

REPRO MED SYSTEMS INC  
Form 10-Q  
October 07, 2016

**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 August 31, 2016**

Or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_.

**Commission File Number: 0-12305**

**REPRO MED SYSTEMS, INC.**

(Exact name of registrant as specified in its charter)

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New York  
(State or Other Jurisdiction of Incorporation or  
Organization)

13-3044880  
(I.R.S. Employer Identification No.)

24 Carpenter Road, Chester, New York  
(Address of Principal Executive Offices)

10918  
(Zip Code)

**(845) 469-2042**

(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. [X] 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 (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes [X] No [ ]

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

Large accelerated filer [ ]

Accelerated filer [ ]

Non-accelerated filer [ ]

Smaller reporting company [X]

(Do not check if a smaller reporting company)

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

As of October 7, 2016, 37,746,300 shares of common stock, \$.01 par value per share, were outstanding, which excludes 2,787,623 shares of Treasury Stock.



**REPRO MED SYSTEMS, INC.**

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**PART I – FINANCIAL INFORMATION****Item 1. Financial Statements****REPRO MED SYSTEMS, INC.****BALANCE SHEETS**

<b>ASSETS</b>	<b>August 31, 2016 (Unaudited)</b>	<b>February 29, 2016</b>
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$ 3,966,106	\$ 4,201,949
Certificates of deposit	261,118	261,118
Accounts receivable less allowance for doubtful accounts and returns of \$23,384 at August 31, 2016 and \$37,486 at February 29, 2016	1,345,268	1,350,180
Inventory	1,073,847	1,040,277
Prepaid expenses	365,723	265,123
<b>TOTAL CURRENT ASSETS</b>	<b>7,012,062</b>	<b>7,118,647</b>
Property and equipment, net	968,458	996,822
Patents, net of accumulated amortization of \$157,432 and \$147,380 at August 31, 2016 and February 29, 2016, respectively	331,241	247,691
Other assets	31,490	31,140
<b>TOTAL ASSETS</b>	<b>\$ 8,343,251</b>	<b>\$ 8,394,300</b>
 <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES</b>		
Deferred capital gain - current portion	\$ 22,481	\$ 22,481
Accounts payable	710,033	307,764
Accrued expenses	571,924	499,406
Accrued payroll and related taxes	109,220	148,766
Accrued tax liability	—	129,497
<b>TOTAL CURRENT LIABILITIES</b>	<b>1,413,658</b>	<b>1,107,914</b>
Deferred capital gain - less current portion	33,736	44,976
Deferred tax liability	92,822	123,111
<b>TOTAL LIABILITIES</b>	<b>1,540,216</b>	<b>1,276,001</b>
 <b>STOCKHOLDERS' EQUITY</b>	 404,875	 404,875

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Common stock, \$0.01 par value, 50,000,000 shares authorized, 40,487,532 shares issued; 37,699,909 shares outstanding at August 31, 2016 and 37,966,501 shares outstanding at February 29, 2016		
Additional paid-in capital	4,075,584	3,968,342
Retained earnings	2,704,011	3,019,940
	7,184,470	7,393,157
Less: Treasury stock at cost, 2,787,623 shares at August 31, 2016 and 2,521,031 at February 29, 2016	(367,435)	(246,858)
Less: Deferred compensation cost	(14,000)	(28,000)
<b>TOTAL STOCKHOLDERS' EQUITY</b>	<b>6,803,035</b>	<b>7,118,299</b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 8,343,251</b>	<b>\$ 8,394,300</b>

The accompanying notes are an integral part of these financial statements

**REPRO MED SYSTEMS, INC.****STATEMENTS OF OPERATIONS (UNAUDITED)**

	For the Three Months Ended		For the Six Months Ended	
	August 31		August 31	
	2016	2015	2016	2015
NET SALES	\$ 3,147,930	\$ 3,166,177	\$ 6,138,096	\$ 5,796,722
Cost of goods sold	1,193,338	1,159,448	2,246,692	2,272,133
Gross Profit	1,954,592	2,006,729	3,891,404	3,524,589
<b>OPERATING EXPENSES</b>				
Selling, general and administrative	1,932,164	1,391,143	4,111,754	2,869,483
Research and development	67,686	38,711	124,355	92,376
Depreciation and amortization	73,699	70,094	143,855	134,813
Total Operating Expenses	2,073,549	1,499,948	4,379,964	3,096,672
Net (Loss)/Operating Profit	(118,957)	506,781	(488,560)	427,917
<b>Non-Operating (Expense)/Income</b>				
Gain (Loss) currency exchange	(5,888)	9,313	9,744	(5,757)
Loss on disposal of fixed assets	—	(8,718)	—	(13,324)
Interest and other income	385	1,026	1,139	2,129
<b>TOTAL OTHER (EXPENSES)</b>				
<b>INCOME</b>	(5,503)	1,621	10,883	(16,952)
<b>(LOSS)/INCOME BEFORE TAXES</b>	(124,460)	508,402	(477,677)	410,965
Income Tax Benefit/(Expense)	41,848	(173,188)	161,749	(140,391)
<b>NET (LOSS)/INCOME</b>	\$ (82,612)	\$ 335,214	\$ (315,928)	\$ 270,574
<b>NET (LOSS)/INCOME PER SHARE</b>				
Basic	\$ (0.00)	\$ 0.01	\$ (0.01)	\$ 0.01
Diluted	\$ (0.00)	\$ 0.01	\$ (0.01)	\$ 0.01
<b>WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING</b>				
Basic	37,857,312	38,006,667	37,911,646	38,006,667
Diluted	37,857,312	38,006,667	37,911,646	38,006,667

The accompanying notes are an integral part of these financial statements



**REPRO MED SYSTEMS, INC.**  
**STATEMENTS OF CASH FLOWS**  
**(UNAUDITED)**

	<b>For the Six Months Ended</b>	
	<b>August 31,</b>	
	<b>2016</b>	<b>2015</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net (Loss)/Income	\$ (315,928)	\$ 270,574
Adjustments to reconcile net loss to net cash provided by operating activities:		
Amortization of deferred compensation cost	14,000	14,000
Stock based compensation expense	107,242	—
Depreciation and amortization	143,855	134,813
Deferred capital gain - building lease	(11,240)	(11,240)
Deferred taxes	(30,289)	(4,760)
Loss on disposal of fixed assets	—	13,324
Provision for returns and doubtful accounts	(14,102)	152
Changes in operating assets and liabilities:		
Decrease in accounts receivable	19,013	214,083
Increase in inventory	(33,571)	(69,073)
Increase in prepaid expense	(100,600)	(18,039)
Increase in other assets	(350)	—
Increase in accounts payable	402,269	66,579
Decrease in accrued payroll and related taxes	(39,546)	(16,956)
Increase in accrued expense	72,518	66,468
(Decrease) Increase in accrued tax liability	(129,497)	44,307
<b>NET CASH PROVIDED BY OPERATING ACTIVITIES</b>	<b>83,774</b>	<b>704,232</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Payments for property and equipment	(105,440)	(100,110)
Proceeds on disposal of fixed assets	—	13,550
Payments for patents	(93,600)	(17,887)
<b>NET CASH USED IN INVESTING ACTIVITIES</b>	<b>(199,040)</b>	<b>(104,447)</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Purchase of treasury stock	(120,577)	—
<b>NET CASH USED IN FINANCING ACTIVITIES</b>	<b>(120,577)</b>	<b>—</b>
<b>NET (DECREASE)/INCREASE IN CASH AND CASH EQUIVALENTS</b>	<b>(235,843)</b>	<b>599,785</b>
<b>CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD</b>	<b>4,201,949</b>	<b>2,557,235</b>
<b>CASH AND CASH EQUIVALENTS, END OF PERIOD</b>	<b>\$ 3,966,106</b>	<b>\$ 3,157,020</b>

Supplemental Information

Cash paid during the periods for:

Interest	\$	—	\$	—
Taxes	\$	—	\$	—

NON-CASH FINANCING AND INVESTING ACTIVITIES

Issuance of common stock as compensation	\$	—	\$	—
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The accompanying notes are an integral part of these financial statements

**REPRO MED SYSTEMS, INC.**

**NOTES TO THE UNAUDITED FINANCIAL STATEMENTS**

**NOTE 1 NATURE OF OPERATIONS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**NATURE OF OPERATIONS**

REPRO MED SYSTEMS, INC. (the “Company”, “RMS”) designs, manufactures and markets proprietary medical devices primarily for the ambulatory infusion market and emergency medical applications in compliance with the United States Food and Drug Administration (the “FDA”) quality and regulatory system and international standards for quality management system. The Company operates as one segment.

