

REPROS THERAPEUTICS INC.  
Form 10-Q  
August 14, 2017

**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 June 30, 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

2408 Timberloch Place, Suite B-7

76-0233274

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(State or other jurisdiction of incorporation or organization) The Woodlands, Texas 77380 (IRS Employer Identification No.)  
(Address of principal executive offices and zip code)

(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 August 7, 2017, there were outstanding 37,615,350 shares of Common Stock, par value \$.001 per share, of the Registrant.

**REPROS THERAPEUTICS INC.**

For the Quarter Ended June 30, 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 and six month periods ended June 30, 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. AND SUBSIDIARY

## CONDENSED CONSOLIDATED BALANCE SHEETS

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

	June 30, 2017	December 31, 2016
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$3,768	\$ 8,688
Restricted cash	916	-
Prepaid expenses and other current assets	268	66
Total current assets	4,952	8,754
Fixed assets, net	1	3
Non-current restricted cash	916	-
Total assets	\$5,869	\$ 8,757
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities		
Accounts payable	\$1,457	\$ 1,880
Accrued expenses	1,275	779
Total current liabilities	2,732	2,659
Long-term liabilities		
Accrued severance	916	-
Warrant liability	2,530	-
Total liabilities	6,178	2,659
Commitment & Contingencies (note 8)		
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, 32,571,109 and 25,938,602 shares issued, respectively; 32,458,759 and 25,826,252 shares outstanding, respectively, as of June 30, 2017 and December 31, 2016	33	26
Additional paid-in capital	328,676	326,981
Cost of treasury stock, 112,350 shares	(1,380 )	(1,380 )
Accumulated deficit	(327,638)	(319,529 )
Total stockholders' equity	(309 )	6,098

Total liabilities and stockholders' equity	\$5,869	\$ 8,757
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The accompanying notes are an integral part of these condensed consolidated financial statements.

## REPOS THERAPEUTICS INC. AND SUBSIDIARY

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited and in thousands except per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Revenues and other income				
Interest income	\$ 7	\$ 15	\$ 14	\$ 31
Total revenues and other income	7	15	14	\$ 31
Expenses				
Research and development	1,140	3,243	3,214	7,009
General and administrative	906	1,052	4,749	2,147
Change in fair value of warrant liability	160	-	160	-
Total expenses	2,206	4,295	8,123	9,156
Net loss	\$ (2,199 )	\$ (4,280 )	\$ (8,109 )	\$ (9,125 )
Loss per share – basic and diluted	\$ (0.08 )	\$ (0.18 )	\$ (0.30 )	(0.38 )
Shares used in loss per share calculation:				
Basic	28,398	24,319	27,340	24,319
Diluted	28,398	24,319	27,340	24,319

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



## REPOS THERAPEUTICS INC. AND SUBSIDIARY

## CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

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

	Common Stock		Additional	Treasury Stock		Accumulated	Total
	Shares	Amount	Paid-in Capital	Shares	Amount	Deficit	Stockholders' Equity
Balance at December 31, 2016	25,938,602	\$ 26	\$ 326,981	112,350	\$(1,380)	\$( 319,529 )	\$ 6,098
Stock based compensation	-	-	563	-	-	-	563
Issuance of 849,157 shares of common stock pursuant to the Equity Distribution Agreement at a weighted average price of \$1.20, net of offering costs of \$32	849,157	1	1,020	-	-	-	1,021
Issuance of 2,744,125 shares of common stock at \$0.60 per share, Series A and Series B warrants, and pre-funded Series C warrants at \$0.60 per share in the May Public Offering, net of offering costs of \$508	2,744,125	3	(1,213 )	-	-	-	(1,210 )
Exercise of 2,245,875 Series C Warrants to purchase common stock for cash at \$0.001 per share	2,245,875	2	1,277	-	-	-	1,279
Net Number Cashless Exercise of 210,000 Series B Warrants to purchase common stock	715,575	1	48	-	-	-	49
Issuance of 50,000 shares of restricted common stock	50,000	-	-	-	-	-	-
Issuance of 27,775 shares of common stock for vested RSUs	27,775	-	-	-	-	-	-
Net Loss	-	-	-	-	-	(8,109 )	(8,109 )
Balance at June 30, 2017	32,571,109	\$ 33	\$ 328,676	112,350	\$(1,380)	\$( 327,638 )	\$ (309 )
Balance at December 31, 2015	24,430,461	\$ 24	\$ 322,179	112,350	\$(1,380)	\$( 302,256 )	\$ 18,567

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Stock based compensation	-	-	1,037	-	-	-	1,037
Exercise of 1,333 Series A warrants to purchase common stock for cash at \$0.01 per share	1,333	-	-	-	-	-	-
Net Loss	-	-	-	-	-	(9,125 )	(9,125 )
Balance at June 30, 2016	24,431,794	\$ 24	\$ 323,216	112,350	\$(1,380)	\$( 311,381 )	\$ 10,479

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

## REPROS THERAPEUTICS INC. AND SUBSIDIARY

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited and in thousands)

