

REPRO MED SYSTEMS INC
Form 10-Q
January 14, 2015

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 November 30, 2014

or

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

For the transition period from _____ to _____.

Commission File Number: 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)

n/a

(Former name, former address, and former fiscal year, if changed since last report)

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. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

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 January 14, 2015, 38,081,667 shares of common stock, \$.01 par value per share, were outstanding.

REPRO MED SYSTEMS, INC.

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PART I – FINANCIAL INFORMATION**ITEM 1. FINANCIAL STATEMENTS.****REPRO MED SYSTEMS, INC.****BALANCE SHEETS**

	November 30, 2014 Unaudited	February 28, 2014
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 2,247,919	\$ 2,227,398
Certificates of deposit	259,470	258,590
Accounts receivable less allowance for doubtful accounts of \$32,864 and \$26,450 for November 30, 2014 and February 28, 2014, respectively	1,708,908	1,744,813
Inventory	1,571,096	818,723
Prepaid expenses	244,792	245,767
Total Current Assets	6,032,185	5,295,291
PROPERTY & EQUIPMENT, net	1,196,029	839,059
OTHER ASSETS		
Patents, net of accumulated amortization of \$126,570 and \$119,436 at November 30, 2014 and February 28, 2014, respectively	127,897	43,305
Other	31,053	31,053
Total Other Assets	158,950	74,358
TOTAL ASSETS	\$ 7,387,164	\$ 6,208,708
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Deferred capital gain - current portion	\$ 22,481	\$ 22,481
Accounts payable	678,542	246,622
Accrued expenses	426,186	263,465
Accrued payroll and related taxes	65,218	72,976
Accrued tax liability	—	166,358
Total Current Liabilities	1,192,427	771,902

OTHER LIABILITIES			
Deferred capital gain - less current portion		73,076	89,936
Deferred tax liability		130,299	155,000
Total Other Liabilities		203,375	244,936
TOTAL LIABILITIES		1,395,802	1,016,838
STOCKHOLDERS' EQUITY			
Common stock, \$0.01 par value, 50,000,000 shares authorized, 40,356,667 and 38,936,667 shares issued; 38,081,667 and 36,661,667 shares outstanding at November 30, 2014, and February 28, 2014, respectively		403,567	389,367
Additional paid-in capital		3,855,094	3,512,294
Retained earnings		1,937,701	1,483,959
		6,196,362	5,385,620
Less: Treasury stock, 2,275,000 shares at cost		(142,000)	(142,000)
Deferred compensation cost		(63,000)	(51,750)
Total Stockholders' Equity		5,991,362	5,191,870
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$	7,387,164	\$ 6,208,708

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 Nine Months Ended	
	November 30,		November 30,	
	2014	2013	2014	2013
NET SALES	\$ 2,655,155	\$ 2,179,921	\$ 7,797,030	\$ 6,064,265
COST AND EXPENSE				
Cost of goods sold	1,075,158	854,734	3,054,246	2,370,062
Selling, general and administrative	1,257,134	975,731	3,439,258	2,890,679
Research and development	116,885	50,864	406,705	131,734
Depreciation and amortization	71,544	57,979	202,224	170,506
TOTAL COSTS AND EXPENSES	2,520,721	1,939,308	7,102,433	5,562,981
NET OPERATING PROFIT	134,434	240,613	694,597	501,284
OTHER INCOME/(EXPENSES)				
Gain (Loss) currency exchange	(23,483)	3,910	(33,198)	(7,080)
Interest expense	—	—	(512)	(4,547)
Interest and other income	1,143	1,166	4,058	5,612
TOTAL OTHER INCOME/(EXPENSE)	(22,340)	5,076	(29,652)	(6,015)
NET PROFIT BEFORE TAXES	112,094	245,689	664,945	495,269
Provision for Income Taxes	(19,402)	(83,735)	(211,203)	(169,252)
NET INCOME	\$ 92,692	\$ 161,954	\$ 453,742	\$ 326,017
NET INCOME PER SHARE				
Basic	\$ —	—\$	0.01	\$ 0.01
Diluted	\$ —	—\$	0.01	\$ 0.01
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING				
Basic	38,081,667	36,661,667	37,499,849	36,661,667
Diluted	38,081,667	36,661,667	37,499,849	36,661,667

