

REPROS THERAPEUTICS INC.

FORM 10-Q (Quarterly Report)

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2017

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
(State or other jurisdiction of
incorporation or
organization)

2408 Timberloch Place, Suite B-7
The Woodlands, Texas 77380
(Address of principal executive offices
and zip code)

76-0233274
(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 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 No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging Growth Company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act

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

As of May 5, 2017, there were outstanding 26,732,074 shares of Common Stock, par value \$.001 per share, of the Registrant.

REPROS THERAPEUTICS INC.

For the Quarter Ended March 31, 2017

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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 success of the clinical trials for Proellex ®; the progress of the Company's enclomiphene product candidate; 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, 2016.

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 month periods ended March 31, 2017 are not necessarily indicative of the results that may be expected for the year ending December 31, 2017. 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, 2016.

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)

	<u>March 31,</u> <u>2017</u>	<u>December 31,</u> <u>2016</u>
ASSETS		
Current assets		
Cash and cash equivalents	\$ 3,235	\$ 8,688
Restricted cash	916	-
Prepaid expenses and other current assets	304	66
Total current assets	4,455	8,754
Fixed assets, net	2	3
Non-current restricted cash	916	-
Total assets	\$ 5,373	\$ 8,757
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 1,657	\$ 1,880
Accrued expenses	1,179	779
Total current liabilities	2,836	2,659
Long-term liabilities:		
Accrued severance	916	-
Total liabilities	3,752	2,659
Commitments & 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, 26,797,769 and 25,938,602 shares issued, respectively; 26,685,419 and 25,826,252 shares outstanding, respectively	27	26
Additional paid-in capital	328,413	326,981
Cost of treasury stock, 112,350 shares	(1,380)	(1,380)
Accumulated deficit	(325,439)	(319,529)
Total stockholders' equity	1,621	6,098
Total liabilities and stockholders' equity	\$ 5,373	\$ 8,757

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 March 31,	
	2017	2016
Revenues and other income		
Interest income	\$ 7	\$ 17
Total revenues and other income	7	17
Expenses		
Research and development	2,074	3,765
General and administrative	3,843	1,096
Total expenses	5,917	4,861
Net loss	\$ (5,910)	\$ (4,844)
Loss per share - basic and diluted	\$ (0.22)	\$ (0.20)
Shares used in loss per share calculation:		
Basic	26,270	24,318
Diluted	26,270	24,318

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)

	<u>Common Stock</u>		<u>Additional</u>	<u>Treasury Stock</u>		<u>Accumulated</u>	<u>Total</u>
	<u>Shares</u>	<u>Amount</u>	<u>Paid-in</u>	<u>Shares</u>	<u>Amount</u>	<u>Deficit</u>	<u>Stockholders'</u>
			<u>Capital</u>				<u>Equity</u>
Balance at December 31, 2016	25,938,602	\$ 26	\$ 326,981	112,350	\$ (1,380)	\$ (319,529)	\$ 6,098
Stock based compensation	-	-	436	-	-	-	436
Issuance of 828,057 shares of common stock at a weighted average share price of \$1.20, net of offering costs of \$31	828,057	1	996	-	-	-	997
Issuance of 20,000 shares of restricted common stock	20,000	-	-	-	-	-	-
Issuance of 11,110 share common stock for vested RSUs	11,110	-	-	-	-	-	-
Net loss	-	-	-	-	-	(5,910)	(5,910)
Balance at March 31, 2017	<u>26,797,769</u>	<u>\$ 27</u>	<u>\$ 328,413</u>	<u>112,350</u>	<u>\$ (1,380)</u>	<u>\$ (325,439)</u>	<u>\$ 1,621</u>
Balance at December 31, 2015	24,430,461	\$ 24	\$ 322,179	112,350	\$ (1,380)	\$ (302,256)	\$ 18,567
Stock based compensation	-	-	516	-	-	-	516
Net loss	-	-	-	-	-	(4,844)	(4,844)
Balance at March 31, 2016	<u>24,430,461</u>	<u>\$ 24</u>	<u>\$ 322,695</u>	<u>112,350</u>	<u>\$ (1,380)</u>	<u>\$ (307,100)</u>	<u>\$ 14,239</u>

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

REPROS THERAPEUTICS INC.

(A development stage company)

REPROS THERAPEUTICS INC. AND SUBSIDIARY

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited and in thousands)

	Three Months Ended March 31,	
	2017	2016
Cash Flows from Operating Activities		
Net loss	\$ (5,910)	\$ (4,844)
Depreciation	1	2
Noncash stock-based compensation	436	516
(Increase) decrease in prepaid expenses and other current assets	(238)	(209)
Increase (decrease) in accounts payable and accrued expenses	1,093	(812)
Net cash used in operating activities	(4,618)	(5,347)
Cash Flows from Investing Activities		
Capital expenditures	-	-
Net cash used in investing activities	-	-
Cash Flows from Financing Activities		
Proceeds from issuance of common stock, net of offering costs	997	-
Net cash provided by financing activities	997	-
Net decrease in cash, cash equivalents and restricted cash	(3,621)	(5,347)
Cash, cash equivalents and restricted cash at beginning of period	8,688	21,393
Cash, cash equivalents and restricted cash at end of period	\$ 5,067	\$ 16,046

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

REPOS THERAPEUTICS INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2017

(Unaudited)

NOTE 1 — Organization, Operations, Liquidity and Recent Developments

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

We are 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 uterine fibroids and endometriosis. We completed a low dose escalating study as permitted by the Food and Drug Administration (“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 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 uterine fibroids and endometriosis while remaining on partial clinical hold. This guidance indicated that the highest allowed dose will be 12 mg daily. On December 29, 2014, we announced that we have initiated a Phase 2B study for low dose oral Proellex® in the treatment of uterine fibroids. This study was fully enrolled in January 2016 and on November 14, 2016, we announced positive clinical data from this study after two 18-week courses of treatment as compared to placebo. On April 10, 2017, the Company announced that it had a meeting with the FDA to discuss the progress and next steps in the development of Proellex® for the treatment of uterine fibroids. Shortly before the meeting, the Company was notified that the meeting would be a type C/Guidance meeting, rather than a type B/End of phase 2 meeting as previously anticipated. At the meeting, the FDA confirmed that Proellex® will continue on the current partial clinical hold while they consult with liver experts within the FDA regarding previously disclosed effects on the liver.

The Company has an active Investigational New Drug Application (“IND”) for the vaginal delivery of Proellex® for the treatment of uterine fibroids. Since the clinical hold relates only to oral delivery of Proellex®, this IND has no clinical hold issues. In the first quarter of 2012, we initiated a Phase 2 vaginal administration study for the treatment of uterine fibroids and subsequently reported the final study results in January 2013. We held an end of Phase 2 meeting with the FDA in May 2013, to discuss a Phase 3 study design for vaginally delivered Proellex as a treatment for uterine fibroids. The FDA recommended that a Phase 2B study should be conducted prior to commencing a Phase 3 program. On December 29, 2014, we announced that we have initiated a Phase 2B study for vaginally delivered Proellex® in the treatment of uterine fibroids. This study was fully enrolled in January 2016 and on November 14, 2016, we announced positive clinical data from this study after two 18-week courses of treatment as compared to placebo.