	Six Months Ended June 30,	
	2017	2016
Cash Flows from Operating Activities		
Net loss	\$ (8,109 )	\$ (9,125 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	2	3
Noncash stock-based compensation	563	1,037
Change in fair value of warrant liability	160	-
Increase in prepaid expenses and other current assets	(202 )	(166 )
Increase (decrease) in accounts payable and accrued expenses	989	(632 )
Net cash used in operating activities	(6,597 )	\$ (8,883 )
Cash Flows from Investing Activities		
Capital expenditures	-	-
Net cash used in investing activities	-	-
Cash Flows from Financing Activities		
Issuance of common stock and warrants, net of offering costs	3,507	-
Proceeds from exercise of stock warrants	2	-
Net cash provided by financing activities	3,509	-
Net decrease in cash, cash equivalents and restricted cash	(3,088 )	(8,883 )
Cash, cash equivalents and restricted cash at beginning of period	8,688	21,393
Cash, cash equivalents and restricted cash at end of period	\$ 5,600	\$ 12,510
Noncash transactions:		
Settlement of warrant liability due to cashless warrant exercises	\$ (49 )	-

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

**REPROS THERAPEUTICS INC. AND SUBSIDIARY**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**June 30, 2017**

(Unaudited)

**NOTE 1 — Organization, Operations, Liquidity and Recent Developments**

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

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. On July 17, 2017, the Company announced that it received preliminary feedback from the FDA on the oral Proellex® clinical development program. The Proellex® program will remain on partial clinical hold, and based upon the FDA’s review of all the existing liver function safety data, the FDA has indicated that the Company will be required to compile a large pre-approval safety data base to support future development. The Company expects to receive final guidance during the third quarter of 2017.

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. In light of the FDA guidance on the oral Proellex® development program, the Company is assessing increasing its focus on the vaginal delivery of Proellex®.

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 Applications (“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. As part of the ongoing review process, the Company has filed responses to the EMAs questions in the third quarter of 2017.

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.

## **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. Ladenburg receives a commission of 3% of the gross sales price of all ATM Shares sold through it under the Equity Distribution Agreement. Effective May 9, 2017, the Company terminated the Sales Agreement and the related ATM Program. During the three and six month periods ended June 30, 2017, we sold 21,100 and 849,157 ATM Shares, respectively, at a weighted average share price of \$1.17 and \$1.20, respectively, for proceeds of approximately \$25,000 and \$1,021,000, respectively, net of expenses including approximately \$1,000 and \$32,000, respectively, in commissions to Ladenburg.

On May 23, 2017, the Company sold 2,744,125 shares of common stock and pre-funded Series C Warrants to purchase up to 2,245,875 shares of common stock in an underwritten public offering to certain investors (the “May Public Offering”). Each share of common stock was sold at a price of \$0.60 and each Series C Warrant was issued with an exercise price of \$0.60 per share of common stock, \$0.60 of which was pre-funded at closing and \$0.001 was payable upon exercise. This May Public Offering also included the issuance of Series A Warrants to purchase 3,742,500 shares of our common stock at an initial exercise price of \$0.84 per share and Series B Warrants to purchase 2,495,000 shares of our common stock at an initial exercise price of \$0.92 per share. Each share of common stock and each pre-funded Series C Warrant to purchase a share of common stock were sold together with a Series A Warrant to purchase 0.75 share of common stock and a Series B Warrant to purchase 0.50 share of common stock. The net proceeds to the Company from the sale of common stock and warrants, after deducting underwriting discounts and commissions and other offering expenses, were approximately \$2.5 million. For further discussion of the May Public Offering, see Note 6 to the financial statements included herein.

As of June 30, 2017, we had accumulated losses of \$327.6 million, approximately \$3.8 million in cash and cash equivalents, and accounts payable and accrued expenses of approximately \$3.6 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 with our restricted cash of \$1.8 million. 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 end 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 three and six month periods ended June 30, 2017 are not necessarily indicative of the results to be expected for the full year.

### **Changes in Accounting Policies**



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 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.

#### **New Accounting Pronouncements Not Yet Adopted**

In July 2017, the FASB issued ASU No. 2017-11, "(Part I) Accounting or Certain Financial Instruments with Down Round Features" ("ASU 2017-11"), which changes the classification analysis of certain equity-linked financial instruments with down round features. When determining whether certain financial instruments should be classified as liabilities or equity instruments, a down round feature will no longer preclude equity classification when assessing whether the instrument is indexed to an entity's own stock. ASU 2017-11 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. The Company is currently evaluating the impact of this standard on its consolidated 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 its consolidated financial statements.

In May 2014, the FASB issued Accounting Standards Update 2014-09, "Revenue from Contracts with Customers" ("ASU 2014-09"). ASU 2014-09 is a comprehensive new revenue recognition model requiring a company to recognize revenue to depict the transfer of goods or services to a customer at an amount reflecting the consideration it expects to receive in exchange for those goods or services. In adopting ASU 2014-09, companies may use either a full

retrospective or a modified retrospective approach. Additionally, this guidance requires improved disclosures regarding the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. On July 9, 2015, the FASB voted to delay the effective date of this standard by one year. This deferral resulted in ASU 2014-09 being effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2017, 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 June 30, 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 (in thousands):

	June 30, 2017	June 30, 2016
Cash and cash equivalents	\$ 3,768	\$ 12,510
Restricted cash, current	916	—
Restricted cash, noncurrent	916	—
Total	\$ 5,600	\$ 12,510

**NOTE 3 — Accrued Expenses**

Accrued expenses consist of the following (in thousands):

	June 30, 2017	December 31, 2016
Current accrued expenses:		
Personnel related costs	\$ 1,108	\$ 512
Research and development costs	70	174
Other	97	93
Total current accrued expenses	\$ 1,275	\$ 779
Long-term accrued expenses:		
Accrued severance	\$ 916	\$ —
Total long-term accrued expenses	\$ 916	\$ —

**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, restricted stock units and warrants. In all applicable periods, all potential common stock equivalents were anti-dilutive and, accordingly, were not included in the computation of diluted loss per share.