**BASIS OF PRESENTATION**

The accompanying unaudited financial statements as of August 31, 2016, have been prepared in accordance with generally accepted accounting principles and with instructions to SEC regulation S-X for interim financial statements.

In the opinion of the Company’s management, the financial statements contain all adjustments consisting of normal recurring accruals necessary to present fairly the Company’s financial position as of August 31, 2016, and the results of operations and cash flow for the three month and six month periods ended August 31, 2016, and 2015.

The results of operations for the three and six months ended August 31, 2016, and 2015 are not necessarily indicative of the results to be expected for the full year. These interim financial statements should be read in conjunction with the financial statements and notes thereto of the Company and management’s discussion and analysis of financial condition and results of operations included in the Company’s Annual Report for the year ended February 29, 2016, as filed with the Securities and Exchange Commission on Form 10-K.

**USE OF ESTIMATES IN THE FINANCIAL STATEMENTS**

The preparation of financial statements in conformity with U.S. generally accepted accounting principles (“U.S. GAAP”) requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates. Important estimates include but are not limited to, asset lives, valuation allowances, inventory, and accruals.

#### RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2014-09—Revenue from Contracts with Customers. The ASU clarifies the principles for recognizing revenue and develops a common revenue standard for U.S. GAAP and International Financial Reporting Standards (“IFRS”) that removes inconsistencies and weaknesses in revenue requirements, provides a more robust framework for addressing revenue issues, improves comparability of revenue recognition practices across entities, industries, jurisdictions and capital markets, provides more useful information to users of the financial statements through improved disclosure requirements and simplifies the preparation of financial statements by reducing the number of requirements to which an entity must refer. The amendments in this update are effective for the annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period. Full or modified retrospective adoption is required and early application is not permitted. On July 9, 2015, the FASB issued ASU No. 2015-14 Revenue from Contracts with Customers (Topic 606); Deferral of the Effective Date, which (a) delays the effective date of ASU 2014-09, Revenue from Contracts with Customers (Topic 606), by one year to annual periods beginning after December 15, 2017 and (b) allows early adoption of the ASU by all entities as of the original effective date for public entities. In March 2016, the FASB issued ASU No. 2016-08 Revenue from Contracts with Customers (Topic 606); Principal versus Agent Considerations (Reporting Revenue Gross versus Net), which is intended to improve the operability and understandability of the implementation guidance on principal versus agent considerations and the effective date is the same as the requirements in ASU 2014-09. In April 2016, the FASB issued ASU No. 2016-10 Revenue from Contracts with Customers (Topic 606); Identifying Performance Obligations and Licensing, which is intended to clarify identifying performance obligations and the licensing implementation guidance, while retaining the related principles for those areas and the effective date is the same as the requirements in ASU 2014-09. The Company is assessing the impact of the adoption of the ASU on its financial statements, disclosure requirements and methods of adoption.

In June 2016, FASB issued ASU No. 2016-13—Financial Instruments – Credit Losses (Topic 326); Measurement of Credit Losses on Financial Instruments, amends guidance on reporting credit losses for assets held at amortized cost basis and available for sale debt securities. For assets held at amortized cost basis, Topic 326 eliminates the probable initial recognition threshold in current GAAP and, instead, requires an entity to reflect its current estimate of all expected credit losses. The allowance for credit losses is a valuation account that is deducted from the amortized cost basis of the financial assets to present the net amount expected to be collected. For available for sale debt securities, credit losses should be measured in a manner similar to current GAAP, however Topic 326 will require that credit losses be presented as an allowance rather than as a write-down. This ASU affects entities holding financial assets and net investment in leases that are not accounted for at fair value through net income. The amendments affect loans, debt securities, trade receivables, net investments in leases, off balance sheet credit exposures, reinsurance receivables, and any other financial assets not excluded from the scope that have the contractual right to receive cash. The amendments in this update are effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. The Company is assessing the impact of the adoption of the ASU on its financial statements, disclosure requirements and methods of adoption.

In May 2016, FASB issued ASU No. 2016-12—Revenue from Contracts with Customers (Topic 606); Narrow-Scope Improvements and Practical Expedients, which is intended to not change the core principle of the guidance in Topic 606, but rather affect only the narrow aspects of Topic 606 by reducing the potential for diversity in practice at initial application and by reducing the cost and complexity of applying Topic 606 both at transition and on an ongoing basis. The effective date and transition requirements for the amendments in this update are the same as the effective date and transition requirements for Topic 606 (and any other Topic amended by update 2014-09). The Company is assessing the impact of the adoption of the ASU on its financial statements, disclosure requirements and methods of adoption.

In May 2016, the FASB issued ASU No. 2016-11 Revenue Recognition (Topic 605) and Derivatives and Hedging (Topic 815); Rescission of SEC Guidance Because of Accounting Standards Updates 2014-09 and 2014-16 Pursuant to Staff Announcements at the March 3, 2016 Emerging Issues Task Force (“EITF”) Meeting, which is rescinding certain SEC Staff Observer comments that are codified in Topic 605, Revenue Recognition, and Topic 932, Extractive Activities—Oil and Gas, effective upon adoption of Topic 606. The Company does not expect the adoption of the ASU to have any impact on its financial statements.

In March 2016, the FASB issued ASU No. 2016-09 — Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting. The ASU was issued as part of the FASB’s simplification initiative and under the ASU, the areas of simplification in the update involve several aspects of the accounting for share-based payment transactions, including the income tax consequences, classifications of awards as either equity or liabilities, and classification on the statement of cash flows. Some of the areas for simplification apply only to nonpublic entities. The amendment eliminates the guidance in Topic 718 that was indefinitely deferred shortly after the issuance of FASB Statement No. 123 (revised 2004), Share-Based Payment. This should not result in a change in practice because the guidance that is being superseded was never effective. The amendment in this ASU is effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods. Early adoption is permitted for any entity in any interim or annual period. If an entity early adopts the amendments in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. An entity that elects early adoption must adopt all of the amendments in the same period. The Company is assessing the

impact of the adoption of the ASU on its financial statements, disclosure requirements and methods of adoption.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842). The main difference between the current requirement under GAAP and this ASU is the recognition of lease assets and lease liabilities by lessees for those leases classified as operating leases. This ASU requires that a lessee recognize in the statement of financial position a liability to make lease payments (the lease liability) and a right-of-use asset representing its right to use the underlying asset for the lease term (other than leases that meet the definition of a short-term lease). The liability will be equal to the present value of lease payments. The asset will be based on the liability, subject to adjustment, such as for initial direct costs. For income statement purposes, the FASB retained a dual model, requiring leases to be classified as either operating or finance. Operating leases will result in straight-line expense (similar to current operating leases) while finance leases will result in a front-loaded expense pattern (similar to current capital leases). Classification will be based on criteria that are largely similar to those applied in current lease accounting. For lessors, the guidance modifies the classification criteria and the accounting for sales-type and direct financing leases. This is effective for annual and interim periods beginning after December 15, 2018 and early adoption is permitted. This ASU must be adopted using a modified retrospective transition, and provides for certain practical expedients. Transition will require application of the new guidance at the beginning of the earliest comparative period presented. We are currently assessing the potential impact of this ASU and expect it will not have a material impact on our consolidated financial condition and results of operations upon adoption.

In July 2015, the FASB issued ASU No. 2015-11—Simplifying the Measurement of Inventory. The ASU was issued as part of the FASB’s simplification initiative and under the ASU, inventory is measured at the lower of cost and net realizable value, which would eliminate the other two options that currently exist for the market: (1) replacement cost and (2) net realizable value less an approximately normal profit margin. This ASU is effective for interim and annual periods beginning after December 15, 2016. Early application is permitted and should be applied prospectively. The Company does not expect the adoption of the ASU to have any impact on its financial statements.

## STOCK-BASED COMPENSATION

The Company maintains a long-term incentive stock benefit plan under which it grants stock options and restricted stock to certain directors and key employees. The fair value of each option grant is estimated on the date of the grant using the Black-Scholes option-pricing model. All options are charged against income at their fair value. The entire compensation expense of the award is recognized over the vesting period. Shares of stock granted are recorded at the fair value of the shares at the grant date, over the vesting period.

## RECLASSIFICATION

Certain reclassifications have been made to conform prior period data to the current presentation. These reclassifications had no effect on reported net income.

## NOTE 2 RELATED PARTY TRANSACTIONS

On December 20, 2013, we executed an agreement effective March 1, 2014, with a Company director, Dr. Mark Baker, to provide clinical research and support services related to new and enhanced applications for the FREEDOM60® Syringe Infusion System. Authorized by the Board of Directors, the agreement provides for payment of 420,000 shares of common stock valued at \$0.20 per share over a three-year period. Amortization amounted to \$7,000 and \$14,000 for the three and six months ended August 31, 2016 and August 31, 2015, respectively.