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

On February 2, 2015, we announced that we electronically submitted our New Drug Application (“NDA”) to the FDA for enclomiphene. The FDA accepted the NDA for review on April 1, 2015 and later assigned a Prescription Drug User Fee (“PDUFA”) goal date of November 30, 2015. In addition, the Division of Bone, Reproductive and Urologic Products (the “Division”) of the FDA scheduled an advisory committee meeting to review the NDA for November 3, 2015. However, the Division subsequently cancelled the scheduled advisory committee meeting due to questions that arose late in the review regarding the bioanalytical method validation that could affect interpretability of certain pivotal study data. On December 1, 2015, we announced that we had received a Complete Response Letter (“CRL”) from the FDA. A CRL informs companies that an NDA cannot be approved in its present form. In the CRL, the FDA stated that, based on recent scientific developments, the design of the enclomiphene Phase 3 studies is no longer adequate to demonstrate clinical benefit and recommended that Repros conduct an additional Phase 3 study or studies to support approval in the target population. The FDA also noted concerns regarding study entry criteria, titration and bioanalytical method validation in the Phase 3 program.

Subsequently, on February 4, 2016, the Company attended a meeting with the FDA reviewers and senior leaders to discuss resolution of issues identified during the NDA review. The meeting covered a broad range of topics surrounding the NDA data as well as emerging agency and expert thinking regarding the treatment of hypogonadism. The Company believes based on the meeting that the FDA is not closed to considering secondary hypogonadism as an indication. Additionally, in January 2016, the Company initiated a Phase 2 double-blind, placebo controlled, proof of concept study, ZA-205, in obese secondary hypogonadal men to assess the impact of enclomiphene on metabolic parameters and quality of life under a diet and exercise regimen. This study was fully enrolled in February 2016 and 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”) which, as previously reported, has assigned the United Kingdom as the primary rapporteur and France as the co-rapporteur for the application review.

On December 6, 2016, the Company participated in the industry presentation at the Bone, Reproductive and Urologic Drugs’ Advisory Committee meeting. The advisory panel provided the FDA with advice regarding a clinical and regulatory path to approval for products, such as enclomiphene, in subjects with obesity-related hypogonadism who wish to maintain spermatogenesis. The panel voted 16 to 5 that the achievement of testosterone improvement while maintaining evidence of spermatogenesis was not sufficient, in and of itself, to provide evidence of clinical benefit. At the meeting, numerous panel members suggested that an additional endpoint related to symptoms should be assessed.

Recent Developments

On February 1, 2017, Joseph S. Podolski left as our President and Chief Executive Officer, and also as a member of our Board of Directors.

Following Mr. Podolski’s departure, Larry Dillaha, M.D. was appointed to serve, on an interim basis, as the Company’s President and Chief Executive Officer. On April 10, 2017, the Company announced that Dr. Dillaha had been appointed as permanent President and Chief Executive Officer. Dr. Dillaha, age 53, has since November 2016 been the Chief Executive Officer and a member of the Board of Directors of CavtheRx, a pre-IND stage, virtual company focused on developing Caveolin Modulators for a variety of inflammatory indications. From April 2014 through January 2017, Dr. Dillaha was the Chief Operating Officer and Chief Medical Officer of New Haven Pharmaceuticals, a specialty pharmaceutical company. From April 2010 through March 2014, Dr. Dillaha was the Chief Medical Officer of Insys Therapeutics, from March 2006 through March 2010, Dr. Dillaha was the Chief Medical Officer of Sciele Pharma, both specialty pharmaceutical companies, and from 2002 through February 2006, Dr. Dillaha was Medical Director, Cardiovascular at Sanofi-Synthelabo/Sanofi. Before that, Dr. Dillaha was a physician in private practice. Dr. Dillaha received his undergraduate degree from the University of Tennessee, Knoxville and his M.D. from the University of Tennessee, Memphis.

In connection with his leaving and in accordance with the terms of his Employment Agreement, dated as of June 16, 2014 (the “Employment Agreement”), Mr. Podolski entered into a Release Agreement with the Company (the “Release Agreement”) dated as of February 1, 2017. The Release Agreement was previously filed with the Securities and Exchange Commission as an exhibit to the Company’s Current Report on Form 8-K filed on February 2, 2017. In accordance with the Employment Agreement, conditioned upon entering into the Release Agreement, Mr. Podolski was treated as having been terminated without Cause (as defined in the Employment Agreement) and will thus receive the following benefits in connection with his separation: (1) a severance payment equal to an amount equal to three times the amount that results from (x) the sum of (i) Mr. Podolski’s annual base salary (at the rate in effect immediately before the date of termination) and target bonus for the fiscal year in which the termination occurs, (ii) Mr. Podolski’s annual base salary for each of the two calendar years immediately prior to the calendar year in which the termination date occurs and (iii) the annual bonus that was actually earned and paid to Mr. Podolski for the two fiscal years that immediately precede the fiscal year in which the termination date occurs, divided by (y) three; (2) reimbursement of amounts paid for COBRA coverage for the eighteen (18) month period following the date of separation for Mr. Podolski, his spouse and his eligible dependents, less the amount that he would be required to contribute for medical and dental coverage if he remained an active employee of the Company; (3) all outstanding stock options held by Mr. Podolski that are not vested and exercisable as of the date of termination will become fully vested and exercisable on the date of termination and all outstanding stock options held by Mr. Podolski on his date of termination will remain exercisable for the shorter of (x) a period of two (2) years from the date of termination or (y) the remaining term of the option.

Pursuant to the Employment Agreement, which was previously filed with the Securities and Exchange Commission as an exhibit to the Company’s Current Report on Form 8-K filed on June 20, 2014, the Release Agreement indicates that Mr. Podolski is bound by certain restrictive covenants, including non-compete and non-solicitation provisions. The Release Agreement also contains a release by Mr. Podolski of all claims against the Company, subject to certain enumerated exceptions.

The Company recorded a charge in the first quarter of 2017 of \$2.8 million related to Mr. Podolski’s departure.

Liquidity

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 March 31, 2017, we sold 828,057 ATM Shares at a weighted average share price of \$1.20, for proceeds of approximately \$997,000, net of expenses including approximately \$31,000 in commissions to Ladenburg. Between April 1, 2017 and May 8, 2017, we sold an aggregate of 21,100 ATM Shares at a weighted average share price of \$1.17, for proceeds of approximately \$25,000, net of expenses including approximately \$1,000 in commissions to Ladenburg.