The accompanying notes are an integral part of these Financial Statements

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

	For the Nine Months Ended	
	November 30, 2014	November 30, 2013
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Income	\$ 453,742	\$ 326,017
Adjustments to reconcile net income to net cash provided by operating activities:		
Amortization of deferred compensation cost	72,750	105,975
Depreciation and amortization	202,224	170,506
Deferred capital gain - building lease	(16,860)	(16,858)
Deferred Taxes	(24,701)	—
Changes in operating assets and liabilities:		
Decrease (Increase) in accounts receivable	35,905	(163,483)
(Increase) Decrease in inventory	(752,373)	194,121
Decrease (Increase) in prepaid expense	975	(72,462)
Decrease in other assets	—	29,316
Increase in accounts payable	431,920	96,058
Decrease in accrued payroll and related taxes	(7,758)	(28,095)
Increase in accrued expense	162,721	48,510
Decrease in accrued tax liability	(166,358)	(90,503)
NET CASH PROVIDED BY OPERATING ACTIVITIES	392,187	599,102
CASH FLOWS FROM INVESTING ACTIVITIES		
Payments for property and equipment	(552,060)	(146,908)
Purchase of certificates of deposit	(880)	(20,539)
Payments for patents	(91,726)	(1,231)
NET CASH USED IN INVESTING ACTIVITIES	(644,666)	(168,678)
CASH FLOWS FROM FINANCING ACTIVITIES		
Payments on note payable to related parties	—	(437,832)
Payments on notes payable	—	(1,474)
Proceeds from sale of securities, net of legal and other fees of \$15,000	273,000	—
NET CASH PROVIDED BY (USED IN) FINANCING ACTIVITIES	273,000	(439,306)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	20,521	(8,882)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	2,227,398	1,930,321
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 2,247,919	\$ 1,921,439

Supplemental Information

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Cash paid during the periods for:

Interest	\$	512	\$	4,547
Taxes	\$	404,891	\$	260,773

NON-CASH FINANCING AND INVESTING ACTIVITIES

Issuance of common stock as compensation	\$	84,000	\$	—
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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

NATURE OF OPERATIONS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

THE NATURE OF OPERATIONS

Repro Med Systems, Inc. (the “Company”) designs, manufactures, and markets proprietary medical devices primarily for the ambulatory infusion market and emergency medical applications. The FDA regulates these products. We use the d/b/a (doing business as) name RMS Medical Products, and use RMS as part of the branding of some products.

BASIS OF PRESENTATION

The accompanying unaudited financial statements as of November 30, 2014, 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 November 30, 2014, and the results of operations and cash flow for the three-month and nine-month periods ended November 30, 2014, and 2013.

The results of operations for the three months and nine months ended November 30, 2014, and 2013 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 28, 2014, 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 (“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.

EMPLOYEE STOCK AWARDS

In July 2012, 1,465,000 shares were authorized to issue to employees as share compensation valued at \$0.18 per share, the market value on the date of the board authorization. The value of these shares was amortized into operations over the one to two year restriction on the shares. Amortization amounted to \$0 and \$25,875 for the three-months ended November 30, 2014, and November 30, 2013, respectively; and \$51,750 and \$105,975 for the nine-months ended November 30, 2014, and November 30, 2013, respectively. Vesting of all shares was completed on August 31, 2014.

CONSULTING AGREEMENT WITH DIRECTOR

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 \$21,000 for the three-months and nine-months ended November 30, 2014, respectively. In August, 2014, Dr. Baker was paid a previously approved bonus of \$25,000 to assist him in covering taxes due on the grant of common stock.

SALE OF COMMON STOCK AND WARRANTS

On August 8, 2014, the Company executed an agreement with Horton Capital Partners Fund, an institutional investor based in Philadelphia, PA, to sell one million shares of our common stock and warrants to purchase an additional one million shares of common stock at an exercise price of \$0.45 per share. The aggregate purchase price was \$288,000. Fees associated with this transaction totaled \$15,000, for net proceeds of \$273,000.