The following table presents information necessary to calculate loss per share for the three and six month periods ended June 30, 2017 and 2016 (in thousands, except per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Net loss	\$ (2,199 )	\$ (4,280 )	\$ (8,109 )	\$ (9,125 )
Average common shares outstanding	28,398	24,319	27,340	24,319
Basic and diluted loss per share	\$ (0.08 )	\$ (0.18 )	\$ (0.30 )	\$ (0.38 )

Potential common stock of 2,758,080 common shares underlying stock options and restricted stock units and common shares underlying 6,027,500 stock purchase warrants for the period ended June 30, 2017, were excluded from the above calculation of diluted loss per share because they were anti-dilutive. Potential common stock of 2,664,024 underlying stock options for the period ended June 30, 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 units, 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. Additionally, during the six month period ended June 30, 2017, 356,502 stock options either expired or were forfeited.

**NOTE 6 — Stockholders’ Equity****Offerings**

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. Ladenburg receives a commission of 3% of the gross sales price of all ATM Shares sold through it under the Equity Distribution Agreement. Effective May 9, 2017, the Company terminated the Sales Agreement and the related ATM Program.

The table below summarizes our ATM Shares sold during the three and six month periods ended June 30, 2017 (in thousands, except share and per share amounts):

	Three Months Ended June 30, 2017	Six Months Ended June 30, 2017
ATM Shares sold	21,100	849,157

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Weighted average share price	\$ 1.17	\$ 1.20
Net proceeds, net of offering costs	\$ 25	\$ 1,021
Offering commissions to Ladenburg	\$ 1	\$ 32

On May 23, 2017, the Company sold 2,744,125 shares of common stock and pre-funded Series C Warrants to purchase up to 2,245,875 shares of common stock in an underwritten public offering to certain investors (the “May Public Offering”). Each share of common stock was sold at a price of \$0.60 and each Series C Warrant was issued with an exercise price of \$0.60 per share of common stock, \$0.60 of which was pre-funded at closing and \$0.001 was payable upon exercise. This May Public Offering also included the issuance of Series A Warrants to purchase 3,742,500 shares of our common stock at an initial exercise price of \$0.84 per share and Series B Warrants to purchase 2,495,000 shares of our common stock at an initial exercise price of \$0.92 per share. Each share of common stock and each pre-funded Series C Warrant to purchase a share of common stock were sold together with a Series A Warrant to purchase 0.75 share of common stock and a Series B Warrant to purchase 0.50 share of common stock. The net proceeds to the Company from the sale of common stock and warrants, after deducting underwriting discounts and commissions and other offering expenses, were approximately \$2.5 million.

The Series A warrants are exercisable, subject to certain limitations, upon issuance and expire five years from issuance and the Series B and Series C warrants are exercisable, subject to certain limitations, upon issuance and expire two years from issuance. The Series A and Series B warrants contain anti-dilution provisions that reduce the exercise price of the warrants if certain dilutive issuances occur, subject to a floor of \$0.17 per share. Each of the warrants contain a cashless exercise provision in the event there is no effective registration statement covering the shares to be issued upon exercise of the warrants and a net cash settlement feature at the option of the warrant holder in certain limited circumstances in which the Company fails to timely deliver registered common shares upon a warrant exercise. Additionally, beginning 30 days after the issuance date, a Series B warrant holder is permitted to effect a cashless exercise and receive a net number of shares equal to the product of (i) 200% of the applicable warrant exercise percentage of the initial warrant amount and (ii) the quotient obtained by dividing (a) the difference obtained by subtracting (x) the market price, from (y) the initial exercise price of the Series B Warrants by (b) the market price (the “Net Number Cashless Exercise”).

Due to the net cash settlement feature at the option of the warrant holder discussed above, the Series A and Series B warrants are classified as liabilities under the caption “Warrant liability” in the accompanying balance sheets and recorded at estimated fair value at issuance with any subsequent change in fair value of the outstanding warrants since issuance reflected in “Change in fair value of warrant liability” in the accompanying statements of operations. Additionally, for the period ended June 30, 2017, any share settlement of the warrant liability upon a warrant exercise is reflected as a noncash settlement of the pro-rata share of the warrant liability and issuance of common stock. See Note 7 to the financial statements included herein for discussion regarding the fair value of the warrants.