As of March 31, 2017, we had accumulated losses of \$325.4 million, approximately \$3.2 million in cash and cash equivalents, and accounts payable and accrued expenses of approximately \$3.8 million, in the aggregate. Included in our accrued expenses is \$1.8 million related to the accrued severance payments due Mr. Podolski upon his termination, which are anticipated to be paid in the first quarter of 2018 and 2019. We anticipate that our current liquidity will be sufficient to continue the development of our product candidates and meet our obligations as they become due through the second quarter of 2017. We continue to explore potential additional financing alternatives, including corporate partnering opportunities, that would provide sufficient funds to enable us to continue to develop our two product candidates through FDA approval; however, there can be no assurance that we will be successful in raising any such additional funds on a timely basis or at all. The foregoing matters raise substantial doubt about our ability to continue as a going concern.

Basis of Presentation

These financial statements are unaudited; however, in the opinion of management, these statements reflect all adjustments necessary for a fair statement of the results for the periods reported. All such adjustments are of a normal recurring nature unless disclosed otherwise. These financial statements, including notes, have been prepared in accordance with the applicable rules of the SEC and do not include all of the information and disclosures required by U.S. GAAP for complete financial statements.

These interim financial statements should be read in conjunction with the financial statements and notes thereto included in our 2016 Annual Report on Form 10-K. The results of operations for the first quarter of 2017 are not necessarily indicative of the results to be expected for the full year.

Recent Accounting Pronouncements

In November 2016, the FASB issued ASU No. 2016-18, “Statement of Cash Flows (Topic 230): Restricted Cash”. The new standard requires restricted cash to be included with cash and cash equivalents when reconciling the beginning and ending amounts on the statement of cash flows, and requires additional disclosures in the notes to the financial statements. ASU 2016-18 is effective for fiscal years beginning after December 15, 2017 and interim periods within those fiscal years and early adoption is permitted. The Company adopted this standard during the quarter ended March 31, 2017. See Note 2 to the financial statements included herein.

In March 2016, the FASB issued ASU 2016-09, Compensation—Stock Compensation (ASC Topic 718): Improvements to Employee Share-Based Payment Accounting. The new standard simplifies the accounting for stock-based compensation, including amendments on how both taxes related to stock-based compensation and cash payments made to taxing authorities are recorded. ASU 2016-09 is effective for annual reporting periods beginning on or after December 15, 2016, and interim periods within those annual periods and early application is permitted, with any adjustments reflected as of the beginning of the fiscal year of adoption. The Company adopted ASU 2016-09 effective January 1, 2017. The adoption of this standard did not have a material effect on the Company’s financial statements.

In February 2016, FASB issued ASU 2016-02, Leases (ASC Topic 842), which supersedes ASC Topic 840, Leases. The new standard is intended to increase transparency and comparability of organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. The new guidance is effective for financial statements issued for annual reporting periods beginning after December 15, 2018, and early application is permitted. The Company is currently evaluating the impact of this standard on our consolidated financial statements.

In November 2015, the FASB issued ASU No. 2015-17, “Balance Sheet Classification of Deferred Taxes” (“ASU 2015-17”), which requires entities to present deferred tax assets and deferred tax liabilities as noncurrent in a classified balance sheet. The ASU simplifies the current guidance in ASC Topic 740, Income Taxes, which requires entities to separately present deferred tax assets and liabilities as current and noncurrent in a classified balance sheet. ASU 2015-17 is effective for fiscal years beginning after December 15, 2016, and interim periods within those annual periods. The Company adopted ASU 2015-07 effective January 1, 2017. The adoption of this standard did not have a material effect on the Company’s financial statements.

In May 2014, the FASB issued Accounting Standards Update 2014-09, “Revenue from Contracts with Customers” (“ASU 2014-09”). ASU 2014-09 is a comprehensive new revenue recognition model requiring a company to recognize revenue to depict the transfer of goods or services to a customer at an amount reflecting the consideration it expects to receive in exchange for those goods or services. In adopting ASU 2014-09, companies may use either a full retrospective or a modified retrospective approach. Additionally, this guidance requires improved disclosures regarding the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. On July 9, 2015, the FASB voted to delay the effective date of this standard by one year. This deferral resulted in ASU 2014-09 being effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2017, with early adoption being permitted for annual periods beginning after December 15, 2016. Entities have the option of using either a full retrospective or a modified retrospective approach to adopt the guidance. The Company is currently assessing the effects this guidance may have on its consolidated financial statements, as well as the method of transition that the Company will use in adopting the new standard.

NOTE 2 — Cash, Cash Equivalents and Restricted Cash

As of March 31, 2017, the Company maintained \$1.8 million as restricted cash. The funds are being held in accordance with the Release Agreement entered into with Mr. Podolski on February 1, 2017.

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the balance sheets that sum to the total of the same such amounts shown in the statements of cash flows:

	<u>March 31, 2017</u>	<u>March 31, 2016</u>
Cash and cash equivalents	\$ 3,235	\$ 16,046
Restricted cash, current	916	—
Restricted cash, noncurrent	916	—
Total	<u>\$ 5,067</u>	<u>\$ 16,046</u>

NOTE 3 — Accrued Expenses

Accrued expenses consist of the following (in thousands):

	<u>March 31, 2017</u>	<u>December 31, 2016</u>
Current accrued expenses:		
Personnel related costs	\$ 1,005	\$ 512
Research and development costs	126	174
Other	48	93
Total current accrued expenses	<u>\$ 1,179</u>	<u>\$ 779</u>

	<u>March 31, 2017</u>	<u>December 31, 2016</u>
Long-term accrued expenses:		
Accrued severance	\$ 916	\$ --
Total long-term accrued expenses	<u>\$ 916</u>	<u>\$ --</u>

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 shares outstanding 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 month periods ended March 31, 2017 and 2016 (in thousands, except per share amounts):

	Three Months Ended March 31,	
	2017	2016
Net loss	\$ (5,910)	\$ (4,844)
Average common shares outstanding	26,270	24,318
Basic and diluted loss per share	\$ (0.22)	\$ (0.20)

Potential common stock of 3,097,690 common shares underlying stock options and restricted stock units for the period ended March 31, 2017, were excluded from the above calculation of diluted loss per share because they were anti-dilutive. Potential common stock of 2,554,857 underlying stock options for the period ended March 31, 2016, were also excluded from the above calculation of diluted loss per share because they were anti-dilutive.