LEGAL PROCEEDINGS

We commenced a declaratory judgment action in 2013 to establish the invalidity and non-infringement of claims of a patent of a competitor that alleged that our needle sets would infringe. The defendant answered the complaint and asserted various counterclaims that we believe are without merit. We subsequently added claims against the defendant to show that the defendant had engaged in various unfair business practices. The litigation is in early stage discovery.

SUBSEQUENT EVENTS EVALUATION

The Company has evaluated subsequent events through January 14, 2015, the date on which the financial statements were issued. There were no material subsequent events that required recognition or additional disclosure in the financial statements.

EMERGING ACCOUNTING STANDARDS

In June 2014, FASB issued Accounting Standards Update (“ASU”) No. 2014-09, “Revenue from Contracts with Customers”. The update gives entities a single comprehensive model to use in reporting information about the amount and timing of revenue resulting from contracts to provide goods or services to customers. The ASU, which would apply to any entity that enters into contracts to provide goods or services, would supersede the revenue recognition requirements in Topic 605, Revenue Recognition, and most industry-specific guidance throughout the Industry Topics of the Codification. Additionally, the update would supersede some cost guidance included in Subtopic 605-35, Revenue Recognition – Construction-Type and Production-Type Contracts. The update removes inconsistencies and weaknesses in revenue requirements and provides a more robust framework for addressing revenue issues and more useful information to users of financial statements through improved disclosure requirements. In addition, the update improves comparability of revenue recognition practices across entities, industries, jurisdictions, and capital markets and simplifies the preparation of financial statements by reducing the number of requirements to which an entity must refer. The update is effective for annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period. The Company is currently reviewing the provisions of this ASU to determine if there will be any impact on its results of operations, cash flows or financial condition.

Management does not believe that any of the other standards adopted by the Financial Accounting Standards Board, but which are not yet effective, will have a material effect on the Company’s financial reporting.

LEASED AIRCRAFT

The Company leases an aircraft from a company controlled by the president. The lease payments aggregated were \$5,375 for the three months ended November 30, 2014, and November 30, 2013, and \$16,125 for the nine months ended November 30, 2014, and November 30, 2013. The original lease agreement has expired and the Company is currently on a month-to-month basis for rental payments.

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, market acceptance of FREEDOM60®, availability of sufficient capital to continue operations, and dependence on key personnel. When used in this report, the words “estimate,” “project,” “believe,” “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 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 and attracting and maintaining key personnel that could cause the actual results to differ materially. Repro-Med 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.

THREE MONTHS ENDED NOVEMBER 30, 2014 VS. NOVEMBER 30, 2013

Net sales increased 21.8% overall from \$2,179,921 in the quarter ended November 30, 2013, to \$2,655,155 in the quarter ended November 30, 2014. The Company’s sales, compared with the same period in 2013, improved in both domestic and international markets, with sales increasing in the FREEDOM60® and RMS HIGH-Flo™ product lines. RES-Q-VAC® sales also improved. The quarter’s net sales were an increase of 6.0% over the sales of \$2,504,850 reported for the prior quarter ending August 31, 2014.

Net Operating Profit was \$134,434 for the quarter ended November 30, 2014, as compared with \$240,613 during the same period last year. This decline is attributable to increased R&D investment, increased sales and administrative costs, and legal costs associated with the engagement of Dechert LLP and other firms to strengthen our patent positions and represent us in litigation. The rapid weakening of the Euro also resulted in a foreign exchange loss of \$23,483 as compared to a gain of \$3,910 in 2013. Net income decreased from \$161,954 for the quarter ended November 30, 2013, to \$92,692 for the quarter ended November 30, 2014. Despite the increase in sales compared to the prior quarter ending August 31, 2014, Net Operating Profit and Net Income decreased from \$319,064 and \$202,994, respectively. Our fiscal third quarter has traditionally experienced a spike in sales and marketing costs due to the scheduling of a number of international and domestic trade shows, including the annual Medica show in Dusseldorf which provides the opportunity to meet our major international customers in one venue and the bi-annual

European Society for Immunodeficiencies (ESID) in Prague, which provides additional exposure of our products to clinical professionals. We also incurred legal costs not present in the second quarter, and added a production engineer and an international sales coordinator at the end of August.

