able to initiate a Phase 2B study in the fourth quarter of 2014.

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 full enrolled in the first half of 2015.

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. The Company believes it may be able to initiate this study in the fourth quarter of 2014. 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.

Vaginal Administration

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

vaginally delivered Proellex® and, as a result, we commenced a Phase 2 vaginal administration study for uterine fibroids in the first quarter of 2012. In January 2013, we reported the final study results which indicated the 12 mg dose achieved statistically significant improvement in menstrual bleeding, uterine fibroid symptoms and reduction in fibroid volume even with the low number of subjects enrolled into the study (n=12 @ 12 mg). Based on these findings, the Company believes the 12 mg dose is appropriate for further development. We 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. The Company believes it may be able to initiate the Phase 2B study in the fourth quarter of 2014.

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) completion and submission of the NDA for Androxal®, (ii) conducting a Phase 2B vaginal administration trial for Proellex® in the treatment of uterine fibroids, (iii) conducting a Phase 2 trial for low dose oral Proellex® for endometriosis and (iv) conducting an efficacy trial for low dose oral Proellex® for uterine fibroids.

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 28 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 September 30, 2014 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.

Capitalized Patent and Patent Application Costs

We capitalize the cost associated with building our patent library for Androxal® and Proellex®. As of September 30, 2014, other assets consist of capitalized patent and patent application costs in the amount of $3.4 million. Patent costs, which include legal and application costs related to the patent portfolio, are being amortized over the lesser of the legal life of the patent (typically 20 years) or the estimated economic life of the patent. Amortization of patent costs was $80,000 and $51,000 for the three month periods ended September 30, 2014 and 2013, respectively, and was $237,000 and $148,000 for the nine month periods ended September 30, 2014 and 2013, respectively.

We review capitalized patent and patent application costs for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. An impairment exists when estimated undiscounted cash flows expected to result from the patent are less than its carrying amount. The impairment loss recognized represents the excess of the patent cost as compared to its estimated fair value. We believe that our remaining capitalized patent and patent application costs were not impaired as of September 30, 2014.

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

Accrued Expenses

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

projected cost to treat a patient in our trials, and we recognize this cost over the estimated term of the study based on the number of patients enrolled in the trial on an ongoing basis, beginning with patient enrollment. As actual costs become known to us, we adjust our accruals. To date, our estimates have not differed significantly from the actual costs incurred. However, subsequent changes in estimates may result in a material change in our accruals, which could also materially affect our balance sheet and results of operations.

R&D Expense

Research and development, or R&D, expenses include salaries and related employee expenses, contracted regulatory affairs activities, insurance coverage for clinical trials and prior product sales, contracted research and consulting fees, facility costs, amortization of capitalized patent 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 September 30, 2014, 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, 2014. This guidance is not expected to have a material effect on our consolidated financial statements.

Results of Operations

Comparison of the three month and nine month periods ended September 30, 2014 and 2013

Revenues and Other Income

Total revenues and other income was $2,000 for the three month period ended September 30, 2014 as compared to $3,000 for the same period in the prior year. Total revenue and other income was $7,000 for the nine month period ended September 30, 2014 as compared to $6,000 for the same period in the prior year. The decrease for the three month period ended September 30, 2014 as compared to the same period in the prior year was primarily due to a decrease in interest income as a result of decreased cash balances. The increase for the nine month period ended September 30, 2014 as compared to the same period in the prior year was primarily due to an increase in interest income as a result of increased cash balances.

Research and Development Expenses

Research and development, or R&D, expenses include contracted services relating to our clinical product development activities which include preclinical studies, clinical trials, regulatory affairs and bulk manufacturing scale-up activities and bulk active ingredient purchases for preclinical and clinical trials primarily relating to our two products in clinical development, which are Androxal® and Proellex®. Research and development expenses also include internal operating expenses relating to our general research and development activities. R&D expenses increased 28%, or approximately $1.3 million, to $6.1 million for the three month period ended September 30, 2014 as compared to $4.8 million for the same period in the prior year. Our primary R&D expenses for the three month periods ended September 30, 2014 and 2013 are shown in the following table (in thousands):

Research and Development	Three months ended September 30, 2014	Three months ended September 30, 2013	Variance	Change (%)
Androxal® clinical development	$ 3,931	$ 2,743	$ 1,188	43 %
Proellex® clinical development	338	422	(84)	(20)%
Payroll and benefits	1,082	1,058	24	2 %
Operating and occupancy	756	563	193	34 %
Total	$ 6,107	$ 4,786	$ 1,321	28 %

R&D expenses increased 22%, or approximately $3.8 million, to $20.9 million for the nine month period ended September 30, 2014 as compared to $17.1 million for the same period in the prior year. Our primary R&D expenses for the nine month periods ended September 30, 2014 and 2013 are shown in the following table (in thousands):

Research and Development	Nine months ended September 30, 2014	Nine months ended September 30, 2013	Variance	Change (%)
Androxal® clinical development	$ 14,036	$ 11,609	$ 2,427	21 %
Proellex® clinical development	1,402	1,104	298	27 %
Payroll and benefits	3,216	2,835	381	13 %
Operating and occupancy	2,228	1,584	644	41 %
Total	$ 20,882	$ 17,132	$ 3,750	22 %

The increases in R&D expenses for both the three and nine month periods ended September 30, 2014 as compared to the same periods in the prior year, were primarily due to the completion of the Phase 3 studies, ZA-303, ZA-304 and ZA-305. R&D expenses related to the clinical development of Proellex® decreased for the three month period ended September 30, 2014 as compared to the same period in the prior year, due to decreased drug manufacturing activities associated with Proellex®. R&D expenses related to the clinical development of Proellex® increased for the nine month period ended September 30, 2014 as compared to the same period in the prior year, due to increased expenses associated with our Phase 2 endometriosis study.