The following table reflects the warrant activity of the Company for the six month period ended June 30, 2017:

	Series A	Series B	Series C	Shares of Common Stock Issued
	Warrants	Warrants	Warrants	
Balance, December 31, 2016	—	—	—	
Issuance of warrants	3,742,500	2,495,000	2,245,875	
Series C Warrants exercised to purchase common stock for cash at \$0.001 per share	—	—	(2,245,875)	2,245,875
Net Number Cashless Exercise of Series B Warrants for the issuance of 715,575 shares of common stock	—	(210,000 )	—	715,575
Balance, June 30, 2017	3,742,500	2,285,000	—	

Through August 11, 2017, an additional 1,832,834 Series B Warrants were exercised under the cashless alternative provision and as a result the Company has issued 5,455,730 shares of common stock.



On July 24, 2017, the Company filed a shelf registration statement on Form S-3 (File No. 333-219428, the “July 2017 Registration Statement”) to permit the continued exercise of the Series A Warrants and Series B Warrants following the expiration, on that date, of the Company’s prior Registration Statement on Form S-3, as amended (File No. 333-197253). The July 2017 Registration Statement was declared effective by the SEC on August 4, 2017. Between the expiration of the prior registration statement and the effectiveness of the July 2017 Registration Statement, exercises of the Series A Warrants and Series B Warrants continued to be permitted under the prior registration statement pursuant to Rule 415(a)(5) under the Securities Act of 1933, as amended.

#### **NOTE 7 — Fair Value Measurements**

The FASB has established a framework for measuring fair value in generally accepted accounting principles. That framework provides a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (level 1 measurements) and the lowest priority to unobservable inputs (level 3 measurements). The three levels of the fair value hierarchy are described as follows:

*Level 1.* Inputs to the valuation methodology are unadjusted quoted prices for identical assets or liabilities in active markets.

*Level 2.* Inputs to the valuation methodology include:

- Quoted prices for similar assets or liabilities in active markets
- Quoted prices for identical or similar assets or liabilities in inactive markets

- Inputs other than quoted prices that are observable for the asset or liability
- Inputs that are derived principally from or corroborated by observable market data by correlation or other means

If the asset or liability has a specified (contractual) term, the level 2 input must be observable for substantially the full term of the asset or liability.

*Level 3.* Inputs to the valuation methodology are unobservable and significant to the fair value measurement.

The asset or liability's fair value measurement level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. Valuation techniques used need to maximize the use of observable inputs and minimize the use of unobservable inputs.

The table below presents our assets and liabilities that are measured at fair value on a recurring basis at June 30, 2017 and are categorized using the fair value hierarchy (in thousands):

	Total	Level 1	Level 2	Level 3
Cash and cash equivalents	\$3,768	\$3,768	\$—	\$ —
Restricted cash	\$1,832	\$1,832	\$—	\$ —
Warrant liability	\$(2,530)	\$—	\$(2,530)	\$ —

The table below presents our assets and liabilities that are measured at fair value on a recurring basis at December 31, 2016 and are categorized using the fair value hierarchy (in thousands):

	Total	Level 1	Level 2	Level 3
Cash and cash equivalents	\$8,688	\$8,688	\$ —	\$ —

All cash and cash equivalents and restricted cash as of June 30, 2017 and December 31, 2016 were held in accounts backed by U.S. government securities.

On May 23, 2017, as a result of the May Public Offering (described in Note 6 to the financial statements included herein), the Company issued Series A, Series B and Series C warrants that include a net cash settlement feature at the

option of the warrant holder in certain limited circumstances in which the Company fails to timely deliver registered common shares upon a warrant exercise. All Series C warrants were exercised in June 2017. The Series A and Series B warrants are classified as liabilities under the caption “Warrant liability” in the accompanying balance sheets and recorded at estimated fair value at issuance with any subsequent change in fair value of the outstanding warrants since issuance reflected in “Change in fair value of warrant liability” in the accompanying statements of operations. The fair value of the Series A and Series B warrant liability at the issue date was \$2,419,000 after giving effect to anti-dilution adjustments under the assumption that the anti-dilution mechanism contained in the Series A and Series B warrants was in effect. The following summarizes the change in the Warrant liability for the six months ended June 30, 2017 (in thousands):

	Series A Warrants	Series B Warrants	Total
Warrant liability at date of issue	\$ (1,831 )	\$ (588 )	\$ (2,419 )
Share settlement due to warrant exercises	-	49	49
Change in fair value	(157 )	(3 )	(160 )
Warrant liability at June 30, 2017	\$ (1,988 )	\$ (542 )	\$ (2,530 )

The Company will continue to adjust the Warrant liability for changes in fair value of the outstanding warrants until the earlier of the exercise of the warrants, modification of the warrants, or expiration of the warrants.

The fair value of the Company's warrant liability recorded in the Company's financial statements was determined using the Monte Carlo simulation valuation method with the quoted market price of the Company's common stock, market volatility of the Company's stock, no dividend yield, an expected life based on the remaining contractual term of the outstanding warrants and a risk free interest rate based on USD overnight indexed swaps with a maturity equivalent to the warrants' expected life.

The Company calculated the estimated fair value of the Series A and Series B warrants on the issuance date and at June 30, 2017 using the following weighted average assumptions:

	Issue Date			
	(May 23, 2017)		June 30, 2017	
Risk-free interest rate	1.46	%	1.82	%
Contractual term	3.3 years		3.8 years	
Expected volatility	85.8	%	98.7	%

**NOTE 8 — Commitments and Contingencies**

None.