On October 21, 2015, Cyril Narishkin was appointed to the Board of Directors and Interim Chief Operating Officer of the Company. Also effective October 21, 2015, we entered into a consulting agreement with Mr. Narishkin, to support our expanded management team and accelerate our growth opportunities under his role of Interim Chief Operating Officer. The agreement provided for payment of \$16,000 per month for eight days per month, of which half was to be paid in cash and half was to be paid in shares of common stock. Effective January 1, 2016, the agreement provided for the same payment of \$16,000 per month, of which seventy-five percent was to be paid in cash and twenty-five percent was to be paid in shares of common stock.

On June 24, 2016, Cyril Narishkin executed a termination and general release agreement, which terminated his previous consulting agreement, and resigned as an officer and director for personal reasons. Mr. Narishkin will be compensated for services as a consultant through January 31, 2017 at a monthly rate of \$16,000 per month for up to eight days of service a month upon request of the Company. Mr. Narishkin was granted compensation of \$48,000 and \$150,000 for the three and six months ended August 31, 2016, respectively. In accordance with the agreement, the Company repurchased 96,542 shares of common stock of the Company owned by Mr. Narishkin at an aggregate purchase price of \$43,393.

#### LEASED AIRCRAFT

The Company leases an aircraft from a company controlled by Andrew Sealfon, the Company's President and Chief Executive Officer. The lease payments were \$5,375 and \$10,750 for the three and six months ended August 31, 2016 and August 31, 2015, respectively. The original lease agreement has expired and the Company is currently on a month-to-month basis for rental payments.

#### BUILDING LEASE

Mr. Mark Pastreich, a director, is a principal in the entity that owns the building leased by Company. The Company is in year seventeen of a twenty-year lease. There have been no changes to lease terms since his directorship and none are expected through the life of the current lease. The lease payments were \$33,126 and \$66,252 for the three and six months ended August 31, 2016 and August 31, 2015, respectively.



**NOTE 3 PROPERTY AND EQUIPMENT**

Property and equipment consists of the following at:

	<b>August 31, 2016</b>	<b>February 29, 2016</b>
Land	\$ 54,030	\$ 54,030
Building	171,094	171,094
Furniture, office equipment, and leasehold improvements	989,500	923,394
Manufacturing equipment and tooling	954,910	961,486
	2,169,534	2,110,004
Less: accumulated depreciation	1,201,076	1,113,182
Property and equipment, net	\$ 968,458	\$ 996,822

**NOTE 4 LEGAL PROCEEDINGS**

On September 20, 2013, the Company commenced in the United States District Court for the Eastern District of California a declaratory judgment action against competitor, EMED Technologies Corp. (“EMED”) to establish the invalidity of one of EMED’s patents and non-infringement of the Company’s needle sets. EMED answered the complaint and asserted patent infringement and unfair business practice counterclaims. The Company responded by asserting its own unfair business practice claims against EMED. Both parties have requested injunctive relief and monetary damages. On June 16, 2015, the Court issued what it termed a “narrow” preliminary injunction against the Company from making certain statements regarding some of EMED’s products. On June 23, 2016, EMED filed a motion claiming that certain language in the Company’s device labeling does not comply with the injunction and seeking to prevent the Company from distributing the FREEDOM60 until the Company complies with the injunction.

On September 9, 2016, the Court issued an order to show cause concerning the Company’s compliance with the injunction, to which the Company responded on September 23, 2016. The Company advised the Court that the language in the Company’s labeling that EMED has challenged is language that the FDA directed the Company to use in its labeling. The Court’s decision is pending. On March 24, 2016, EMED filed a motion seeking a second preliminary injunction prohibiting RMS from selling three of its products in California. The Company opposed that motion on April 19, 2016. A decision on the motion is still pending. Discovery is ongoing.

On June 25, 2015, EMED filed a claim of patent infringement for the second of its patents, also directed to the Company’s needle sets, in the United States District Court for the Eastern District of Texas. This second patent is related to the one concerning the Company’s declaratory judgment action. Given the close relationship between the two patents, the Company requested that the Texas suit be transferred to California. Also, based on a validity review of the patent in the U.S. Patent and Trademark Office (“USPTO”), discussed below, the Company requested the Texas suit be stayed. On May 12, 2016, the Court entered an order staying the case until after the Patent Trial and Appeal Board at the USPTO issues a final written decision regarding the validity of the patent.

On September 11, 2015, the Company requested an ex parte reexamination of the patent in the first filed case, and on September 17, 2015 the Company requested an inter partes review (“IPR”) of the patent in the second filed case. On November 20, 2015, the USPTO instituted the ex parte reexamination request having found a substantial new question of patentability concerning EMED’s patent in the first filed case. A decision to institute the IPR for EMED’s patent in the second filed case was ordered by the USPTO on February 19, 2016 having determined a reasonable likelihood all claims of the patent may be found to be unpatentable. Both the ex parte reexamination and the inter partes review are ongoing.

Although the Company believes it has meritorious claims and defenses in these actions and proceedings, their outcomes cannot be predicted with any certainty. If any of these actions against the Company are successful, they could have a material adverse effect on the Company’s business, results of operations, financial condition and cash flows.

#### **NOTE 5 STOCKHOLDERS’ EQUITY**

On September 30, 2015, RMS’s Board of Directors authorized a stock repurchase program pursuant to which the Company will make open market purchases of up to 1,000,000 shares of the Company’s outstanding common stock. The purchases will be made through a broker to be designated by the Company with price, timing and volume restrictions based on average daily trading volume, consistent with the safe harbor rules of the Securities and Exchange Commission (the “Commission”) for such repurchases.

On June 29, 2016, the Board of Directors approved the amendment to the stock repurchase program increasing the authorized 1,000,000 shares to be repurchased to 2,000,000 shares.

As of August 31, 2016, the Company had repurchased 350,456 shares at an average price of \$0.45 under the program.

**NOTE 6 STOCK-BASED COMPENSATION**

On September 30, 2015, the Board of Directors approved the 2015 Stock Option Plan (“the Plan”) authorizing the Company to grant stock option awards to certain officers, employees and consultants under the plan, subject to shareholder approval at the Annual Meeting of Shareholders held on September 6, 2016. The total number of shares of common stock of the Company, par value \$0.01 per share (“Common Stock”), with respect to which awards may be granted pursuant to the Plan was not exceed 2,000,000 shares.

On June 29, 2016, the Board of Directors approved the amendment to the Plan authorizing the total number of shares of common stock authorized to be subject to awards granted under the Plan to be increased to 4,000,000 shares. On September 6, 2016, at the Annual Shareholder Meeting, the Company’s shareholders approved the Plan as amended.

As of August 31, 2016, the Company had awarded 965,000 options to certain executives and key employees under the plan.

On October 21, 2015, the Board of Directors of the Company approved non-employee director compensation of \$25,000 each annually, to be paid quarterly half in cash and half in common stock, beginning September 1, 2015. The per share weighted average fair value of stock options granted during the six months ended August 31, 2016 and August 31, 2015 was \$0.19 and zero, respectively. The fair value of each award is estimated on the grant date using the Black-Scholes option pricing model with the following weighted average assumptions used for grants in the six months ended August 31, 2016. Historical information was the primary basis for the selection of the expected volatility, expected dividend yield and the expected lives of the options. The risk-free interest rate was selected based upon yields of the U.S. Treasury issues with a term equal to the expected life of the option being valued:

	<b>2016</b>	<b>August 31,</b>	<b>2015</b>
Dividend yield	0.00%		—
Expected Volatility	59.00%		—
Weighted-average volatility	—		—
Expected dividends	—		—
Expected term (in years)	5 Years		—
Risk-free rate	2.17%		—

The following table summarizes the status of the Company’s stock option plan:

	Six Months Ended August 31,		2015	
	2016			
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at March 1	1,060,000	\$ 0.38	—	\$ —
Granted	—	\$ —	—	\$ —
Exercised	—	\$ —	—	\$ —
Forfeited	95,000	\$ 0.38	—	\$ —
Outstanding at August 31, 2016,	965,000	\$ 0.38	—	\$ —
Options exercisable at August 31,	—	\$ —	—	\$ —
Weighted average fair value of options granted during the period	—	\$ —	—	\$ —
Stock-based compensation expense	—	\$ 75,084	—	\$ —

Total stock-based compensation expense for stock option awards totaled \$75,084 and zero for the six months ended August 31, 2016 and August 31, 2015, respectively.