Selling, General and Administrative costs increased from \$975,731 in 2013 to \$1,257,134 in 2014 due, in part, to salary and benefit costs, the expansion of the sales staff with the addition of a full-time representative in Europe and a coordinator for international sales in our US office, and legal costs associated with the engagement of Dechert LLP and other firms to review and strengthen our patent and litigation positions, partially offset by a reduction in the amortization of costs associated with the 2012 employee stock awards.

Cost of goods sold increased \$220,424, or 25.8%, from \$854,734 to \$1,075,158 due, in part, to an increase in sales. The gross profit margin decreased slightly this quarter to 59.5% compared with 60.8% for the same quarter in 2013, partially as the result of changes in product mix and a continuing shift in distribution channels. A manufacturing engineer was added to the production department in the middle of August to assist in the introduction of new products and to implement additional efficiencies in our manufacturing lines.

Research and Development expenses increased \$66,021, or 129.8%, from \$50,864 in 2013 to \$116,885 as a result of increased investment in new product development.

Depreciation and amortization expenses increased by \$13,565 from \$57,979 in 2013 to \$71,544 in 2014 due to increased investment in capital and intellectual assets, including new equipment purchases, facility upgrades and patents associated with new products.

NINE MONTHS ENDED NOVEMBER 30, 2014 VS. NOVEMBER 30, 2013

Net sales increased 28.6% overall from \$6,064,265 for the nine-month period ended November 30, 2013, to \$7,797,030 in the nine-month period ended November 30, 2014. The Company's sales improved in both domestic and international markets, with sales increasing in the FREEDOM60® and RMS HIGH-Flo™ product lines. Despite an increase in third quarter RES-Q-VAC sales, nine-month sales in this product line declined as domestic demand softened and the Company continued to focus its sales efforts on higher growth infusion products.

Net Operating Profit was \$694,597 for the nine months ended November 30, 2014, as compared with \$501,284 during the same period last year. This change is attributable to the increase in sales, which was partially offset by increases in cost of goods sold, substantially increased R&D investment, increased sales and administrative costs, and legal costs associated with the engagement of Dechert LLP and other firms to strengthen our patent positions and represent us in litigation. The rapid weakening of the Euro toward the end of the third quarter resulted in an increase in currency exchange losses on sales to European customers, which rose from \$7,080 in 2013 to \$33,198 in 2014. Net income increased from \$326,017 to \$453,742 in the nine-month period ended November 30, 2014.

Selling, General and Administrative costs increased from \$2,890,679 in 2013 to \$3,439,258 in 2014 due, in part, to the expansion of the sales staff with the addition of a full-time representative in Europe in February, the addition of a coordinator for international sales activities in our US office in August, and higher salary and benefit costs, partially offset by a reduction in the amortization of costs associated with the 2012 employee stock awards.

Cost of goods sold increased \$684,184, or 28.9%, from \$2,370,062 to \$3,054,246 due to an increase in sales, increases in production and quality assurance staff, higher salary and benefit costs and changes in product mix and distribution channels. The gross profit margin was virtually unchanged for the nine-month period ended November 30, 2014 at 60.8% compared to 60.9% for the same period in 2013.

Interest expense decreased to \$512 in 2014 from \$4,547 for the comparative nine-month period in 2013 as a result of retirement of long-term debt in 2013.

Research and Development expenses increased \$274,971, or 208.7%, from \$131,734 in 2013 to \$406,705 because of increased investment in development of new products and enhancements to existing product lines.

Depreciation and amortization expenses increased by \$31,718 from \$170,506 in 2013 to \$202,224 in 2014 due to increased investment in capital and intellectual assets, including new equipment purchases, facility upgrades and patents associated with new products. We opened a second cleanroom in June, 2014, to increase production capacity

and improve manufacturing efficiencies.

LIQUIDITY AND CAPITAL RESOURCES

Net Cash provided from Operations was \$392,187 for the nine months ended November 30, 2014, as compared with net cash provided by operations of \$599,102 for the previous nine months ended November 30, 2013. This change is primarily due to an increase in accounts payable, accrued expenses, and higher net income, offset by an increase in inventory levels. Our cash position remained basically unchanged. However, the increase in accounts payable as compared to the quarter ended August 31, 2014, reflected certain large invoices for operational and capital expenses that were paid in December.