## 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.*

### **Repos 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. On July 17, 2017, the Company announced that it received preliminary feedback from the FDA on the oral Proellex® clinical development program. The Proellex® program will remain on partial clinical hold, and based upon the FDA's review of all the existing liver function safety data, the FDA has indicated that the Company will be required to compile a large pre-approval safety data base to support future development. The Company expects to receive final guidance during the third quarter of 2017.

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. In light of the FDA guidance on the oral Proellex® development program, the Company is assessing increasing its focus on the vaginal delivery of Proellex®.

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”) which, as previously reported, has assigned the United Kingdom as the primary rapporteur and France as the co-rapporteur for the application review. As part of the ongoing review process, the Company has filed responses to the EMAs questions in the third quarter of 2017.

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.

## **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. Ladenburg receives a commission of 3% of the gross sales price of all ATM Shares sold through it under the Equity Distribution Agreement. Effective May 9, 2017, the Company terminated the Sales Agreement and the related ATM Program. During the three and six month period ended June 30, 2017, we sold 21,100 and 849,157 ATM Shares, respectively, at a weighted average share price of \$1.17 and \$1.20, respectively, for proceeds of approximately \$25,000 and \$1,021,000, respectively, net of expenses including approximately \$1,000 and \$32,000, respectively, in commissions to Ladenburg. Effective May 9, 2017, the Company terminated the Sales Agreement and the related ATM Program.



On May 23, 2017, the Company sold 2,744,125 shares of common stock and pre-funded Series C Warrants to purchase up to 2,245,875 shares of common stock in an underwritten public offering to certain investors (the “May Public Offering”). Each share of common stock was sold at a price of \$0.60 and each Series C Warrant was issued with an exercise price of \$0.60 per share of common stock, \$0.60 of which was pre-funded at closing and \$0.001 was payable upon exercise. This May Public Offering also included the issuance of Series A Warrants to purchase 3,742,500 shares of our common stock at an initial exercise price of \$0.84 per share and Series B Warrants to purchase 2,495,000 shares of our common stock at an initial exercise price of \$0.92 per share. Each share of common stock and each pre-funded Series C Warrant to purchase a share of common stock were sold together with a Series A Warrant to purchase 0.75 share of common stock and a Series B Warrant to purchase 0.50 share of common stock. The net proceeds to the Company from the sale of common stock and warrants, after deducting underwriting discounts and commissions and other offering expenses, were approximately \$2.5 million.

As of June 30, 2017, we had accumulated losses of \$327.6 million, approximately \$3.8 million in cash and cash equivalents, and accounts payable and accrued expenses of approximately \$3.6 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 with our restricted cash of \$1.8 million. 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 end 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. On July 17, 2017, the Company announced that it received preliminary feedback from the FDA on the oral Proellex® clinical development program. The Proellex® program will remain on partial clinical hold, and based upon the FDA's review of all the existing liver function safety data, the FDA has indicated that the Company will be required to compile a large pre-approval safety data base to support future development. The Company expects to receive final guidance during the third quarter of 2017.

### *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. In light of the FDA guidance on the oral Proellex® development program, the Company is assessing increasing its focus on the vaginal delivery of Proellex®.

## **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. As part of the ongoing review process, the Company has filed responses to the EMAs questions in the third quarter of 2017.

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**

The Company is assessing increasing its focus on the vaginal delivery of 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 end 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.reprosr.com](http://www.reprosr.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 nine full-time employees. We utilize the services of contract research organizations, contract manufacturers and various consultants to assist us in performing clinical and regulatory services for the clinical development of our products. We are substantially dependent on our various contract groups to adequately perform the activities required to obtain regulatory approval of our products.

We have accumulated net operating losses through June 30, 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.

### *Warrant Liability*

In May 2017, we sold shares of common stock and pre-funded Series C Warrants to purchase common stock in an underwritten public offering which also included the issuance of Series A and Series B Warrants to purchase common stock. Due to a net cash settlement feature at the option of the warrant holder in each of the Series A and Series B warrants, the warrants are classified as liabilities under the caption "Warrant liability" in the accompanying balance sheets and recorded at estimated fair value at issuance with any subsequent change in fair value of the outstanding warrants since issuance reflected in "Change in fair value of warrant liability" in the accompanying statements of operations. Additionally, for the period ended June 30, 2017, any share settlement of the Warrant liability upon a warrant exercise is reflected as a noncash settlement of the pro-rata share of the Warrant liability and issuance of common stock.

We used the Monte Carlo simulation valuation method to estimate the fair value of the Series A and Series B warrants. The Monte Carlo simulation valuation method utilizes the quoted market price of the Company's common stock, market volatility of the Company's stock, no dividend yield, an expected life based on the remaining contractual term of the outstanding warrants and a risk-free interest rate. The risk-free interest rate is based on USD overnight indexed swaps with a maturity equivalent to the warrants' expected life.

### *Stock-Based Compensation*

We had one stock-based compensation plan at June 30, 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.

### **Changes in Accounting Policies**

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 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.