The weighted-average grant-date fair value of options granted during the six months ended August 31, 2016 and August 31, 2015 was zero for both periods. The total intrinsic value of options exercised during the six months ended August 31, 2016 and August 31, 2015, was zero for both periods.

The following table presents information pertaining to options outstanding at August 31, 2016:

<b>Range of Exercise Price</b>	<b>Number Outstanding</b>	<b>Weighted Average Remaining Contractual Life</b>	<b>Weighted Average Exercise Price</b>	<b>Number Exercisable</b>	<b>Weighted Average Exercise Price</b>
\$0.36 - \$0.38	965,000	5 years	\$ 0.37	—	—

As of August 31, 2016, there was \$0.1 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under the Plan. That cost is expected to be recognized over a weighted-average period of 17 months. The total fair value of shares vested during the six months ended August 31, 2016 and August 31, 2015, was zero for both periods.

## **PART I – ITEM 2. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.**

This Quarterly Report on Form 10-Q contains certain “forward-looking” statements (as such term is defined in the Private Securities Litigation Reform Act of 1995) and information relating to us that are based on the beliefs of the management, as well as assumptions made and information currently available.

Our actual results may vary materially from the forward-looking statements made in this report due to important factors such as uncertainties associated with future operating results, unpredictability related to Food and Drug Administration regulations, introduction of competitive products, limited liquidity, reimbursement related risks, government regulation of the home health care industry, success of the research and development effort, expanding the market of FREEDOM60®, availability of sufficient capital to continue operations, dependence on key personnel and the outcome of litigation. When used in this report, the words “estimate,” “project,” “believe,” “may,” “will,” “anticipate,” “intend,” “expect” and similar expressions are intended to identify forward-looking statements. Such statements reflect current views with respect to future events based on currently available information and are subject to risks and uncertainties that could cause actual results to differ materially from those contemplated in such forward-looking statements. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. These statements involve risks and uncertainties with respect to the ability to raise capital if or when needed to develop and market new products, acceptance in the marketplace of new and existing products, ability to penetrate new markets, our success in enforcing and obtaining patents, obtaining required Government approvals, attracting and maintaining key personnel and succeeding in defending litigation claims that could cause the actual results to differ materially. Our actual results, performance and achievements could differ materially from those expressed or implied in these forward-looking statements. The Company does not undertake any obligation to release publicly any revision to these forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events.

Throughout this report, “RMS,” the “Company,” “we,” “us” and “our” refer to Repro Med Systems, Inc.

## RESULTS OF OPERATIONS

### Three Months Ended August 31, 2016 compared to August 31, 2015

#### Net Sales

The following table summarizes our net sales for the three months ended August 31, 2016 and 2015:

	Three Months Ended August 31,		Change from Prior Year		% of Sales	
	2016	2015	\$	%	2016	2015
<b>Sales</b>						
Domestic	\$ 2,469,180	\$ 2,656,449	\$ (187,269)	(7.1)%	78.4%	83.9%
International	678,750	509,728	169,022	33.2%	21.6%	16.1%
<b>Total</b>	\$ 3,147,930	\$ 3,166,177	\$ (18,247)	(0.6)%		

Total net sales were down \$18,247 or 0.6% for the quarter ended August 31, 2016 compared to the quarter ended August 31, 2015. Domestic sales were down \$0.2 million or 7.1% quarter over quarter mostly due to a large clinical trial last year. The international market increased \$0.2 million or 33.2% mostly due to increased demand by existing customers and new customers, and an increase in Res-Q-Vac sales. We continue to concentrate the majority of our efforts in our infusion product lines, specifically towards new applications in both domestic and international markets. We anticipate sales to continue to increase as new markets, including new patient therapies and new countries, continue to develop and as we work on new enhancements to the FREEDOM60 that we believe will expand markets even further. For example, our efforts to reenter into the antibiotic market resulted in a large home care hospital system selecting the FREEDOM60 for all patients receiving this therapy.

### Gross Profit

Our gross profit for the three months ended August 31, 2016 and 2015 is as follows:

	Three Months Ended August 31,		Change from Prior Year	
	2016	2015	\$	%
Gross Profit	\$ 1,954,592	\$ 2,006,729	\$ (52,137)	(2.6)%
Stated as a Percentage of Net Sales	62.1%	63.4%		

Gross profit decreased \$0.1 million or 2.6% in the three months ended August 31, 2016, as compared to the same period in 2015. This decrease in the quarter was mostly driven by the slightly lower sales and increases in sales rebates related to a specific customer contract renewal in the quarter compared to the same period last year.

### Selling, general and administrative and Research and development

Our selling, general and administrative expenses and research and development costs for the three months ended August 31, 2016 and 2015 are as follows:

	Three Months Ended August 31,		Change from Prior Year	
	2016	2015	\$	%
Selling, general and administrative	\$ 1,932,164	\$ 1,391,143	\$ 541,021	38.9%
Research and development	67,686	38,711	28,975	74.8%
	\$ 1,999,850	\$ 1,429,854	\$ 569,996	39.9%
	63.5%	45.2%		

Stated as a Percentage of Net  
Sales

Selling, general and administrative expenses increased \$0.5 million during the three months ended August 31, 2016 compared to the same period last year. The majority of this increase came from professional fees and consulting fees for operations management and regulatory initiatives and payroll and related expenses in our sales department as a result of the reorganization efforts last year and an increase in headcount internationally. These increases were partially offset by lower recruiting fees paid related to our reorganization last year in the three months ended August 31, 2015.

Research and development expenses increased by 74.8%, primarily due to additional engineering resources and consulting services. We continue to actively pursue new product development and enhance existing product lines based on demand from the marketplace which includes feedback from sales and marketing at RMS and our distributors, the RMS clinical advisory panel, and our strategic business partners. We believe that such efforts have been useful in helping us to maintain our competitive position, increase revenue from our existing customer base and expand our market reach. Although our research and development efforts have allowed us to develop the Freedom60, our HIgH-Flo needle sets, and the FreedomEdge® in 2015, there can be no assurance that our research and development will result in additional commercially successful products.

Depreciation and amortization

Depreciation and amortization expense increased by 5.1% up to \$73,699 in the three months ended August 31, 2016 compared with \$70,094 in the three months ended August 31, 2015 as a result of continued investment in capital assets mostly related to production and for new patent applications and maintenance of existing patents.



Net (Loss)/Income

	Three Months Ended August 31,		Change from Prior Year	
	2016	2015	\$	%
Net (Loss)/Income	\$ (82,612)	\$ 335,214	\$ (417,826)	(124.6)%
Stated as a Percentage of Net Sales	(2.6)%	10.6%		

Our net loss for the three months ended August 31, 2016 was \$0.1 million compared to net income of \$0.3 million for the three months ended August 31, 2015, a \$0.4 million decrease, which was mostly a result of the increase in selling, general and administrative expenses of \$0.5 million as described above.

**Six Months Ended August 31, 2016 compared to August 31, 2015**Net Sales

The following table summarizes our net sales for the six months ended August 31, 2016 and 2015:

	Six Months Ended Aug 31,		Change from Prior Year		% of Sales	
	2016	2015	\$	%	2016	2015
<b>Sales</b>						
Domestic	\$ 4,933,025	\$ 4,665,523	\$ 267,502	5.7%	80.4%	80.5%
International	1,205,071	1,131,199	73,872	6.5%	19.6%	19.5%
<b>Total</b>	\$ 6,138,096	\$ 5,796,722	\$ 341,374	5.9%		

Net sales increased in the six months ended August 31, 2016 by \$0.3 million or 5.9% compared to the six months ended August 31, 2015. This increase was mostly driven by sales of our infusion products which resulted from both organic growth and new customers.

Gross Profit

Our gross profit for the six months ended August 31, 2016 and 2015 is as follows:

	Six Months Ended Aug 31,		Change from Prior Year	
	2016	2015	\$	%
Gross Profit	\$ 3,891,404	\$ 3,524,589	\$ 366,815	10.4%
Stated as a Percentage of Net Sales	63.4%	60.8%		

Gross profit increased \$0.4 million or 10.4% in the six months ended August 31, 2016 compared to the same period in 2015. This was mostly due to the increase in sales. As a percentage of sales we showed an improvement of 2.6% due to our lean manufacturing initiatives to streamline operations which have resulted in increased capacity and decreased direct assembly labor costs, as well as the moratorium on the medical device tax.