NOTE 5 — Stock-Based Compensation

On February 1, 2017, the Board of Directors (the “Board”) granted Larry Dillaha, the Company’s then interim President and Chief Executive Officer a grant of 50,000 stock options to vest upon the successful completion of certain milestones. Additionally, the Board awarded to Katherine Anderson, the Company’s Chief Financial Officer, 10,000 restricted shares of common stock per month on the first day of each month beginning February 1, 2017 and ending on July 1, 2017, to vest on the last day of the month of grant. On February 13, 2017, the Board awarded Michael Wyllie, a non-employee director of the Company, and Larry Dillaha, a grant of 50,000 stock options each. Both option awards will vest upon the successful completion of certain milestones. On February 13, 2017, the Board awarded each board member a grant of 40,000 restricted stock unites, to settle in shares of the Company’s common stock and to vest in equal monthly installments over the three years following the date of grant.

NOTE 6 — Commitments and Contingencies

Therapeutic uses of our enclomiphene product candidate are covered in the United States by approximately ten issued U.S. patents and eleven pending patent applications. Foreign coverage of therapeutic uses of our enclomiphene product candidate includes approximately 85 issued foreign patents and more than 100 foreign pending patent applications. The issued patents and pending applications relate to methods for treating certain conditions including the treatment of testosterone deficiency in men, the treatment of diabetes mellitus Type 2, the treatment of metabolic syndrome and conditions associated therewith, and the treatment of infertility in hypogonadal men. Enclomiphene (the trans-isomer of clomiphene) is purified from clomiphene citrate. A third party individual holds two issued patents related to the use of anti-estrogen such as clomiphene citrate and others for use in the treatment of androgen deficiency and disorders related thereto. We requested re-examination of one of these patents by the U.S. Patent and Trademark Office (“PTO”) based on prior art. The patent holder amended the claims in the re-examination proceedings, which led the PTO to determine that the amended claims were patentable in view of those publications under consideration and a re-examination certificate was issued. We subsequently filed a second request for re-examination by the PTO in light of a number of additional publications. The request was granted and all of the claims were finally rejected by the PTO in the re-examination. The patent holder appealed the rejections to the PTO Board of Patent Appeals and Interferences (the “PTO Board”) which ultimately reversed the rejections of several dependent claims in view of those publications under consideration. The patent holder filed a Notice of Appeal to the Federal Circuit on September 28, 2010 contesting the rejections maintained by the PTO Board. A decision was rendered by the Court of Appeals for the Federal Circuit on December 12, 2011, affirming the rejection of the appealed claims. The PTO issued an Ex Parte Reexamination Certificate on April 29, 2013, canceling the rejected claims and confirming the patentability of the remaining claims. Nevertheless, we believe that our development of enclomiphene does not infringe any of the remaining claims and that all of the remaining claims are invalid on various grounds including additional prior art publications. We also believe that the second of these two patents is invalid in view of published prior art not considered by the PTO. If necessary, we intend to vigorously defend any and all claims that may be brought by the holder of such patents in a court of competent jurisdiction in order to develop enclomiphene further. Adverse determinations in litigation proceedings could require us to seek licenses which may not be available on commercially reasonable terms, or at all, or subject us to significant liabilities, in which case we may not be able to successfully commercialize or out-license enclomiphene until such patents expire or are otherwise no longer in force.

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

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

Repros Therapeutics Inc.

The Company was organized on August 20, 1987. We are a biopharmaceutical company focused on the development of new drugs to treat hormonal and reproductive system disorders.

We are developing 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 uterine fibroids and endometriosis. We completed a low dose escalating study as permitted by the Food and Drug Administration ("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 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 uterine fibroids and endometriosis while remaining on partial clinical hold. This guidance indicated that the highest allowed dose will be 12 mg daily. On December 29, 2014, we announced that we have initiated a Phase 2B study for low dose oral Proellex® in the treatment of uterine fibroids. This study was fully enrolled in January 2016 and on November 14, 2016, we announced positive clinical data from this study after two 18-week courses of treatment as compared to placebo. On April 10, 2017, the Company announced they had a meeting with the FDA to discuss the progress and next steps in the development of Proellex® for the treatment of uterine fibroids. Shortly before the meeting, the Company was notified that the meeting would be a type C/Guidance meeting, rather than a type B/End of phase 2 meeting as previously anticipated. At the meeting, the FDA confirmed that Proellex® will continue on the current partial clinical hold while they consult with liver experts within the FDA regarding previously disclosed effects on the liver.

The Company has an active Investigational New Drug Application ("IND") for the vaginal delivery of Proellex® for the treatment of uterine fibroids. Since the clinical hold relates only to oral delivery of Proellex®, this IND has no clinical hold issues. In the first quarter of 2012, we initiated a Phase 2 vaginal administration study for the treatment of uterine fibroids and subsequently reported the final study results in January 2013. We held an end of Phase 2 meeting with the FDA in May 2013, to discuss a Phase 3 study design for vaginally delivered Proellex as a treatment for uterine fibroids. The FDA recommended that a Phase 2B study should be conducted prior to commencing a Phase 3 program. On December 29, 2014, we announced that we have initiated a Phase 2B study for vaginally delivered Proellex® in the treatment of uterine fibroids. This study was fully enrolled in January 2016 and on November 14, 2016, we announced positive clinical data from this study after two 18-week courses of treatment as compared to placebo. However, the Company plans to propose the oral route of administration for Phase 3 development.

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

In December 2011, we completed a Phase 2B study of enclomiphene in men with secondary hypogonadism, but naïve to testosterone treatment, at the recommendation of the FDA. Top line results of this study demonstrated that enclomiphene was generally well tolerated compared to placebo and that there were no drug related serious adverse events that led to discontinuation. We met with the FDA in May 2012 to discuss the design of pivotal Phase 3 efficacy studies for enclomiphene as well as the components of the overall drug development program required for a New Drug Application (“NDA”) submission and agreed on registration requirements for enclomiphene oral therapy for the treatment of secondary hypogonadism. In July 2012, we announced that we reached an agreement with the FDA for the design of the pivotal efficacy studies for enclomiphene for the treatment of secondary hypogonadism. The pivotal studies were conducted under a Special Protocol Assessment (“SPA”). We have completed both Phase 3 pivotal efficacy studies. On March 27, 2013, we announced that the top-line results from our first pivotal Phase 3 study, ZA-301, met both co-primary endpoints mandated by the FDA, and we announced on September 16, 2013, that we met both co-primary endpoints in the second pivotal study, ZA-302. Additionally, on September 16, 2013, we announced the results from ZA-300, a six-month safety study. This study identified no new safety issues. On October 22, 2013, we announced that we received guidance from the FDA instructing the Company to request a meeting to discuss the adequacy of studies ZA-301 and ZA-302. In addition to this guidance, the FDA further noted that they would allow us to run head-to-head studies against approved testosterone replacement products. These head-to-head studies, ZA-304 and ZA-305, were initiated in January 2014 and subsequently completed in September and August 2014, respectively. Both of these head-to-head studies achieved superiority for both co-primary endpoints and most secondary endpoints as compared to the approved testosterone replacement product. On October 21, 2014, we announced the results from ZA-303, a 52 week, single-blind, placebo-controlled Phase 3 study to evaluate the effects on bone mineral density. In this study, no new safety signals were identified, including no evidence of negative effects on bone mineral density. On February 2, 2015, we announced that we electronically submitted our NDA to the FDA for enclomiphene. The FDA accepted the NDA for review on April 1, 2015 and later assigned a Prescription Drug User Fee (“PDUFA”) goal date of November 30, 2015. In addition, the Division of Bone, Reproductive and Urologic Products (the “Division”) of the FDA scheduled an advisory committee meeting to review the NDA for November 3, 2015. However, the Division subsequently cancelled the scheduled advisory committee meeting due to questions that arose late in the review regarding the bioanalytical method validation that could affect interpretability of certain pivotal study data. On December 1, 2015, we announced that we had received a Complete Response Letter (“CRL”) from the FDA. A CRL informs companies that an NDA cannot be approved in its present form. In the CRL, the FDA stated that, based on recent scientific developments, the design of the enclomiphene Phase 3 studies is no longer adequate to demonstrate clinical benefit and recommended that Repros conduct an additional Phase 3 study or studies to support approval in the target population. The FDA also noted concerns regarding study entry criteria, titration and bioanalytical method validation in the Phase 3 program.