### **New Accounting Pronouncements Not Yet Adopted**

In July 2017, the FASB issued ASU No. 2017-11, "(Part I) Accounting or Certain Financial Instruments with Down Round Features" ("ASU 2017-11"), which changes the classification analysis of certain equity-linked financial instruments with down round features. When determining whether certain financial instruments should be classified as liabilities or equity instruments, a down round feature will no longer preclude equity classification when assessing whether the instrument is indexed to an entity's own stock. ASU 2017-11 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. The Company is currently evaluating the impact of this standard on its consolidated 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 its consolidated financial statements.

In May 2014, the FASB issued Accounting Standards Update 2014-09, “Revenue from Contracts with Customers” (“ASU 2014-09”). ASU 2014-09 is a comprehensive new revenue recognition model requiring a company to recognize revenue to depict the transfer of goods or services to a customer at an amount reflecting the consideration it expects to receive in exchange for those goods or services. In adopting ASU 2014-09, companies may use either a full retrospective or a modified retrospective approach. Additionally, this guidance requires improved disclosures regarding the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. On July 9, 2015, the FASB voted to delay the effective date of this standard by one year. This deferral resulted in ASU 2014-09 being effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2017, 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 and six month periods ended June 30, 2017 and 2016*

#### *Revenues and Other Income*

Total revenues and other income decreased to \$7,000 for the three month period ended June 30, 2017 as compared to \$15,000 for the same period in the prior year. Total revenues and other income decreased to \$14,000 for the six month period ended June 30, 2017 as compared to \$31,000 for the same period in the prior year. The decrease in revenues and other income in both periods is primarily due to lower cash balances during the three and six month periods ended June 30, 2017 as compared to the comparable periods 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 65%, or \$2.1 million, to \$1.1 million for the three month period ended June 30, 2017, as compared to \$3.2 million for the same period in the prior year. Our primary R&D expenses for the three month periods ended June 30, 2017 and 2016 are shown in the following table (in thousands):

	<b>Three months ended June 30,</b>				
	2017	2016	Variance	Change (%)	
Research and Development					
Proellex® clinical development	\$ 129	\$ 990	\$ (861 )	(87	)%
Enclomiphene clinical development	211	1,000	(789 )	(79	)%
Payroll and benefits	569	710	(141 )	(20	)%
Operating and occupancy	231	543	(312 )	(57	)%
Total	\$ 1,140	\$ 3,243	\$ (2,103 )	(65	)%

The clinical development expenses related to Proellex® decreased for the three month period ended June 30, 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 June 30, 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 20%, or approximately \$141,000, to \$569,000 for the three month period ended June 30, 2017, as compared to \$710,000 for the same period in the prior year. Salaries for the three month period ended June 30, 2017 were \$357,000 as compared to \$425,000 for the same period in the prior year. Also during the three month period ended June 30, 2017, the Company incurred \$169,000 in severance expense related to a reduction in its workforce. As a result of this reduction in workforce, non-cash stock-based compensation decreased \$197,000 for the three month period ended June 30, 2017, as compared to the same period in the prior year.

Operating and occupancy expenses decreased 57%, or approximately \$312,000, to \$231,000 for the three month period ended June 30, 2017 as compared to \$543,000 for the same period in the prior year, primarily due to decreased legal expenses and other outside services.

R&D expenses decreased 54%, or approximately \$3.8 million, to \$3.2 million for the six month period ended June 30, 2017, as compared to \$7.0 million for the same period in the prior year. Our primary R&D expenses for the six month periods ended June 30, 2017 and 2016 are shown in the following table (in thousands):

Research and Development	Six months ended June 30,			Change (%)
	2017	2016	Variance	
Proellex® clinical development	\$649	\$2,146	\$(1,497)	(70)%
Enclomiphene clinical development	541	2,181	(1,640)	(75)%
Payroll and benefits	1,207	1,422	(215)	(15)%
Operating and occupancy	817	1,260	(443)	(35)%
Total	\$3,214	\$7,009	\$(3,795)	(54)%

For the six month period ended June 30, 2017, as compared to the same period in 2016, R&D expenses related to the clinical development of Proellex® decreased 70%, or approximately \$1.5 million, primarily due to decreased expenses associated with our Phase 2b clinical trials for the treatment of uterine fibroids and endometriosis. R&D expenses related to the clinical development of enclomiphene decreased 75%, or approximately \$1.6 million, due to decreased expenses associated with our Phase 2 proof of concept study, ZA-205.

Payroll and benefits expenses decreased 15%, or approximately \$215,000, to \$1.2 million for the six month period ended June 30, 2017, as compared to \$1.4 million for the same period in the prior year. Salaries for the six month period ended June 30, 2017 were \$764,000, as compared to \$847,000 for the same period in the prior year. Included in payroll and benefits expense is a charge for non-cash stock-based compensation of \$97,000 for the six month period ended June 30, 2017, as compared to a charge of \$370,000 for the same period in the prior year. Also during the six month period ended June 30, 2017, the Company incurred \$169,000 in severance expense related to a reduction in its workforce.

Operating and occupancy expenses decreased 35%, or approximately \$443,000, to \$817,000 for the six month period ended June 30, 2017, as compared to \$1.3 million for the same period in the prior year, primarily due to decreased legal expenses and outside services.