#### Selling, general and administrative and Research and development

Our selling, general and administrative expenses and research and development costs for the six months ended August 31, 2016 and 2015 are as follows:

	Six Months Ended Aug 31,		Change from Prior Year	
	2016	2015	\$	%
Selling, general and administrative	\$ 4,111,754	\$ 2,869,483	\$ 1,242,271	43.3%
Research and development	124,355	92,376	31,979	34.6%
	\$ 4,236,109	\$ 2,961,859	\$ 1,274,250	43.0%
Stated as a Percentage of Net Sales	69.0%	51.1%		

Selling, general and administrative expenses increased \$1.2 million during the six months ended August 31, 2016 as compared to the same period last year. The majority of this increase came from professional fees, consulting fees for operations management and regulatory initiatives, payroll and related expenses in sales and marketing as a result of our reorganization last year, an increase in headcount internationally, as well as initiatives for our website redesign.

Research and development expenses increased by \$31,979 in the six months ended August 31, 2016 compared to the same period last year mostly due to the addition of staff and outside consulting services. We continue to actively pursue new product development and enhance existing product lines based on demand from the marketplace which includes feedback from sales and marketing at RMS and our distributors, the RMS clinical advisory panel, and our strategic business partners. We believe that such efforts have been useful in helping us to maintain our competitive position, increase revenue from our existing customer base and expand our market reach. Although our research and development efforts have allowed us to develop the Freedom60, our HIgH-Flo needle sets, and the FreedomEdge in 2015, there can be no assurance that our research and development will result in additional commercially successful products.

#### Depreciation and amortization

Depreciation and amortization expense increased by 6.7%, up to \$143,855 in the six months ended August 31, 2016 compared with \$134,813 in the six months ended August 31, 2015 as a result of continued investment in capital assets mostly related to production and for new patent applications and maintenance of existing patents.

#### Net Income

	<b>Six Months Ended Aug 31,</b>		<b>Change from Prior Year</b>	
	<b>2016</b>	<b>2015</b>	<b>\$</b>	<b>%</b>
Net Income/(Loss)	\$ (315,928)	\$ 270,574	\$ (586,502)	(216.8)%
Stated as a Percentage of Net Sales	(5.2)%	4.7%		

Our net loss for the six months ended August 31, 2016 was \$0.3 million compared with net income of \$0.3 million for the six months ended August 31, 2015. This decrease of \$0.6 million is mostly the result of the increase in selling, general and administrative expenses of \$1.2 million described above, partially offset by increased sales.

### **LIQUIDITY AND CAPITAL RESOURCES**

Our principal source of liquidity is our cash of \$4.2 million as of August 31, 2016, and cash flows from operations.

Our principal source of operating cash inflows is from sales of our products to customers. Our principal cash outflows relate to the purchase and production of inventory and related costs, selling, general and administrative expenses, research and development costs, capital expenditures and patent costs.

We believe that as of August 31, 2016, cash on hand and cash expected to be generated from future operating activities will be sufficient to fund our operations, including further research and development and capital expenditures for the next 12 months. We believe the FREEDOM60 continues to find a solid following in the subcutaneous immune globulin market and this market is expected to continue to increase both domestically and internationally.

On September 30, 2015, RMS's Board of Directors authorized a stock repurchase program pursuant to which the Company will make open market purchases of up to 1,000,000 shares of the Company's Outstanding Common Stock. The purchases will be made through a broker to be designated by the Company with price, timing and volume restrictions based on average daily trading volume, consistent with the safe harbor rules of the Securities and Exchange Commission for such repurchases. As of August 31, 2016, the Company had repurchased 350,456 shares at an average price of \$0.45 under the program.

On June 29, 2016, the Board of Directors approved the amendment to the stock repurchase program increasing the authorized 1,000,000 shares to be repurchased to 2,000,000 shares.

#### Cash Flows

The following table summarizes our cash flows:

	<b>Six Months Ended</b>		<b>Six Months Ended</b>	
	<b>August 31, 2016</b>		<b>August 31, 2015</b>	
Net cash provided by operating activities	\$	83,774	\$	704,232
Net cash used in investing activities	\$	(199,040)	\$	(104,447)
Net cash used in financing activities	\$	(120,577)	\$	—

### Operating Activities

Net cash provided by operating activities of \$0.1 million for the six months ended August 31, 2016, was primarily attributable to the non-cash charges of \$0.1 million for depreciation and amortization of long lived tangible and intangible assets, \$14,000 of deferred compensation costs and stock based compensation expense of \$0.1 million.

Also adding to the positive cash flow was an increase in accounts payable of \$0.4 million mostly due to professional fees. Offsetting all of these items were the net loss of \$0.3 million, an increases in prepaids and a decrease in the accrued tax liability due to the net loss year to date. Net cash provided by operating activities of \$0.7 million for the six months ended August 31, 2015, was primarily attributable to our net income of \$0.3 million, non-cash charges of \$0.1 million for depreciation and amortization of long lived tangible and intangible assets, \$14,000 of deferred compensation costs, a reduction of accounts receivable of \$0.2 million and an increase in accounts payable and accrued expense of \$0.1 million.

### Investing Activities

Our net cash used in investing activities of \$0.2 million and \$0.1 million for the six months ended August 31, 2016 and August 31, 2015, respectively, were primarily attributable to our continued investment in capital assets mostly related to production and for new patent applications and maintenance of existing patents.

### Financing Activities

Our net cash used in financing activities of \$0.1 million for the six months ended August 31, 2016 was attributable to stock repurchases under the Company's repurchase program.

## **NON-GAAP FINANCIAL MEASURES**

Management of the Company believes that investors' understanding of the Company's performance is enhanced by disclosing non-GAAP financial measures as a reasonable basis for comparison of the Company's ongoing results of operations. These non-GAAP measures should not be considered a substitute for GAAP-basis measures and results. Our non-GAAP measures may not be comparable to non-GAAP measures of other companies. The table below provides a disclosure of these non-GAAP financial measures to the most closely analogous measure determined in accordance with GAAP.

Non-GAAP financial measures should not be considered a substitute for, or superior to, measures of financial performance prepared in accordance with GAAP. They are limited in value because they exclude charges that have a material effect on our reported results and, therefore, should not be relied upon as the sole financial measures to evaluate our financial results. The non-GAAP financial measures are meant to supplement, and to be viewed in conjunction with, GAAP financial results.

We disclose and discuss EBITDA as a non-GAAP financial measure in our public releases, including quarterly earnings releases, and other filings with the Securities and Exchange Commission. We define EBITDA as earnings (net income) before interest, income taxes, depreciation and amortization. We believe that EBITDA is used by investors and other users of our financial statements as a supplemental financial measure that, when viewed with our GAAP results and the accompanying reconciliation, we believe provides additional information that is useful to gain an understanding of the factors and trends affecting our business. We also believe the disclosure of EBITDA helps investors meaningfully evaluate and compare our cash flow generating capacity from quarter to quarter and year to year. EBITDA is used by management as a supplemental internal measure for planning and forecasting overall expectations and for evaluating actual results against such expectations. Because management uses EBITDA for such purposes, the Company uses EBITDA, adjusted for certain items, as a significant criterion for determining the amount of annual cash incentive compensation paid to our executive officers and employees. We have historically found that EBITDA is superior to other metrics for our company-wide cash incentive program, as it is more easily explained and understood by our typical employee.

We also include the use of non-GAAP normalized net income in our earnings releases. RMS management evaluates its business and makes certain operating decisions (e.g., budgeting, forecasting, employee compensation, asset management and resource allocation) using normalized net income. Management believes that because this measure provides it with useful supplemental information for evaluating and operating the business, investors would find it beneficial to have the opportunity to view the business in the same manner. Normalized net income is a measure that focuses on the Company's operations and facilitates comparison from period to period on a consistent basis. Management also believes it is appropriate in evaluating the Company's operations to exclude professional fees related to litigation and regulatory items because these costs are not expected to continue in the long term.

A reconciliation of our non-GAAP measures is below:

<b>Reconciliation of GAAP Net (Loss)/Income to Non-GAAP Normalized EBITDA:</b>	<b>Three Months Ended August 31</b>		<b>Six Months Ended August 31</b>	
	<b>2016</b>	<b>2015</b>	<b>2016</b>	<b>2015</b>
GAAP Net (Loss)/Income	\$ (82,612)	\$ 335,214	\$ (315,928)	\$ 270,574
Tax (Benefit)/Expense	(41,848)	173,188	(161,749)	140,391
Depreciation	73,699	70,094	143,855	134,813
Professional Fees (1)	302,031	223,949	920,175	223,949
Non-GAAP Normalized EBITDA	\$ 251,270	\$ 802,445	\$ 586,353	\$ 769,727

<b>Reconciliation of GAAP Net (Loss)/Income to Non-GAAP Normalized Net Income:</b>	<b>2016</b>		<b>2015</b>	
	<b>2016</b>	<b>2015</b>	<b>2016</b>	<b>2015</b>
GAAP Net (Loss)/Income	\$ (82,612)	\$ 335,214	\$ (315,928)	\$ 270,574
Professional Fees (1)	302,031	223,949	920,175	223,949
Tax Expense on Professional Fees	(102,222)	(75,811)	(312,198)	(75,480)
Non-GAAP Normalized Net Income	\$ 117,197	\$ 483,352	\$ 292,049	\$ 419,043

(1) Includes consulting and professional fees related to regulatory and litigation.