Subsequently, on February 4, 2016, the Company attended a meeting with the FDA reviewers and senior leaders to discuss resolution of issues identified during the NDA review. The meeting covered a broad range of topics surrounding the NDA data as well as emerging agency and expert thinking regarding the treatment of hypogonadism. The Company believes based on the meeting that the FDA is not closed to considering secondary hypogonadism as an indication. Additionally, in January 2016, the Company initiated a Phase 2 double-blind, placebo controlled, proof of concept study, ZA-205, in obese secondary hypogonadal men to assess the impact of enclomiphene on metabolic parameters and quality of life under a diet and exercise regimen. This study was fully enrolled in February 2016 and 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.

On December 6, 2016, the Company participated in the industry presentation at the Bone, Reproductive and Urologic Drugs’ Advisory Committee meeting. The advisory panel provided the FDA with advice regarding a clinical and regulatory path to approval for products, such as enclomiphene, in subjects with obesity-related hypogonadism who wish to maintain spermatogenesis. The panel voted 16 to 5 that the achievement of testosterone improvement while maintaining evidence of spermatogenesis was not sufficient, in and of itself, to provide evidence of clinical benefit. At the meeting, numerous panel members suggested that an additional endpoint related to symptoms should be assessed.

Recent Developments

On February 1, 2017, Joseph S. Podolski left as our President and Chief Executive Officer, and also as a member of our Board of Directors.

Following Mr. Podolski’s departure, Larry Dillaha, M.D. was appointed to serve, on an interim basis, as the Company’s President and Chief Executive Officer. On April 10, 2017, the Company announced that Dr. Dillaha had been appointed as permanent President and Chief Executive Officer. Dr. Dillaha, age 53, has since November 2016 been the Chief Executive Officer and a member of the Board of Directors of CavtheRx, a pre-IND stage, virtual company focused on developing Caveolin Modulators for a variety of inflammatory indications. From April 2014 through January 2017, Dr. Dillaha was the Chief Operating Officer and Chief Medical Officer of New Haven Pharmaceuticals, a specialty pharmaceutical company. From April 2010 through March 2014, Dr. Dillaha was the Chief Medical Officer of Insys Therapeutics, from March 2006 through March 2010, Dr. Dillaha was the Chief Medical Officer of Sciele Pharma, both specialty pharmaceutical companies, and from 2002 through February 2006, Dr. Dillaha was Medical Director, Cardiovascular at Sanofi-Synthelabo/Sanofi. Before that, Dr. Dillaha was a physician in private practice. Dr. Dillaha received his undergraduate degree from the University of Tennessee, Knoxville and his M.D. from the University of Tennessee, Memphis.

In connection with his leaving and in accordance with the terms of his Employment Agreement, dated as of June 16, 2014 (the “Employment Agreement”), Mr. Podolski entered into a Release Agreement with the Company (the “Release Agreement”) dated as of February 1, 2017. The Release Agreement was previously filed with the Securities and Exchange Commission as an exhibit to the Company’s Current Report on Form 8-K filed on February 2, 2017. In accordance with the Employment Agreement, conditioned upon entering into the Release Agreement, Mr. Podolski was treated as having been terminated without Cause (as defined in the Employment Agreement) and will thus receive the following benefits in connection with his separation: (1) a severance payment equal to an amount equal to three times the amount that results from (x) the sum of (i) Mr. Podolski’s annual base salary (at the rate in effect immediately before the date of termination) and target bonus for the fiscal year in which the termination occurs, (ii) Mr. Podolski’s annual base salary for each of the two calendar years immediately prior to the calendar year in which the termination date occurs and (iii) the annual bonus that was actually earned and paid to Mr. Podolski for the two fiscal years that immediately precede the fiscal year in which the termination date occurs, divided by (y) three; (2) reimbursement of amounts paid for COBRA coverage for the eighteen (18) month period following the date of separation for Mr. Podolski, his spouse and his eligible dependents, less the amount that he would be required to contribute for medical and dental coverage if he remained an active employee of the Company; (3) all outstanding stock options held by Mr. Podolski that are not vested and exercisable as of the date of termination will become fully vested and exercisable on the date of termination and all outstanding stock options held by Mr. Podolski on his date of termination will remain exercisable for the shorter of (x) a period of two (2) years from the date of termination or (y) the remaining term of the option.

Pursuant to the Employment Agreement, which was previously filed with the Securities and Exchange Commission as an exhibit to the Company's Current Report on Form 8-K filed on June 20, 2014, the Release Agreement indicates that Mr. Podolski is bound by certain restrictive covenants, including non-compete and non-solicitation provisions. The Release Agreement also contains a release by Mr. Podolski of all claims against the Company, subject to certain enumerated exceptions.

The Company recorded a charge in the first quarter of 2017 of \$2.8 million related to Mr. Podolski's departure.

Liquidity

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 March 31, 2017, we sold 828,057 ATM Shares at a weighted average share price of \$1.20, for proceeds of approximately \$997,000, net of expenses including approximately \$31,000 in commissions to Ladenburg. Between April 1, 2017 and May 8, 2017, we sold an aggregate of 21,100 ATM Shares at a weighted average share price of \$1.17, for proceeds of approximately \$25,000, net of expenses including approximately \$1,000 in commissions to Ladenburg.

As of December 31, 2016, we had accumulated losses of \$325.4 million, approximately \$3.2 million in cash and cash equivalents, and accounts payable and accrued expenses of approximately \$3.8 million, in the aggregate. Included in our accrued expenses is \$1.8 million related to the accrued severance payments due Mr. Podolski upon his termination, which are anticipated to be paid in the first quarter of 2018 and 2019. We anticipate that our current liquidity will be sufficient to continue the development of our product candidates and meet our obligations as they become due through the second quarter of 2017. We continue to explore potential additional financing alternatives, including corporate partnering opportunities, that would provide sufficient funds to enable us to continue to develop our two product candidates through FDA approval; however, there can be no assurance that we will be successful in raising any such additional funds on a timely basis or at all. The foregoing matters raise substantial doubt about our ability to continue as a going concern.