Through June 30, 2017 we have incurred approximately \$72.0 million for the development of Proellex® and approximately \$74.1 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 decreased 14%, or approximately \$146,000, to \$906,000 for the three month period ended June 30, 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 June 30, 2017 and 2016 are shown in the following table (in thousands):

	Three months ended June 30,				
General and Administrative	2017	2016	Variance	Change (%)	
Payroll and benefits	\$ 450	\$ 637	\$ (187 )	(29 )	%
Operating and occupancy	456	415	41	10	%
Total	\$ 906	\$ 1,052	\$ (146 )	(14 )	%

G&A payroll and benefits expenses include salaries, bonuses, non-cash stock-based compensation expense, fringe benefits, recruiting fees and severance pay. Included in payroll and benefits expense is a charge for non-cash stock-based compensation of \$147,000 for the three month period ended June 30, 2017 as compared to a charge of \$344,000 for the same period in the prior year. Additionally, salaries for the three month period ended June 30, 2017 were \$232,000 as compared to \$257,000 for the same period in the prior year.

G&A operating and occupancy expenses, which include expenses to operate as a public company, increased 10%, or approximately \$41,000, to \$456,000 for the three month period ended June 30, 2017 as compared to \$415,000 for the same period in the prior year primarily due to an increase in consulting fees.

G&A expenses increased 121%, or approximately \$2.6 million, to \$4.8 million for the six month period ended June 30, 2017, as compared to \$2.2 million for the same period in the prior year. Our primary G&A expenses for the six month periods ended June 30, 2017 and 2016 are shown in the following table (in thousands):

	Six months ended June 30,				
General and Administrative	2017	2016	Variance	Change (%)	
Payroll and benefits	\$ 3,863	\$ 1,256	\$ 2,607	208	%
Operating and occupancy	886	891	(5 )	(1 )	%
Total	\$ 4,749	\$ 2,147	\$ 2,602	121	%

G&A payroll and benefits expenses include salaries, bonuses, non-cash stock-based compensation expense, severance pay, recruiting fees and fringe benefits. Included in payroll and benefits expense is a charge for non-cash stock-based

compensation of \$465,000 for the six month period ended June 30, 2017, as compared to a charge of \$667,000 for the same period in the prior year. Additionally, salaries for the six month period ended June 30, 2017 were \$469,000, as compared to \$514,000 for the same period in the prior year. Also included in payroll and benefits for the six month period ended June 30, 2017, was a charge of \$2.8 million related to the departure of Mr. Podolski.

G&A operating and occupancy expenses, which include expenses to operate as a public company, decreased approximately \$5,000, to \$886,000 for the six month period ended June 30, 2017, as compared to \$891,000 for the same period in the prior year.

#### *Change in Fair Value of Warrant Liability*

As a result of the May Public Offering (described in Note 6 to the financial statements included herein), the Company issued Series A, Series B and Series C warrants that include a net cash settlement feature at the option of the warrant holder in certain limited circumstances in which the Company fails to timely deliver registered common shares upon a warrant exercise. All Series C warrants were exercised in June 2017. The Series A and Series B warrants are classified as liabilities under the caption "Warrant liability" in the accompanying balance sheets and recorded at estimated fair value at issuance with any subsequent change in fair value of the outstanding warrants since issuance reflected in "Change in fair value of warrant liability" in the accompanying statements of operations. For a detailed discussion on the change in fair value of warrant liability, see Note 7 to the financial statements included herein.

#### Off-Balance Sheet Arrangements

As of June 30, 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. Ladenburg receives a commission of 3% of the gross sales price of all ATM Shares sold through it under the Equity Distribution Agreement. Effective May 9, 2017, the Company terminated the Sales Agreement and the related ATM Program. During the three and six month period ended June 30, 2017, we sold 21,100 and 849,157 ATM Shares, respectively, at a weighted average share price of \$1.17 and \$1.20, respectively, for proceeds of approximately \$25,000 and \$1,021,000, respectively, net of expenses including approximately \$1,000 and \$32,000, respectively, in commissions to Ladenburg. Effective May 9, 2017, the Company terminated the Sales Agreement and the related ATM Program.

On May 23, 2017, the Company sold 2,744,125 shares of common stock and pre-funded Series C Warrants to purchase up to 2,245,875 shares of common stock in an underwritten public offering to certain investors (the “May Public Offering”). Each share of common stock was sold at a price of \$0.60 and each Series C Warrant was issued with an exercise price of \$0.60 per share of common stock, \$0.60 of which was pre-funded at closing and \$0.001 was payable upon exercise. This May Public Offering also included the issuance of Series A Warrants to purchase 3,742,500 shares of our common stock at an initial exercise price of \$0.84 per share and Series B Warrants to purchase 2,495,000 shares of our common stock at an initial exercise price of \$0.92 per share. Each share of common stock and each pre-funded Series C Warrant to purchase a share of common stock were sold together with a Series A Warrant to purchase 0.75 share of common stock and a Series B Warrant to purchase 0.50 share of common stock. The net proceeds to the Company from the sale of common stock and warrants, after deducting underwriting discounts and commissions and other offering expenses, were approximately \$2.5 million.

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 \$3.8 million as of June 30, 2017 as compared to \$8.7 million as of December 31, 2016. All cash and cash equivalents as of June 30, 2017 and December 31, 2016 were held in an account backed by U.S. government securities.

