REPROS THERAPEUTICS INC.
Form 10-Q
November 09, 2016

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, 2016

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 4, 2016, there were outstanding 25,425,178 shares of Common Stock, par value $.001 per share, of the Registrant.

REPROS THERAPEUTICS INC.

For the Quarter Ended September 30, 2016

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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 ide 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 enclomiphene product candidate; 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 Food and Drug Administration and regulatory bodies in other jurisdictions, including the European Medicines Agency; 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, 2015.

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 nine month periods ended September 30, 2016 are not necessarily indicative of the results that may be expected for the year ending December 31, 2016. 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, 2015.

REPROS THERAPEUTICS INC.

(A development stage company)

REPROS THERAPEUTICS INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED BALANCE SHEETS

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

	September 30, 2016	December 31, 2015
ASSETS		
Current Assets		
Cash and cash equivalents	$ 10,505	$ 21,393
Prepaid expenses and other current assets	158	84
Total current assets	10,663	21,477
Fixed assets, net	4	8
Total assets	$ 10,667	$ 21,485
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Accounts payable	$ 1,815	$ 1,969
Accrued expenses	494	949
Total current liabilities	2,309	2,918
Commitments and contingencies (note 5)		
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, 25,239,134 and 24,430,461 shares issued, respectively and 25,126,784 and 24,318,111 shares outstanding, respectively	25	24
Additional paid-in capital	325,263	322,179
Cost of treasury stock, 112,350 shares	(1,380)	(1,380)
Accumulated deficit	(315,550)	(302,256)
Total stockholders' equity	8,358	18,567

Total liabilities and stockholders' equity	$ 10,667	$ 21,485

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

REPROS THERAPEUTICS INC.

(A development stage company)

REPROS THERAPEUTICS INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited and in thousands except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenues and Other Income				
Interest income	$ 10	$ 1	$ 41	$ 3
Total revenues and other income	10	1	41	3
Expenses				
Research and development	3,182	5,506	10,191	19,277
General and administrative	997	1,100	3,144	3,647
Total expenses	4,179	6,606	13,335	22,924
Net loss	$ (4,169)	$ (6,605)	$ (13,294)	$ (22,921)
Loss per share - basic and diluted:	$ (0.17)	$ (0.27)	$ (0.55)	$ (0.94)
Weighted average shares used in loss per share calculation:				
Basic	24,495	24,318	24,372	24,291
Diluted	24,495	24,318	24,372	24,291

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

REPROS THERAPEUTICS INC.

(A development stage company)

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			Total Stockholders'
	Shares	Amount	Capital	Shares	Amount	Accumulated Deficit	Equity
Balance at December 31, 2015	24,430,461	$ 24	$ 322,179	112,350	$ (1,380)	$ (302,256)	$ 18,567
Stock based compensation	-	-	1,491	-	-	-	1,491
Exercise of 1,333 Series A warrants to purchase common stock for cash @ $0.01 per share	1,333	-	-	-	-	-	-
Issuance of 807,340 shares of common stock at a weighted average share price of $2.15, net of offering costs of $145	807,340	1	1,593	-	-	-	1,594
Net loss	-	-	-	-	-	(13,294)	(13,294)
Balance at September 30, 2016	25,239,134	$ 25	$ 325,263	112,350	$ (1,380)	$ (315,550)	$ 8,358
Balance at December 31, 2014	24,388,523	$ 24	$ 318,437	112,350	$ (1,380)	$ (273,064)	$ 44,017
Stock based compensation	-	-	2,925	-	-	-	2,925
Exercise of 37,093 Series A warrants to purchase common stock for cash @ $0.01 per share	37,093	-	-	-	-	-	-
Issuance of 4,845 shares of common stock for the cashless exercise of 15,000 stock options	4,845	-	-	-	-	-	-
Net loss	-	-	-	-	-	(22,921)	(22,921)
Balance at September 30, 2015	24,430,461	$ 24	$ 321,362	112,350	$ (1,380)	$ (295,985)	$ 24,021

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

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REPROS THERAPEUTICS INC.

(A development stage company)

REPROS THERAPEUTICS INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited and in thousands)

	Nine Months Ended September 30,	
	2016	2015
Cash Flows from Operating Activities		
Net loss	$ (13,294)	$ (22,921)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	4	21
Noncash stock-based compensation	1,491	2,925
Increase in prepaid expenses and other current assets	(74)	(124)
Decrease in accounts payable and accrued expenses	(609)	(433)
Net cash used in operating activities	(12,482)	(20,532)
Cash Flows from Investing Activities		
Net cash used in investing activities	-	-
Cash Flows from Financing Activities		
Proceeds from issuance of common stock, net of offering costs	1,594	-
Proceeds from a shareholder transaction	-	102
Net cash provided by financing activities	1,594	102
Net decrease in cash and cash equivalents	(10,888)	(20,430)
Cash and cash equivalents at beginning of period	21,393	46,620
Cash and cash equivalents at end of period	$ 10,505	$ 26,190