Net cash from financing had a net change of \$712,306. In 2014, we received net cash proceeds of \$273,000 from the sale of common stock, while in 2013 we expended \$439,306 to retire high interest debt.

During the nine month period, we invested heavily in facility upgrades, patent and trademark protection, and new production equipment for products both in development and expected to be introduced in the upcoming year. We also opened a second cleanroom in June.

As a result of our revenues from operations and our available capital at the end of this period, we expect to meet or exceed the Company's liquidity needs for the next twelve months.

MANAGEMENT CHANGES

As of June 9, 2014, Mike R. Boscher, Chief Financial Officer, is no longer associated with the Company. Barry Short, 54, who had been serving as the Company's Director of Administration, was promoted to the position of Interim Chief Financial Officer.

On June 9, 2014, the Company created the new position of Chief Operating Officer. Rick McWhorter, 66, who had been serving as a management consultant to the Company, was appointed to the position on an interim basis. On December 19, 2014, Mr. McWhorter's contract ended and Andrew Sealfon, CEO, assumed the additional role of COO. The Company announced that Mr. McWhorter was expected to continue to consult on growth opportunities in the upcoming year.

BRANDING AND RECOGNITION

We continue to enhance marketing effects with an expanded schedule of advertising for our product lines in appropriate industry publications on a monthly basis. The Company also exhibited at several infusion and EMS trade shows in the first and second quarters of the fiscal year. We have also expanded our patient and provider outreach efforts.

FREEDOM60® SYRINGE INFUSION SYSTEM

The FREEDOM60® Syringe Infusion System, 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, cost effective and maintenance free, with no batteries to replace and no cumbersome IV pole. For the infusion professional, FREEDOM60® delivers accurate infusion rates and uniform flow profiles providing consistent transfer of medication.

The FREEDOM60® is popular in the treatment of Primary Immune Deficiency by injecting immune globulin (IgG) under the skin as a subcutaneous administration (SCIg). This method has provided patients with vastly improved quality of life with much fewer unpleasant side effects over the traditional intravenous route. The FREEDOM60® is an ideal system for this administration since the patient is able to self-medicate at home. The pump is easily configured for this application, and the FREEDOM60® is the lowest cost infusion system available in a heavily cost constrained market. We have advertised to the IgG market that FREEDOM60® operates in "dynamic equilibrium," that is, the pump finds 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.

We have expanded the use of the FREEDOM60® to cover antibiotics including the widely used and somewhat difficult to administer Vancomycin and beta lactams with longer infusion times. We have also found a following for FREEDOM60® for use in treating thalassemia with the drug Desferal®. In Europe, we found success in using the FREEDOM60® for pain control, specifically post-operative epidural pain administration. Our European market also

uses the FREEDOM60® for chemotherapy as well as subcutaneous immune globulin.

RMS HIGH-FLO™ SUBCUTANEOUS SAFETY NEEDLE SET

We received approval from the U.S. Food and Drug Administration (FDA) on May 20, 2011, for domestic marketing of our new subcutaneous needle administration set. Previously available internationally, the needle set is branded the RMS High-Flo™ Subcutaneous Safety Needle Set.

On June 5, 2012, we announced that the results of an Active Controlled Clinical Simulated Use Study confirmed that RMS High-Flow™ Subcutaneous Needle Sets are “safety sets.” 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 were renamed to RMS High-Flo™ Subcutaneous Safety Needle Sets to reflect the safety feature.

The FDA cleared a 510(k) on May 6, 2013, for enhancements to the RMS Subcutaneous Safety Needle Sets which included formally recognizing our clinical studies to support the safety needle set claim, additional lengths of 4mm and 14mm, use for greater than 24 hours, non-pyrogenic claims, the use of up to eight sites, and the 24 gauge needle.

The RMS High-Flo™ Subcutaneous Safety Needle Set was developed as an improvement in performance and safety over similar devices. Our design permits drug flows which are the same or faster than those achieved with larger gauge needles currently on the market. Offered in needle lengths of 4mm, 6mm, 9mm, 12mm and 14mm, the sets are available in combinations for single, double, triple, quadruple, penta and hexa infusions. Using a Low Residual “Y” Connector, needle sets can deliver to as many as eight infusion sites.