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. 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 without add-back hormonal therapy.

We have conducted numerous studies with Proellex® dosing approximately 900 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 (amenorrhea). Over 80% of women on both the 12.5 and 25 mg doses exhibited amenorrhea during the three month trial, whereas all women on placebo exhibited at least one menses. The key symptom of uterine fibroids is excessive menstrual bleeding. The induction of amenorrhea continues to be the primary endpoint in our uterine fibroids clinical studies.

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 daily. 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.

Low Dose Oral Study

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

On July 16, 2012, we announced that we held a teleconference with the FDA to discuss the development of low dose oral Proellex® as a treatment for endometriosis. Subsequently, on October 8, 2012, we announced that the FDA has agreed to reclassify the full clinical hold to a partial clinical hold on low dose oral Proellex® to allow us to conduct a Phase 2 study in the treatment of endometriosis. We initiated this 60 subject, four month active dosing study in November 2012 and it was fully enrolled in January 2016. On September 7, 2016, we announced positive clinical data for the first course of treatment in this Phase 2 study.

On October 31, 2013, the Company held a meeting with the FDA to discuss the clinical development plan for low dose oral Proellex® in the treatment of uterine fibroids. During the meeting, the FDA provided guidance for endpoints it believed acceptable for the treatment of uterine fibroids in an efficacy study and instructed the Company to submit a request for lifting the full clinical hold. The Company has followed the FDA's recommendations and submitted the study protocol and the request for the full hold lift. Additionally, on March 17, 2014, we announced that the FDA indicated that we may proceed to conduct Phase 1 and Phase 2 studies of low dose oral Proellex® for endometriosis and uterine fibroids while remaining on partial clinical hold. This guidance indicated that the highest allowed dose will be 12 mg daily. On December 29, 2014, we announced that we have initiated a Phase 2B study for low dose oral Proellex® in the treatment of uterine fibroids. This study was fully enrolled in January 2016 and on November 14, 2016, we announced positive clinical data from this study after two 18-week courses of treatment as compared to placebo. On January 30, 2017, we announced the FDA has granted the Company an end of phase 2 meeting to discuss the phase 3 requirements for Proellex in the treatment of uterine fibroids. Subsequently, on April 10, 2017, the Company announced that it had a meeting with the FDA to discuss the progress and next steps in the development of Proellex® for the treatment of uterine fibroids. Shortly before the meeting, the Company was notified that the meeting would be a type C/Guidance meeting, rather than a type B/End of phase 2 meeting as previously anticipated. At the meeting, the FDA confirmed that Proellex® will continue on the current partial clinical hold while they consult with liver experts within the FDA regarding previously disclosed effects on the liver. Further, the FDA agreed to accept additional information from the Company and its panel of liver experts for consideration by the FDA's internal advisory liver team. The Company expects to submit the additional information and a proposed clinical protocol within a month. The Company intends to announce further information following receipt of additional guidance from the FDA.

Vaginal Administration

We are assessing vaginal administration of Proellex® to avoid first pass liver effects and achieve higher reproductive tract concentrations of the drug while minimizing systemic exposure. We reported results from two in vivo animal studies which confirmed reduced maximum circulating concentrations of the drug when administered vaginally, as well as efficacy signals at substantially lower doses than oral administration. The Company has an active IND for the vaginal delivery of Proellex® for the treatment of uterine fibroids. Since the clinical hold relates only to the oral delivery of Proellex®, this IND has no clinical hold issues. In the first quarter of 2012, we initiated a Phase 2 vaginal administration study for the treatment of uterine fibroids. In January 2013, we reported the final study results which indicated the 12 mg dose achieved statistically significant improvement in menstrual bleeding, uterine fibroid symptoms and reduction in fibroid volume even with the low number of subjects enrolled into the study (n=12 @ 12 mg). Based on these findings, the Company believes the 12 mg dose is appropriate for further development. We held an end of Phase 2 meeting with the FDA in May 2013, to discuss a Phase 3 study design for the vaginally delivered Proellex as a treatment for uterine fibroids. The FDA recommended that a Phase 2B study should be conducted prior to commencing a Phase 3 program. On December 29, 2014, we announced that we have initiated a Phase 2B study for vaginally delivered Proellex® in the treatment of uterine fibroids. This study was fully enrolled in January 2016 and on November 14, 2016, we announced positive clinical data from this study after two 18-week courses of treatment as compared to placebo.

Enclomiphene

Product Overview

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

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

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

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

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

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

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

On July 9, 2012, we announced that we reached an agreement with the FDA for the design of the pivotal efficacy studies for enclomiphene for the treatment of secondary hypogonadism. The pivotal studies were conducted under an SPA. On March 27, 2013, we announced that the top-line results from our first pivotal Phase 3 study, ZA-301, met both co-primary endpoints mandated by the FDA and we announced on September 16, 2013, that we met both co-primary endpoints in the second pivotal study, ZA-302.

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

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

On February 2, 2015, we announced that we electronically submitted our NDA to the FDA for enclomiphene. The FDA accepted the NDA for review on April 1, 2015 and later assigned a PDUFA goal date of November 30, 2015. In addition, 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 CRL from the FDA. A CRL informs companies that an NDA cannot be approved in its present form. In the CRL, the FDA stated that, based on recent scientific developments, the design of the enclomiphene Phase 3 studies is no longer adequate to demonstrate clinical benefit and recommended that Repros conduct an additional Phase 3 study or studies to support approval in the target population. The FDA also noted concerns regarding study entry criteria, titration and bioanalytical method validation in the Phase 3 program. Subsequently, on February 4, 2016, the Company attended a meeting with the FDA reviewers and senior leaders to discuss resolution of issues identified during the NDA review. The meeting covered a broad range of topics surrounding the NDA data as well as emerging agency and expert thinking regarding the treatment of hypogonadism. The Company believes based on the meeting that the FDA is not closed to considering secondary hypogonadism as an indication. Additionally, in January 2016, the Company initiated a Phase 2 double-blind, placebo controlled, proof of concept study, ZA-205, in obese secondary hypogonadal men to assess the impact of enclomiphene on metabolic parameters and quality of life under a diet and exercise regimen. This study was fully enrolled in February 2016 and 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”) which, as previously reported, has assigned the United Kingdom as the primary rapporteur and France as the co-rapporteur for the application review.