## **FDA**

On February 29, 2016, the Company received a Warning Letter (WL NYK-2016-26) from the New York District Office of U.S. Food and Drug Administration (“FDA”) (“the Letter”) pursuant to observations arising from an FDA site inspection of the Company’s manufacturing facility which occurred over a three week period in June 2015.

The Letter identified a variety of concerns and requested submission of a response to the FDA to which the Company filed its initial response to on March 18, 2016. The Company has subsequently had further telephonic and written communications with the FDA. The FDA has not completed its review of our responses and subsequent submissions. There is no deadline for a reply by the FDA, and the Company’s manufacturing and distribution continue without interruption.

The Company is awaiting an unannounced site re-inspection before the FDA’s indication that our response sufficiently addresses the issues identified in the Letter.

## OUR PRODUCTS

RMS is a cutting edge medical device manufacturer, collaborating closely within the industry to develop products with a focus on improving the lives of its patients. RMS' unique infusion delivery system is improving the quality of life of more than 15,000 patients around the world. Many patients will need to be on their life saving therapy for the rest of their lives, with a number of patients having safely used RMS' home care FREEDOM infusion system for more than 10 years.

RMS' innovative pumps, flow controlled tubing and subcutaneous needle sets ensure these patients continue to experience their often weekly infusions as a non-event with no adverse reactions. The Company's system gives patients the ability to continue with their daily activities with its easy to use, wearable and portable system. RMS relies on proven scientific principles to innovate and develop mechanical infusion systems by embracing a culture of continuous improvement. At RMS, patients always come first, which is why health care professionals recommend the use of the FREEDOM system for most patients in the U.S. market.

There is a steady increase in patients being diagnosed with diseases that are remedied by the medicines that RMS' FREEDOM system delivers, and the Company is well-positioned to continue to gain market share and help impacted patients gain "freedom" in their lives. Moreover, RMS is poised to expand its product distribution internationally in the near future. Steady U.S. growth forecasts and significant international opportunities ensure that RMS will continue its revenue growth.



## FREEDOM60 SYRINGE INFUSION SYSTEM

The FREEDOM60 Syringe Infusion System (“FREEDOM60”), comprised of the FREEDOM60 Syringe Infusion Pump and RMS Precision Flow Rate Tubing™, is designed for ambulatory medication infusions. For the home care patient, FREEDOM60 is an easy-to-use, lightweight mechanical pump using a 60ml syringe, completely portable and maintenance free, with no batteries to replace. FREEDOM60 offers increased safety, greater reliability and an overall higher quality infusion. For the infusion professional, FREEDOM60 delivers accurate infusion rates and class-leading flow performance. For the home infusion provider, FREEDOM60 is a cost-effective alternative to replace electronic and disposable pumps. Given FREEDOM60’s lower acquisition and operating costs, it frees up significant working capital for growing the Company’s infusion businesses.

The FREEDOM60 operates in “dynamic equilibrium,” which means the pump operates at a safe, low pressure and maintains a balance between what a patient’s subcutaneous tissues are able to manage and what the pump infuses. This balance is created by a safe, limited and controlled pressure, which adjusts the flow rate automatically to the patient’s needs providing a reliable, faster and more comfortable administration with fewer side effects for those patients. Electronic devices will increase infusion pressure while attempting to continue an infusion at the programmed rate, while the FREEDOM60 design maintains a safe, constant pressure and thereby automatically reduces the flow rate as required, if problems of administration occur.

Ambulatory infusion pumps are most prevalent in the outpatient and home care market although RMS believes there is potential in the hospital setting as well. Applications for the FREEDOM60 have been expanded to a wide spectrum by the medical and nursing communities due to its unique constant flow design, fluid dynamics functionality and safety profile. The usage includes the infusion of specialized drugs such as Immunoglobulin G (“IgG”), pain control and chemotherapy. Applications are also being increased for intravenous antibiotics including the widely used yet challenging to administer Vancomycin, and beta lactams which require longer infusion times as a part of antimicrobial stewardship. In Europe, RMS has observed additional patient success with the use of the FREEDOM60 for pain control, specifically post-operative epidural pain administration.

The FREEDOM60 provides a high-quality delivery to the patient at costs comparable to gravity-driven infusions and is designed for the home health care industry, patient emergency transportation and for any time a low-cost infusion is required. RMS continues to meet milestones in building a product franchise with FREEDOM60 and the sale of RMS Precision Flow Rate Tubing. This positions the Company well to expand on the technology of dynamic equilibrium for other home infusion devices.

In March, 2015, at the National Home Infusion Association Show in Phoenix, Arizona, RMS introduced the FreedomEdge Syringe Infusion Pump (“FreedomEdge”). The FreedomEdge uses all of the trusted technology of the FREEDOM60 in a new, smaller package ideal for use with 20ml or 30ml syringe sizes. Similar to the FREEDOM60, the FreedomEdge utilizes the existing RMS Precision Flow Rate Tubing and provides a great alternative and benefits to the patients who do not need the larger dose capacity.

## RMS HIGH-FLO™ SUBCUTANEOUS SAFETY NEEDLE SETS

RMS HIgH-Flo Subcutaneous Safety Needle Sets (“HIgH-Flo”) are designed for self-administration of medicine under the skin. RMS’ needles feature unique design elements specific to subcutaneous self-administration, including a 5-bevel back-cut needle designed for more comfort and less tissue damage. Its needle set design permits drug flows which are the same or faster than those achieved with larger gauge needles currently on the market. This proprietary fluid dynamics engineering, compatible with the FREEDOM60 and FreedomEdge, guarantees the sensitivity of the system’s dynamic equilibrium.

Reflecting RMS’ dedication to clinician safety, the sets’ butterfly wing closures encase needles after use and help to protect against accidental needle stick injuries, an area of concern to the medical community. The sets are called safety needle sets to reflect this integral feature.

The Company expanded the range of HIgH-Flo sets available, including a 24 gauge set for very high flow rates, to meet the delivery demands of new drugs on the market. HIgH-Flo sets are also being used in clinical trials worldwide for a number of medications and therapies.

## RES-Q-VAC® PORTABLE MEDICAL SUCTION

The RES-Q-VAC Portable Medical Suction System (“RES-Q-VAC”) is a lightweight, portable, hand-operated suction device that removes fluids from a patient’s airway by attaching the RES-Q-VAC pump to various proprietary sterile and non-sterile single-use catheters sized for adult and pediatric suctioning. The bottom-hinged, one-hand operation makes it extremely effective and the product is generally found in emergency vehicles, hospitals, disaster kits, mass casualty trailers and wherever portable aspiration is a necessity, including backup support for powered suction systems. Additional markets include nursing homes, hospice, sub-acute, dental and military applications. The Full Stop Protection® filter and disposable features of the RES-Q-VAC reduce the risk of exposing the health professional to human immunodeficiency virus (“HIV”) or Tuberculosis (“TB”) when suctioning a patient or during post treatment cleanup. All of the parts that connect to the pump are disposable.

A critical component and significant advantage of the RES-Q-VAC system is our Full Stop Protection® filter, a patented filtering system that both prevents leakage and overflow of the aspirated fluids, even at full capacity, and traps many air- and fluid-borne pathogens and potentially infectious materials within the sealable container. This protects users from potential exposure to disease and contamination. Full Stop Protection meets the requirement of the Occupational Safety and Health Administration (“OSHA”) ‘Occupational Exposure to Blood Borne Pathogens’ Code of Federal Regulations 29 1910.1030. The Company has received a letter from OSHA confirming that the RES-Q-VAC with Full Stop Protection falls under the engineering controls of the blood borne pathogen regulation and that the product’s use would fulfill the regulatory requirements.

The Centers for Disease Control (“CDC”) and World Health Organization continue to emphasize the importance of minimizing aerosol production during suctioning, in order to reduce the spread of pandemic and epidemic diseases such as Ebola and Influenza. At the current time, we believe that the RES-Q-VAC with Full Stop Protection is the only portable, hand-operated device to comply with CDC directives from 2003.

Hospitals are required under the Emergency Medical Treatment and Labor Act (“EMTALA”) regulations to provide emergency treatment to patients anywhere in the primary facility and up to 250 yards away. The RES-Q-VAC ensures full compliance with these regulations and helps minimize unfavorable outcomes and potential lawsuits. We provide special hospital kits, which are fully stocked to meet all hospital applications, both adult and pediatric.