THE MARKET FOR INFUSION PUMPS & DISPOSABLES

The ambulatory infusion market has been rapidly changing due to reimbursement issues. Insurance reimbursement has drastically reduced the market share of high-end electronic type delivery systems as well as high-cost disposable non-electric devices, providing an opportunity for the FREEDOM60®. We believe market pressures have moved providers to consider alternatives to expensive electronic systems especially for new subcutaneous administrations that usually cannot be done with gravity. Due to cost concerns, some patients have been trained to administer intravenous drugs through IV push where the drug is pushed into the vein directly from a syringe. This is a low-cost option but has been associated with complications and is considered by many to be a high-risk procedure. Thus, the overall trend has been towards syringe pumps due to the low cost of disposables.

IMPORTANCE OF INSURANCE REIMBURSEMENT TO FREEDOM60® SALES

In order to receive more favorable Medicare reimbursement for our FREEDOM60® Syringe Infusion System, we had submitted a formal request for a HCPCS coding verification with the Statistical Analysis Durable Medical Equipment Regional Carrier (SADMERC). It was the determination that the Medicare HCPCS code(s) to bill the four Durable Medical Regional Carriers (DMERCs) should be: "E0779 Ambulatory infusion pump, mechanical, reusable, for infusion 8 hours or greater." The new code significantly increases the reimbursement for the FREEDOM60® for billable syringe pump application approved by Medicare. Current approved uses under Medicare include among others, subcutaneous immune globulin, antivirals, antifungals, and chemotherapeutics.

All possible effects, if any, of the federal government's Public Law 111-148, The Patient Protection and Affordable Care Act, on reimbursements for infusion pumps and related supplies and services cannot be stated with certainty at this time.

COMPETITION FOR THE FREEDOM60®

Competition for the FREEDOM60® for IgG consists mostly of electrically powered infusion devices that are more costly and can create high pressures during delivery that can cause complications for the administration of IgG. However, there can be no assurance that other companies will not enter the market with competitive products that will have an adverse effect on our sales. There is a mechanical pump, manufactured by a competitor, which we do not believe to have FDA clearance, but may be available for sale in Europe. The new pump uses a prior design of a simple coil spring which does not reproduce the constant pressure feature of the FREEDOM60®.

In expanded uses beyond SCIG, competition for FREEDOM60® would come from gravity bags and elastomeric pumps in addition to electric/electronic pumps.

There is the potential for new drugs to enter the market, such as using Hyaluronidase, which can facilitate absorption of IgG, making multiple site infusions unnecessary and changing the market conditions for devices such as the FREEDOM60® Syringe Infusion System and RMS HIGH-Flo™ Subcutaneous Safety Needle Sets. We believe the principle behind the FREEDOM60® is ideal for these new drug combinations, but there can be no assurance that these newer drugs will have the same needs and requirements as the current drugs being used.

There can be no assurance that Medicare will continue to provide reimbursement for the FREEDOM60®, or they may allow reimbursement for other infusion pumps that are currently in the market or new ones that may enter shortly, which could adversely affect our sales into this market.

We are currently involved in legal proceedings with a competitor who has been offering accessories that can be used with the FREEDOM60®.

RES-Q-VAC® PORTABLE MEDICAL SUCTION

The RES-Q-VAC® Emergency Airway Suction System 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 one-hand operation makes it extremely effective and the product is generally found in emergency vehicles, hospitals and wherever portable aspiration is a necessity, including backup support for powered suction systems. The Full Stop Protection® filter (FSP) and disposable features of the RES-Q-VAC® reduce the risk of exposing health professionals to HIV or SARS when suctioning a patient or during post treatment cleanup. All of the parts that connect to the pump are disposable.

A critical component and 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 virtually all airborne and fluid-borne pathogens and potentially infectious materials within the sealable container.

This protects users from potential exposure to disease and contamination. The Full Stop Protection® meets the requirement of the Occupational Safety and Health Administration 'Occupational Exposure to Bloodborne Pathogens' CFR29 1910.1030. The Company has received a letter from OSHA confirming that the RES-Q-VAC® with the Full Stop Protection® falls under the engineering controls of the Bloodborne Pathogen regulation and that the product's use would fulfill the regulatory requirements.