On December 6, 2016, the Company participated in the industry presentation at the Bone, Reproductive and Urologic Drugs' Advisory Committee meeting. The advisory panel provided the FDA with advice regarding a clinical and regulatory path to approval for products, such as enclomiphene, in subjects with obesity-related hypogonadism who wish to maintain spermatogenesis. The panel voted 16 to 5 that the achievement of testosterone improvement while maintaining evidence of spermatogenesis was not sufficient, in and of itself, to provide evidence of clinical benefit. At the meeting, numerous panel members suggested that an additional endpoint related to symptoms should be assessed.

Business Strategy

We plan to focus our clinical program on the clinical development program for low dose oral Proellex® in the treatment of uterine fibroids. We anticipate that our current liquidity will be sufficient to continue the development of our product candidates and meet our obligations as they become due through the second quarter of 2017. We continue to explore potential additional financing alternatives, including corporate partnering opportunities, that would provide sufficient funds to enable us to continue to develop our two product candidates through FDA approval; however, there can be no assurance that we will be successful in raising any such additional funds on a timely basis or at all.

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 currently have 21 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 March 31, 2017 and the value of the tax asset associated with these accumulated net operating losses may be substantially diminished in value due to various tax regulations, including change in control provisions in the tax code. Additionally, during 2013, the Company completed an analysis of its section 382 limit. Based on this analysis, the Company concluded that the amount of net operating loss (“NOL”) carryforwards and the credits available to offset taxable income is limited under section 382. See “Critical Accounting Policies and the Use of Estimates – Income Taxes,” below.

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

Critical Accounting Policies and the Use of Estimates

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

Accrued Expenses

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

Research and Development Expenses

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

Stock-Based Compensation

We had one stock-based compensation plan at March 31, 2017, 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 Company's historical stock option exercise experience does not provide a reasonable basis upon which to estimate expected term. As such, the simplified method was used to calculate the expected term. 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 November 2016, the FASB issued ASU No. 2016-18, "Statement of Cash Flows (Topic 230): Restricted Cash". The new standard requires restricted cash to be included with cash and cash equivalents when reconciling the beginning and ending amounts on the statement of cash flows, and requires additional disclosures in the notes to the financial statements. ASU 2016-18 is effective for fiscal years beginning after December 15, 2017 and interim periods within those fiscal years and early adoption is permitted. The Company adopted this standard during the quarter ended March 31, 2017. See Note 2 to the financial statements included herein.

In March 2016, the FASB issued ASU 2016-09, Compensation—Stock Compensation (ASC Topic 718): Improvements to Employee Share-Based Payment Accounting. The new standard simplifies the accounting for stock-based compensation, including amendments on how both taxes related to stock-based compensation and cash payments made to taxing authorities are recorded. ASU 2016-09 is effective for annual reporting periods beginning on or after December 15, 2016, and interim periods within those annual periods and early application is permitted, with any adjustments reflected as of the beginning of the fiscal year of adoption. The Company adopted ASU 2016-09 effective January 1, 2017. The adoption of this standard did not have a material effect on the Company's financial statements.

In February 2016, FASB issued ASU 2016-02, Leases (ASC Topic 842), which supersedes ASC Topic 840, Leases. The new standard is intended to increase transparency and comparability of organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. The new guidance is effective for financial statements issued for annual reporting periods beginning after December 15, 2018, and early application is permitted. The Company is currently evaluating the impact of this standard on our consolidated financial statements.

In November 2015, the FASB issued ASU No. 2015-17, “Balance Sheet Classification of Deferred Taxes” (“ASU 2015-17”), which requires entities to present deferred tax assets and deferred tax liabilities as noncurrent in a classified balance sheet. The ASU simplifies the current guidance in ASC Topic 740, Income Taxes, which requires entities to separately present deferred tax assets and liabilities as current and noncurrent in a classified balance sheet. ASU 2015-17 is effective for fiscal years beginning after December 15, 2016, and interim periods within those annual periods. The Company adopted ASU 2015-07 effective January 1, 2017. The adoption of this standard did not have a material effect on the Company’s financial statements.

In May 2014, the FASB issued Accounting Standards Update 2014-09, “Revenue from Contracts with Customers” (“ASU 2014-09”). ASU 2014-09 is a comprehensive new revenue recognition model requiring a company to recognize revenue to depict the transfer of goods or services to a customer at an amount reflecting the consideration it expects to receive in exchange for those goods or services. In adopting ASU 2014-09, companies may use either a full retrospective or a modified retrospective approach. Additionally, this guidance requires improved disclosures regarding the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. On July 9, 2015, the FASB voted to delay the effective date of this standard by one year. This deferral resulted in ASU 2014-09 being effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2017, with early adoption being permitted for annual periods beginning after December 15, 2016. Entities have the option of using either a full retrospective or a modified retrospective approach to adopt the guidance. The Company is currently assessing the effects this guidance may have on its consolidated financial statements, as well as the method of transition that the Company will use in adopting the new standard.

Results of Operations

Comparison of the three month periods ended March 31, 2017 and 2016

Revenues and Other Income

Total revenues and other income decreased to \$7,000 for the three month period ended March 31, 2017 as compared to \$17,000 for the same period in the prior year. All revenue in both periods was from interest income, and the decrease was primarily due to lower cash balances for the three month period ended March 31, 2017 as compared to the comparable period in the prior year.

Research and Development Expenses

R&D expenses include contracted services relating to our clinical product development activities which include preclinical studies, clinical trials, expenses associated with our patent portfolio, regulatory affairs, including FDA filing fees, and bulk manufacturing scale-up activities and bulk active ingredient purchases for preclinical and clinical trials primarily relating to our two products in clinical development, which are Proellex® and enclomiphene. Research and development expenses also include internal operating expenses relating to our general research and development activities. R&D expenses decreased 45%, or \$1.7 million, to \$2.1 million for the three month period ended March 31, 2017, as compared to \$3.8 million for the same period in the prior year. Our primary R&D expenses for the three month periods ended March 31, 2017 and 2016 are shown in the following table (in thousands):

Research and Development	Three months ended March 31,		Variance	Change (%)
	2017	2016		
Proellex® clinical development	\$ 520	\$ 1,156	\$ (636)	(55)%
Enclomiphene clinical development	330	1,181	(851)	(72)%
Payroll and benefits	638	712	(74)	(10)%
Operating and occupancy	586	716	(130)	(18)%
Total	\$ 2,074	\$ 3,765	\$ (1,691)	(45)%

The clinical development expenses related to Proellex® decreased for the three month period ended March 31, 2017, as compared to the prior year period, due to decreased expenses associated with our Phase 2b clinical trials for the treatment of uterine fibroids and endometriosis. The clinical development expenses related to enclomiphene decreased for the three month period ended March 31, 2017, as compared to the prior year period, due to decreased expenses associated with our Phase 2 proof of concept study, ZA-205.