Net cash of approximately \$6.6 million and \$8.9 million was used in operating activities during the six month periods ended June 30, 2017 and 2016, respectively. The major use of cash for operating activities for the six month period ended June 30, 2017 was to fund our clinical development programs and associated administrative costs. No cash was used in investing activities during the six month period ended June 30, 2017. Cash provided by financing activities for the six month period ended June 30, 2017 was approximately \$3.5 million primarily from sale of 2,744,125 shares of common stock and pre-funded Series C Warrants to purchase up to 2,245,875 shares of common stock in the May Public Offering at an offering price of \$0.50 per share, net of related underwriting discounts and commissions and other offering costs and the sale of 849,157 ATM Shares at a weighted average share price of \$1.20, net of related offering costs.

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. 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 end 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 \$3.8 million at June 30, 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 June 30, 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 June 30, 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 8 of the Notes to the Condensed Consolidated Financial Statements.

### Item 1A. Risk Factors

Except as follows, 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, 2016 in response to "Item 1A. Risk Factors" to Part I of Form 10-K.

***Our inability to comply with the listing requirements of the NASDAQ Capital Market could result in our common stock being delisted, which could affect our common stock's market price and liquidity and reduce our ability to raise capital.***

We are required to meet certain qualitative and financial tests to maintain the listing of our common stock on the NASDAQ Capital Market. As of March 31, 2017, our stockholders' equity was \$1.6 million. As a result, we did not comply with the NASDAQ's \$2.5 million minimum stockholders' equity requirement under NASDAQ Listing Rule 5550(b)(1). Further, as of March 31, 2017, we did not meet the alternative compliance standards relating to the market value of listed securities or net income from continuing operations. On May 11, 2017, we received a letter from NASDAQ notifying us of our noncompliance with the minimum stockholders' equity requirement.

The Company is evaluating various courses of actions to regain compliance and has submitted to NASDAQ a plan to regain compliance. On July 19, 2017, the Company was notified by NASDAQ that the Company's common stock will remain listed on NASDAQ through at least September 30, 2017, during which time the Company will seek to take actions to regain compliance. If, prior to such date, the Company does not regain compliance, but provides additional information as to a plan to do so, the Company may be eligible for an extension of the September 30 date, through early November. However, there can be no assurance that the Company will be granted this additional time, or that the Company will ultimately be able to regain compliance.

In addition to the Company's non-compliance with the minimum stockholders' equity requirement, on June 14, 2017 the Company received a notification letter from NASDAQ advising the Company that for 30 consecutive business days preceding the date of this notification letter, the closing bid price of the Company's common stock had

been below the \$1.00 per share minimum required for continued listing on the NASDAQ Capital Market pursuant to NASDAQ Marketplace Rule 5550(a)(2), and that the Company thus did not comply with NASDAQ's minimum bid price rule.

This notification letter also stated that the Company will be provided 180 calendar days, or until December 11, 2017, to regain compliance with the minimum bid price rule. To do so, the closing bid price of the Company's common stock must be at or above \$1.00 per share for a minimum of ten consecutive business days prior to that date.

If by December 11, 2017 the Company cannot demonstrate compliance with the minimum bid price rule, the Company may be eligible for additional time. To qualify, the NASDAQ staff will determine whether or not the Company meets the NASDAQ Capital Market initial listing criteria set forth in NASDAQ Marketplace Rule 5550, except for the minimum bid price rule. If the Company meets the initial listing criteria (with the exception of the minimum bid price rule) and provides written notice of its intention to cure the deficiency during the second compliance period, the NASDAQ staff will inform the Company that it has been granted an additional 180 calendar day compliance period.

If the Company is not able to regain compliance or, in the case of the minimum bid price requirement, is not eligible for an additional 180-day compliance period, the NASDAQ staff will provide written notice that the Company's securities will be subject to delisting. At that time, the Company may appeal the NASDAQ staff's determination to delist its securities to a NASDAQ Listing Qualifications Panel. There can be no assurance that the Company will be able to maintain its NASDAQ listing.

If we do not regain compliance with the continued listing requirements for the NASDAQ Capital Market within specified periods and subject to permitted extensions (if any), our common stock may be recommended for delisting (subject to any appeal we would file). If our common stock is delisted, it could be more difficult to buy or sell our common stock and to obtain accurate quotations, and the price of our common stock could suffer a material decline. Delisting would also impair our ability to raise capital.

**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

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Item 6. Exhibits

10.1\* Severance Agreement and General Release, dated June 26, 2017, between the Company and Jaye Thompson.

10.2\* Series A Warrant to Purchase Common Stock, entered into on May 23, 2017 by the Company and various warrant holders identified in a schedule to such exhibit.

10.3\* Series B Warrant to Purchase Common Stock, entered into on May 23, 2017 by the Company and various warrant holders identified in a schedule to such exhibit.

10.4\* Pre-Funded Series C Warrant, entered into on May 23, 2017 by the Company and various warrant holders identified in a schedule to such exhibit.

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: August 14, 2017 By: /s/ Larry M. Dillaha, M.D.  
Larry M. Dillaha, M. D.  
President and Chief Executive Officer  
(Principal Executive Officer)

Date: August 14, 2017 By: /s/ Katherine A. Anderson  
Katherine A. Anderson  
Chief Financial Officer  
(Principal Financial Officer)