Recent concerns are for diseases that are easily transmitted by small aerosolized droplets such as Asian Bird Flu, Swine Flu, and resistant tuberculosis. Other concerns are hepatitis and HIV, among others.

One advantage of our RES-Q-VAC® airway suction system is versatility. With the addition of Full Stop Protection®, we created specific custom RES-Q-VAC® kits for various vertical markets:

Emergency Medicine - we make several special kits for emergency use, which contain all the catheters necessary to treat adults as well as infants or children. These first responder kits are generally non-sterile. We also have special attachments available for the advanced paramedic to treat patients who are intubated.

Respiratory - in-home care, long-term care, situations requiring frequent suctioning such as cystic fibrosis patients, patients with swallowing disorders, elderly, patients on ventilators and with tracheostomies all benefit from the portability, cost and performance of the RES-Q-VAC®. In hospitals, the RES-Q-VAC® provides emergency backup due to power loss or breakdown of the wall suction system.

Hospital Use - for crash carts, the emergency room, patients in isolation, patient transport (e.g., from ICU to Radiology) and backup for respiratory, RES-Q-VAC® is available sterile with Full Stop Protection® for the ultimate in performance and to meet all the OSHA regulations and CDC guidelines for use in treating patients in isolation, and in any location. Hospitals are required under the 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 for both adult and pediatric.

Nursing Homes, Hospice, Sub-acute - we provide special configurations for dining areas and portable suctioning for outside events and travel. Chronic suction can be accommodated with RES-Q-VAC®, which can be left by the bedside for immediate use during critical times.

Dental Applications - we offer a version of the RES-Q-VAC®, called DENTAL-EVAC, which addresses the needs of oral surgeons for emergency backup suction during a procedure. DENTAL-EVAC is supplied with the dental suction attachments such as saliva ejector and high volume evacuator.

Military Applications - due to its lightweight, portability, and rapid deployment, we believe that the RES-Q-VAC® is ideal for any military situation. In addition, exposure to chemical weapons of mass destruction such as Sarin is best treated by rapid, aggressive, and repeated suctioning. We believe that the RES-Q-VAC®'s compact size, powerful pump, and full protection of the user from any contamination, gives us a competitive edge in this market.

We continue actively pursuing a direct sales effort into the hospital market working with direct sales and several regional distributors in the respiratory market. We also work with national regional distributors who are well represented in the hospital respiratory market.

COMPETITION FOR 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. 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.

Laerdal has more resources than Rebro-Med Systems and had begun marketing the V-Vac™ before RES-Q-VAC® entered the market. Another competitor is Ambu, with the Res-Cue brand pump, a product similar to our design, made in China. We believe that the product is not as well made or as versatile, and may not be purchased by the military segment of the market due to lines of supply concerns. We believe that the addition of 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 healthcare professionals concerning exposure to disease and we believe the RES-Q-VAC® provides improved protection for these users.

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 Chief 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 Chief 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 Chief 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 November 30, 2014, that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS.

We commenced a declaratory judgment action in 2013 to establish the invalidity and non-infringement of claims of a patent of a competitor that alleged that our needle sets would infringe. The defendant answered the complaint and asserted various counterclaims that we believe are without merit. We subsequently added claims against the defendant to show that the defendant had engaged in various unfair business practices. The litigation is in early stage discovery.

ITEM 1A. RISK FACTORS.

Not required for smaller reporting companies.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.

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.

On August 8, 2014, we executed an agreement with Horton Capital Partners Fund, an institutional investor based in Philadelphia, PA, to sell one million shares of our common stock and warrants to purchase an additional one million shares of common stock at an exercise price of \$0.45 per share. The aggregate purchase price was \$288,000.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

ITEM 5. OTHER INFORMATION.

None.

ITEM 6. EXHIBITS.

- 31.1 Certification of Principal Executive Officer Pursuant to Section 302 of Sarbanes-Oxley Act 2002
- 31.2 Certification of Chief 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 Chief 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.

January 14, 2015

/s/ Andrew I. Sealfon

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

January 14, 2015

/s/ Barry K. Short

Barry K. Short, Treasurer and Chief Financial Officer
(Interim)