Payroll and benefits expenses decreased 10%, or approximately \$74,000, to \$638,000 for the three month period ended March 31, 2017, as compared to \$712,000 for the same period in the prior year. Included in payroll and benefits expense is a charge for non-cash stock-based compensation of \$118,000 for the three month period ended March 31, 2017 as compared to a charge of \$193,000 for the same period in the prior year. Additionally, salaries for the three month period ended March 31, 2017 were \$408,000 as compared to \$422,000 for the same period in the prior year.

Operating and occupancy expenses decreased 18%, or approximately \$130,000, to \$586,000 for the three month period ended March 31, 2017 as compared to \$716,000 for the same period in the prior year, primarily due to decreased legal expenses and other outside services.

To date through March 31, 2017 we have incurred approximately \$71.8 million for the development of Proellex® and approximately \$73.8 million for the development of enclomiphene. These accumulated costs exclude any internal operating expenses and expenses associated with the patent portfolio.

General and Administrative Expenses

General and administrative (“G&A”) expenses increased 251%, or approximately \$2.7 million, to \$3.8 million for the three month period ended March 31, 2017 as compared to \$1.1 million for the same period in the prior year. Our primary G&A expenses for the three month periods ended March 31, 2017 and 2016 are shown in the following table (in thousands):

General and Administrative	Three months ended March 31,		Variance	Change (%)
	2017	2016		
Payroll and benefits	\$ 3,413	\$ 620	\$ 2,793	450%
Operating and occupancy	430	476	(46)	(10)%
Total	\$ 3,843	\$ 1,096	\$ 2,747	251%

G&A payroll and benefits expenses include salaries, bonuses, non-cash stock-based compensation expense, fringe benefits and severance pay. Included in payroll and benefits expense is a charge for non-cash stock-based compensation of \$318,000 for the three month period ended March 31, 2017 as compared to a charge of \$323,000 for the same period in the prior year. Additionally, payroll and benefits include a charge of \$2.8 million for the three month period ended March 31, 2017 related to the departure of Mr. Podolski.

G&A operating and occupancy expenses, which include expenses to operate as a public company, remained relatively constant at \$430,000 for the three month period ended March 31, 2017 as compared to \$476,000 for the same period in the prior year.

Off-Balance Sheet Arrangements

As of March 31, 2017, 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.

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 March 31, 2017, we sold 828,057 ATM Shares at a weighted average share price of \$1.20, for proceeds of approximately \$997,000, net of expenses including approximately \$31,000 in commissions to Ladenburg. Between April 1, 2017 and May 8, 2017, we sold an aggregate of 21,100 ATM Shares at a weighted average share price of \$1.17, for proceeds of approximately \$25,000, net of expenses including approximately \$1,000 in commissions to Ladenburg.

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 \$3.2 million as of March 31, 2017 as compared to \$8.7 million as of December 31, 2016. All cash and cash equivalents as of March 31, 2017 and December 31, 2016 were held in an account backed by U.S. government securities.

Net cash of approximately \$4.6 million and \$5.3 million was used in operating activities during the three month periods ended March 31, 2017 and 2016, respectively. The major use of cash for operating activities for the three month period ended March 31, 2017 was to fund our clinical development programs and associated administrative costs. No cash was used in investing activities during the three month period ended March 31, 2017. Cash provided by financing activities for the three month period ended March 31, 2017 was approximately \$997,000 due to the 828,057 ATM Shares sold at a weighted average share price of \$1.20, net of related expenses.

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 and meet our obligations as they become due through the second quarter of 2017. We continue to explore potential additional financing alternatives, including corporate partnering opportunities, that would provide sufficient funds to enable us to continue to develop our two product candidates through FDA approval; however, there can be no assurance that we will be successful in raising any such additional funds on a timely basis or at all. Our capital requirements will depend on many factors, which are discussed in detail in “Item 1A., Risk Factors” of Form 10-K for the fiscal year ended December 31, 2016. The uncertainties relating to the foregoing matters raise substantial doubt about our ability to continue as a going concern.

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk. We had cash and cash equivalents of approximately \$3.2 million at March 31, 2017 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 March 31, 2017.

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 March 31, 2017 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, 2015 in response to "Item 1A. Risk Factors" to Part I of Form 10-K.

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

None

Item 3. Defaults Upon Senior Securities.

None

Item 4. Mine Safety Disclosures.

None

Item 5. Other Information

None

Item 6. Exhibits

- 10.1 Release Agreement, dated February 1, 2017, between the Company and Joseph S. Podolski (filed as Exhibit 99.1 to the Company's Current Report on Form 8-K dated February 2, 2017 and incorporated herein by reference).
 - 31.1* Certification Pursuant to Rule 13(a)-14(a) or 15(d)-14(a) of the Exchange Act, As Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (Principal Executive Officer).
 - 31.2* Certification Pursuant to Rule 13(a)-14(a) or 15(d)-14(a) of the Exchange Act, As Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (Principal Financial Officer).
 - 32.1** Certification Furnished Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Principal Executive Officer) (This exhibit shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section. Further, this exhibit shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended.)
 - 32.2** Certification Furnished Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Principal Financial Officer) (This exhibit shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section. Further, this exhibit shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended.)
 - 101.INS* XBRL Instance Document
 - 101.SCH* XBRL Taxonomy Extension Schema Document
 - 101.CAL* XBRL Taxonomy Extension Calculation Linkbase Document
 - 101.DEF* XBRL Taxonomy Extension Definition Linkbase Document
 - 101.LAB* XBRL Taxonomy Extension Label Linkbase Document
 - 101.PRE* XBRL Taxonomy Extension Presentation Linkbase Document
- * Filed herewith.
** Furnished herewith.

SIGNATURES

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

REPROS THERAPEUTICS INC.

Date: May 9, 2017

By: /s/ Larry M. Dillaha, M.D.
Larry M. Dillaha, M. D.
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 9, 2017

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

I, Larry M. Dillaha, M.D., certify that:

1. I have reviewed this quarterly report of Repros Therapeutics Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: May 9, 2017

By: /s/ Larry M. Dillaha, M.D.
Larry M. Dillaha, M.D.
President and Chief Executive Officer
Repros Therapeutics Inc.
(Principal Executive Officer)

I, Katherine A. Anderson, certify that:

1. I have reviewed this quarterly report of Repros Therapeutics Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: May 9, 2017

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

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Repros Therapeutics Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Larry M. Dillaha, M.D., Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

1. The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: May 9, 2017

By: /s/ Larry M. Dillaha, M.D.
Larry M. Dillaha, M.D.
President and Chief Executive Officer
Repros Therapeutics Inc.
(Principal Executive Officer)

A signed original of this written statement required by Section 906 has been provided to Repros and will be retained by Repros and furnished to the Securities and Exchange Commission or its staff upon request.

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Repros Therapeutics Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Katherine A. Anderson, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

1. The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: May 9, 2017

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

A signed original of this written statement required by Section 906 has been provided to Repros and will be retained by Repros and furnished to the Securities and Exchange Commission or its staff upon request.