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Payroll and benefits expenses increased for both the three and nine month periods ended September 30, 2014 as compared to the same periods in the prior year by $24,000 and $381,000, respectively. Included in payroll and benefits expenses is a charge for non-cash stock based compensation of $488,000 and $1.4 million for the three and nine month periods ended September 30, 2014, respectively, as compared to $506,000 and $1.3 million, respectively, for the same periods in the prior year. Additionally, salaries for the three and nine month periods ended September 30, 2014 were $488,000 and $1.5 million, respectively, as compared to $459,000 and $1.2 million, respectively, for the same periods in the prior year. The increases in both non-cash stock based compensation and salaries expenses were due to increased headcount in R&D employees.

Operating and occupancy expenses increased for the three and nine month periods ended September 30, 2014 as compared to the same period in the prior year, due to an increase in costs of professional services and amortization expense, partially offset by a decrease in travel expenses.

To date through September 30, 2014, we have incurred expenses of approximately $57.2 million for the development of Androxal® and approximately $62.3 million for the development of Proellex®. These accumulated costs exclude any internal operating expenses.

General and Administrative Expenses

General and administrative expenses, or G&A, increased 5%, or approximately $62,000, to $1.3 million for the three month period ended September 30, 2014 as compared to $1.2 million for the same period in the prior year. Our primary G&A expenses for the three month periods ended September 30, 2014 and 2013 are shown in the following table (in thousands):

General and Administrative	Three months ended September 30, 2014	Three months ended September 30, 2013	Variance	Change (%)
Payroll and benefits	$ 750	$ 626	$ 124	20 %
Operating and occupancy	527	589	(62)	(11)%
Total	$ 1,277	$ 1,215	$ 62	5 %

G&A payroll and benefits expenses include salaries, bonuses, relocation expense, severance costs, 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 $473,000 for the three month period ended September 30, 2014 as compared to $368,000 for the same period in the prior year. Additionally, salaries for the three month period ended September 30, 2014 were $248,000 as compared to $230,000 for the same period in the prior year.

G&A operating and occupancy expenses, which include expenses to operate as a public company, decreased 11%, or approximately $62,000, to $527,000 for the three month period ended September 30, 2014 as compared to $589,000 for the same period in the prior year. The decrease in operating and occupancy expenses for the three month period ended September 30, 2014 as compared to the same period in the prior year was primarily due to a decrease in costs of professional services.

G&A expenses increased 9%, or approximately $306,000, to $3.8 million for the nine month period ended September 30, 2014 as compared to $3.5 million for the same period in the prior year. Our primary G&A expenses for the nine month periods ended September 30, 2014 and 2013 are shown in the following table (in thousands):

General and Administrative	Nine months ended September 30, 2014	Nine months ended September 30, 2013	Variance	Change (%)
Payroll and benefits	$ 2,265	$ 1,725	$ 540	31 %
Operating and occupancy	1,494	1,728	(234)	(14)%
Total	$ 3,759	$ 3,453	$ 306	9 %

G&A payroll and benefits expenses include salaries, bonuses, relocation expense, severance costs, non-cash stock option compensation expense and fringe benefits. Included in payroll and benefits expense is a charge for non-cash stock based compensation expense of $1.4 million for the nine month period ended September 30, 2014, as compared to $937,000 for the same period in the prior year. Additionally, salaries for the nine month period ended September 30, 2014 were $738,000 as compared to $687,000 for the same period in the prior year.

G&A operating and occupancy expenses, which include expenses to operate as a public company, decreased 14%, or approximately $234,000, to $1.5 million for the nine month period ended September 30, 2014, as compared to $1.7 million for the same period in the prior year. The decrease was primarily due to a decrease in costs of professional services.

Off-Balance Sheet Arrangements

As of September 30, 2014, 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 $53.1 million as of September 30, 2014 as compared to $75.8 million as of December 31, 2013. All cash and cash equivalents as of September 30, 2014 and December 31, 2013 were held in an account backed by U.S. government securities.

Net cash of approximately $22.0 million and $18.5 million was used in operating activities during the nine month periods ended September 30, 2014 and 2013, respectively. The major use of cash for operating activities for the nine month period ended September 30, 2014 was to fund our clinical development programs and associated administrative costs. Cash used in investing activities during the nine month period ended September 30, 2014 was approximately $828,000 primarily for capitalized patent and patent application costs for Androxal® and Proellex®. Cash provided by financing activities during the nine month period ended September 30, 2014 was approximately $147,000 as a result of the exercise of 23,334 stock options for cash.

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 through at least the first 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, 2013. Additionally, as discussed in Note 6, there is a third party individual patent holder that claims priority over our patent application for Androxal®.

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, research and development 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 $53.1 million at September 30, 2014 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 September 30, 2014.

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 September 30, 2014 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, 2013 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

31.1*	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (Chief Executive Officer).
31.2*	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (Chief Financial Officer).
32.1*	Certification furnished pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Chief Executive Officer).
32.2*	Certification furnished pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Chief Financial Officer).
101.INS*	XBRL Instance Document
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.

SIGNATURES

In accordance with the requirements of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

REPROS THERAPEUTICS INC.

Date: November 10, 2014

By: /s/ Joseph S. Podolski
Joseph S. Podolski
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 10, 2014

By: /s/ Katherine A. Anderson
Katherine A. Anderson
Chief Financial Officer
(Principal Financial Officer)