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

REPROS THERAPEUTICS INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2016

(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, is a single isomer of clomiphene citrate and is an orally active proprietary small molecule compound. 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. 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. The FDA accepted the NDA for review on April 1, 2015 and later assigned a Prescription Drug User Fee Act ("PDUFA") goal date of November 30, 2015. In addition, the Division of Bone, Reproductive and Urologic Products (the "Division") of the FDA scheduled an advisory committee meeting to review the NDA for November 3, 2015. However, the Division subsequently cancelled the scheduled advisory committee meeting due to questions that arose late in the review regarding the bioanalytical method validation that could affect interpretability of certain pivotal study data. On December 1, 2015, we announced that we had received a Complete Response Letter ("CRL") from the FDA. A CRL informs companies that an NDA cannot be approved in its present form. In the CRL, the FDA stated that, based on recent scientific developments, the design of the enclomiphene Phase 3 studies is no longer adequate to demonstrate clinical benefit and recommended that Repros conduct an additional Phase 3 study or studies to support approval in the target population. The FDA also noted concerns regarding study entry criteria, titration and bioanalytical method validation in the Phase 3 program.

Subsequently, on February 4, 2016, the Company attended a meeting with the FDA reviewers and senior leaders to discuss resolution of issues identified during the NDA review. The meeting covered a broad range of topics surrounding the NDA data as well as emerging agency and expert thinking regarding the treatment of hypogonadism. The Company believes based on the meeting that the FDA is not closed to considering secondary hypogonadism as an

indication. Additionally, in January 2016, the Company initiated a Phase 2 double-blind, placebo controlled, proof of concept study, ZA-205, in obese secondary hypogonadal men to assess the impact of enclomiphene on metabolic parameters and quality of life under a diet and exercise regimen. On August 15, 2016, we reported six month interim results from this study.

Additionally, on September 12, 2016, we reported that we successfully submitted a European centralized marketing authorization application ("MAA") for enclomiphene for the treatment of secondary hypogonadism. This MAA was subsequently accepted by the European Medicines Agency ("EMA") and, as previously reported, has assigned the United Kingdom as the primary rapporteur and France as the co-rapporteur for the application review. We expect to receive questions relating to this application by the end of January 2017.

On September 26, 2016, the Company announced that it will participate in a public Advisory Committee Meeting held by the Bone, Reproductive and Urologic Drugs Division of the FDA. The purpose of the meeting will be to discuss appropriate clinical trial design features, including acceptable endpoints for demonstrating clinical benefit, for drugs intended to treat secondary hypogonadism while preserving or improving testicular function, including spermatogenesis.

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. All three of these Proellex® studies were fully enrolled in January 2016. On April 12, 2016, we announced positive clinical data for the vaginal application of Proellex® in women with severe menstrual bleeding due to uterine fibroids. Additionally, on May 18, 2016, we announced that oral administration of Proellex®, at doses of both 6 and 12 mg, achieved significant reduction in excessive menstrual bleeding, the key symptom of uterine fibroids. On September 7, 2016, we announced positive clinical data for the first course of treatment in premenopausal women with confirmed moderate to severe 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	MAA accepted October 2016; NDA submitted/Complete Response Letter received	
Proellex®		
		Complete second course of treatment in a Phase 2B study (oral delivery) (Q4 2016)
Uterine Fibroids	Phase 2	Complete second course of treatment in a Phase 2B study (vaginal delivery) (Q4 2016)
Endometriosis	Phase 2	Topline data reported September 2016

On August 9, 2016, we entered into an Equity Distribution Agreement (the “Equity Distribution Agreement”) with Ladenburg Thalmann & Co. Inc. (“Ladenburg”), pursuant to which we may issue and sell from time to time through Ladenburg, as sales agent and/or principal, shares of our common stock having an aggregate offering price of up to $10 million (the “ATM Shares”). Ladenburg is not required to sell on our behalf any specific number or dollar amount of the ATM Shares, but Ladenburg, upon acceptance of written instructions from us, agreed to use its commercially reasonable efforts consistent with its customary trading and sales practices, to sell the ATM Shares up to the amount specified, and otherwise in accordance with the terms of a placement notice delivered to Ladenburg. We have no obligation to sell any ATM Shares under the Equity Distribution Agreement, and may at any time suspend sales under the Equity Distribution Agreement, provided that such suspension shall not affect either party’s obligations with respect to the ATM Shares sold prior to the receipt of notice of such suspension. Ladenburg receives a commission of 3% of the gross sales price of all ATM Shares sold through it under the Equity Distribution Agreement. The ATM Shares are issued pursuant to our shelf registration statement on Form S-3, as amended (File No. 333-197253). During

the quarter ended September 30, 2016, we sold 807,340 ATM Shares at a weighted average share price of $2.15, for proceeds of approximately $1.6 million, net of expenses including approximately $52,000 in commissions to Ladenburg. Between October 1, 2016 and November 8, 2016, we sold an aggregate of 298,394 ATM Shares at a weighted average share price of $2.12, for proceeds of approximately $614,000, net of expenses including approximately $19,000 in commissions to Ladenburg.

As of September 30, 2016, we had accumulated losses of $315.6 million, approximately $10.5 million in cash and cash equivalents, and accounts payable and accrued expenses of approximately $2.3 million, in the aggregate. We anticipate that our current liquidity will be