RMS is actively pursuing a direct sales effort into the hospital market, working with direct sales and several regional distributors in the respiratory market. It is also working internationally with distributors who are well represented in the hospital and emergency markets.

## ON-LINE CALCULATOR

In March 2016, the Company introduced its new On-Line Calculator, a tool to help determine which of the Company's Precision Flow Rate Tubing and RMS HIGH-Flo Subcutaneous Needle Sets to use based on the medication being administered and desired time of infusion. Customers responded well to the new calculator and expressed that the new format of the On-Line Calculator, which can be used on any computer, tablet or mobile device, was easy to use and very helpful.

## **COMPETITION**

### The FREEDOM60

Competition for the FREEDOM60 for IgG includes electrically powered infusion devices, which are more costly and can create high pressures during delivery, which can cause complications for the administration of IgG. However, there can be no assurance that other companies, including those with greater resources, will not enter the market with competitive products which will have an adverse effect on our sales.

There is the potential for new drugs to enter the market which might change the market conditions for devices such as the FREEDOM60 and RMS HIGH-Flo Subcutaneous Safety Needle Sets (e.g. Hyaluronidase, which can facilitate absorption of IgG, making multiple site infusions unnecessary). We believe dynamic equilibrium (the principle behind the FREEDOM60) is ideal for new drug combinations, and that they might increase the size of the subcutaneous market, but there can be no assurance that newer drugs will have the same needs and requirements as the current drugs being used.

We are currently involved in legal proceedings with a competitor who has been offering accessories that can be used with the FREEDOM60 (see Part II, Item 1. – Legal Proceedings).

## The RES-Q-VAC

We believe that the RES-Q-VAC is currently the performance leader for manual, portable suction instruments. In the emergency market, the primary competition is the V-VAC™ from Laerdal Medical. The V-VAC™ is more difficult to use, cannot suction infants, and cannot be used while wearing heavy gloves such as in chemical warfare or in the extreme cold. Another competitor is the Ambu® Res-Cue Pump™, a lower-cost product similar to our design, made in China. We believe that the product is not as well made, as ergonomic, nor as versatile, and may not be purchased by the military segment of the market due to lines of supply concerns. We believe that Full Stop Protection substantially separates the RES-Q-VAC from competitive units, which tend to leak fluid when becoming full or could pass airborne pathogens during use. There is a heightened concern from health care professionals concerning exposure to disease and we believe the RES-Q-VAC provides improved protection for these users.

## RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2014-09—Revenue from Contracts with Customers. The ASU clarifies the principles for recognizing revenue and develops a common revenue standard for U.S. GAAP and International Financial Reporting Standards (“IFRS”) that removes inconsistencies and weaknesses in revenue requirements, provides a more robust framework for addressing revenue issues, improves comparability of revenue recognition practices across entities, industries, jurisdictions and capital markets, provides more useful information to users of the financial statements through improved disclosure requirements and simplifies the preparation of financial statements by reducing the number of requirements to which an entity must refer. The amendments in this update are effective for the annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period. Full or modified retrospective adoption is required and early application is not permitted. On July 9, 2015, the FASB issued ASU No. 2015-14 Revenue from Contracts with Customers (Topic 606); Deferral of the Effective Date, which (a) delays the effective date of ASU 2014-09, Revenue from Contracts with Customers (Topic 606), by one year to annual periods beginning after December 15, 2017 and (b) allows early adoption of the ASU by all entities as of the original effective date for public entities. In March 2016, the FASB issued ASU No. 2016-08 Revenue from Contracts with Customers (Topic 606); Principal versus Agent Considerations (Reporting Revenue Gross versus Net), which is intended to improve the operability and understandability of the implementation guidance on principal versus agent considerations and the effective date is the same as the requirements in ASU 2014-09. In April 2016, the FASB issued ASU No. 2016-10 Revenue from Contracts with Customers (Topic 606); Identifying Performance Obligations and Licensing, which is intended to clarify identifying performance obligations and the licensing implementation guidance, while retaining the related principles for those areas and the effective date is the same as the requirements in ASU 2014-09. The Company is assessing the impact of the adoption of the ASU on its financial statements, disclosure requirements and methods of adoption.

In June 2016, FASB issued ASU No. 2016-13—Financial Instruments – Credit Losses (Topic 326); Measurement of Credit Losses on Financial Instruments, amends guidance on reporting credit losses for assets held at amortized cost basis and available for sale debt securities. For assets held at amortized cost basis, Topic 326 eliminates the probable initial recognition threshold in current GAAP and, instead, requires an entity to reflect its current estimate of all

expected credit losses. The allowance for credit losses is a valuation account that is deducted from the amortized cost basis of the financial assets to present the net amount expected to be collected. For available for sale debt securities, credit losses should be measured in a manner similar to current GAAP, however Topic 326 will require that credit losses be presented as an allowance rather than as a write-down. This ASU affects entities holding financial assets and net investment in leases that are not accounted for at fair value through net income. The amendments affect loans, debt securities, trade receivables, net investments in leases, off balance sheet credit exposures, reinsurance receivables, and any other financial assets not excluded from the scope that have the contractual right to receive cash. The amendments in this update are effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. The Company is assessing the impact of the adoption of the ASU on its financial statements, disclosure requirements and methods of adoption.

In May 2016, FASB issued ASU No. 2016-12—Revenue from Contracts with Customers (Topic 606); Narrow-Scope Improvements and Practical Expedients, which is intended to not change the core principle of the guidance in Topic 606, but rather affect only the narrow aspects of Topic 606 by reducing the potential for diversity in practice at initial application and by reducing the cost and complexity of applying Topic 606 both at transition and on an ongoing basis. The effective date and transition requirements for the amendments in this update are the same as the effective date and transition requirements for Topic 606 (and any other Topic amended by update 2014-09). The Company is assessing the impact of the adoption of the ASU on its financial statements, disclosure requirements and methods of adoption.

In May 2016, the FASB issued ASU No. 2016-11 Revenue Recognition (Topic 605) and Derivatives and Hedging (Topic 815); Rescission of SEC Guidance Because of Accounting Standards Updates 2014-09 and 2014-16 Pursuant to Staff Announcements at the March 3, 2016 Emerging Issues Task Force (“EITF”) Meeting, which is rescinding certain SEC Staff Observer comments that are codified in Topic 605, Revenue Recognition, and Topic 932, Extractive Activities—Oil and Gas, effective upon adoption of Topic 606. The Company does not expect the adoption of the ASU to have any impact on its financial statements.

In March 2016, the FASB issued ASU No. 2016-09 — Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting. The ASU was issued as part of the FASB’s simplification initiative and under the ASU, the areas of simplification in the update involve several aspects of the accounting for share-based payment transactions, including the income tax consequences, classifications of awards as either equity or liabilities, and classification on the statement of cash flows. Some of the areas for simplification apply only to nonpublic entities. The amendment eliminates the guidance in Topic 718 that was indefinitely deferred shortly after the issuance of FASB Statement No. 123 (revised 2004), Share-Based Payment. This should not result in a change in practice because the guidance that is being superseded was never effective. The amendment in this ASU is effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods. Early adoption is permitted for any entity in any interim or annual period. If an entity early adopts the amendments in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. An entity that elects early adoption must adopt all of the amendments in the same period. The Company is assessing the impact of the adoption of the ASU on its financial statements, disclosure requirements and methods of adoption.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842). The main difference between the current requirement under GAAP and this ASU is the recognition of lease assets and lease liabilities by lessees for those leases classified as operating leases. This ASU requires that a lessee recognize in the statement of financial position a liability to make lease payments (the lease liability) and a right-of-use asset representing its right to use the underlying asset for the lease term (other than leases that meet the definition of a short-term lease). The liability will be equal to the present value of lease payments. The asset will be based on the liability, subject to adjustment, such as for initial direct costs. For income statement purposes, the FASB retained a dual model, requiring leases to be classified as either operating or finance. Operating leases will result in straight-line expense (similar to current operating leases) while finance leases will result in a front-loaded expense pattern (similar to current capital leases). Classification will be based on criteria that are largely similar to those applied in current lease accounting. For lessors, the guidance modifies the classification criteria and the accounting for sales-type and direct financing leases. This is effective for annual and interim periods beginning after December 15, 2018 and early adoption is permitted. This ASU must be adopted using a modified retrospective transition, and provides for certain practical expedients. Transition will require application of the new guidance at the beginning of the earliest comparative period presented. We are currently assessing the potential impact of this ASU and expect it will not have a material impact on our consolidated financial condition and results of operations upon adoption.

In July 2015, the FASB issued ASU No. 2015-11—Simplifying the Measurement of Inventory. The ASU was issued as part of the FASB’s simplification initiative and under the ASU, inventory is measured at the lower of cost and net realizable value, which would eliminate the other two options that currently exist for the market: (1) replacement cost and (2) net realizable value less an approximately normal profit margin. This ASU is effective for interim and annual periods beginning after December 15, 2016. Early application is permitted and should be applied prospectively. The Company does not expect the adoption of the ASU to have any impact on its financial statements.

### **PART I – ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.**

Not Applicable.

**PART I – ITEM 4. CONTROLS AND PROCEDURES.**

The Company's management, including the Company's Principal Executive Officer and Principal Financial Officer, have evaluated the effectiveness of the Company's disclosure controls and procedures as such is defined in Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Based upon their evaluations, the Principal Executive Officer and Principal Financial Officer concluded that, as of the end of the period covered by this report, the Company's disclosure controls and procedures were effective for the purpose of ensuring that the information required to be disclosed in the reports that the Company files or submits under the Exchange Act with the Securities and Exchange Commission (the "SEC") (1) is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (2) is accumulated and communicated to the Company's management, including its Principal Executive Officer and Principal Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

There have been no changes in the Company's internal control over financial reporting during the quarter ended August 31, 2016, that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.



## **PART II – OTHER INFORMATION**

### **PART II – ITEM 1. LEGAL PROCEEDINGS.**

On September 20, 2013, the Company commenced in the United States District Court for the Eastern District of California a declaratory judgment action against competitor, EMED Technologies Corp. (“EMED”) to establish the invalidity of one of EMED’s patents and non-infringement of the Company’s needle sets. EMED answered the complaint and asserted patent infringement and unfair business practice counterclaims. The Company responded by asserting its own unfair business practice claims against EMED. Both parties have requested injunctive relief and monetary damages. On June 16, 2015, the Court issued what it termed a “narrow” preliminary injunction against the Company from making certain statements regarding some of EMED’s products. On June 23, 2016, EMED filed a motion claiming that certain language in the Company’s device labeling does not comply with the injunction and seeking to prevent the Company from distributing the FREEDOM60 until the Company complies with the injunction.

On September 9, 2016, the Court issued an order to show cause concerning the Company’s compliance with the injunction, to which the Company responded on September 23, 2016. The Company advised the Court that the language in the Company’s labeling that EMED has challenged is language that the FDA directed the Company to use in its labeling. The Court’s decision is pending. On March 24, 2016, EMED filed a motion seeking a second preliminary injunction prohibiting RMS from selling three of its products in California. The Company opposed that motion on April 19, 2016. A decision on the motion is still pending. Discovery is ongoing.

On June 25, 2015, EMED filed a claim of patent infringement for the second of its patents, also directed to the Company’s needle sets, in the United States District Court for the Eastern District of Texas. This second patent is related to the one concerning the Company’s declaratory judgment action. Given the close relationship between the two patents, the Company requested that the Texas suit be transferred to California. Also, based on a validity review of the patent in the U.S. Patent and Trademark Office (“USPTO”), discussed below, the Company requested the Texas suit be stayed. On May 12, 2016, the Court entered an order staying the case until after the Patent Trial and Appeal Board at the USPTO issues a final written decision regarding the validity of the patent.

On September 11, 2015, the Company requested an ex parte reexamination of the patent in the first filed case, and on September 17, 2015 the Company requested an inter partes review (“IPR”) of the patent in the second filed case. On November 20, 2015, the USPTO instituted the ex parte reexamination request having found a substantial new question of patentability concerning EMED’s patent in the first filed case. A decision to institute the IPR for EMED’s patent in the second filed case was ordered by the USPTO on February 19, 2016 having determined a reasonable likelihood all claims of the patent may be found to be unpatentable. Both the ex parte reexamination and the inter partes review are ongoing.

Although the Company believes it has meritorious claims and defenses in these actions and proceedings, their outcomes cannot be predicted with any certainty. If any of these actions against the Company are successful, they could have a material adverse effect on the Company’s business, results of operations, financial condition and cash

flows.

**PART II – ITEM 1A. RISK FACTORS.**

Not Applicable.

**PART II – ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.**

On October 21, 2015, the Board of Directors of the Company approved non-employee director compensation of \$25,000 each annually, to be paid quarterly half in cash and half in common stock, beginning September 1, 2015.

The following table provides information regarding repurchases by the Company of its common stock during the three month period ended August 31, 2016:

### Issuer Purchases of Common Stock

Period (1)	Total Number of Shares Purchased (2)	Average Price Paid Per Share	Total Number of Shares Purchased as Part of Publicly Announced Plan (3)	Maximum Number of Shares that May Yet Be Purchased Under the Plan (3)
June 1, 2016 - June 30, 2016	—	—	—	1,816,594
July 1, 2016 - July 31, 2016	166,392	\$ 0.45	69,850	1,746,744
August 1, 2016 - August 31, 2016	97,200	\$ 0.45	97,200	1,649,544
Total	263,592	\$ 0.45	167,050	

(1) Monthly information is presented by reference to the Company's fiscal months during the second quarter of fiscal 2017.

(2) In July 2016, the Company repurchased 96,542 shares of the Company's common stock owned by Cyril Narishkin at an aggregate purchase price of \$43,393 pursuant to a termination and general release agreement, entered into on June 24, 2016, between the Company and Mr. Narishkin.

(3) On September 30, 2015, RMS's Board of Directors authorized a stock repurchase program pursuant to which the Company will make open market purchases of up to 1,000,000 shares of the Company's outstanding common stock. The purchases will be made through a broker to be designated by the Company with price, timing and volume restrictions based on average daily trading volume, consistent with the safe harbor rules of the Securities and Exchange Commission for such repurchases. As of August 31, 2016, the Company had repurchased 350,456 shares at an average price of \$0.45 under the program. On June 29, 2016, the Board of Directors approved the amendment to the stock repurchase program increasing the authorized 1,000,000 shares to be repurchased to 2,000,000 shares. There is no expiration date to the program.

On September 30, 2015, the Board of Directors also approved the 2015 Stock Option Plan (the "Plan") authorizing the Company to grant awards to certain employees under the plan at fair market value, subject to shareholder approval.

The total number of shares of common stock of the Company, par value \$0.01 per share ("Common Stock"), with respect to which awards may be granted pursuant to the Plan shall not exceed 2,000,000 shares. As of August 31, 2016, the Company awarded 0.1 million options to certain executives and key employees under the Plan.

On June 29, 2016, the Board of Directors approved the amendment to the Plan authorizing the total number of shares of common stock authorized to be granted under the Plan be amended from 2,000,000 shares to 4,000,000 shares. On September 6, 2016, at the Annual Shareholder Meeting, shareholders approved the Plan as amended.

On December 20, 2013, we executed an agreement effective March 1, 2014, with a Company director, Dr. Mark Baker, to provide clinical research and support services related to new and enhanced applications for the FREEDOM60® Syringe Infusion System. Authorized by the Board of Directors, the agreement provides for payment of 420,000 shares of common stock valued at \$0.20 per share over a three-year period.

**PART II – ITEM 3. DEFAULTS UPON SENIOR SECURITIES.**

None.

**PART II – ITEM 4. MINE SAFETY DISCLOSURES.**

Not applicable.

**PART II – ITEM 5. OTHER INFORMATION.**

None.

**PART II – ITEM 6. EXHIBITS.**

- 3(ii) By-Laws of Repro Med Systems, Inc.
- 10.1 Karen Fisher’s Employment Agreement, dated January 15, 2015
- 10.2 Repro Med Systems, Inc. 2015 Stock Option Plan Amendment #1, effective June 29, 2016
- 31.1 Certification of Principal Executive Officer Pursuant to Section 302 of Sarbanes-Oxley Act 2002
- 31.2 Certification of Principal Financial Officer Pursuant to Section 302 of Sarbanes-Oxley Act 2002
- 32.1 Certification of Principal Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act 2002
- 32.2 Certification of Principal Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act 2002
- 101\* Interactive Data Files of Financial Statements and Notes.

\* In accordance with Regulation S-T, the Interactive Data Files in Exhibit 101 to the Quarterly Report on Form 10-Q shall be deemed “furnished” and not “filed”.

**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.

REPRO MED SYSTEMS, INC.

October 7, 2016

/s/ Andrew I. Sealfon

Andrew I. Sealfon, President, Chairman of the Board,  
Director, Chief Executive Officer

October 7, 2016

/s/ Karen Fisher

Karen Fisher, Chief Financial Officer and Treasurer

