

REPRO MED SYSTEMS INC
Form 10-Q
October 15, 2013

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, 2013

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 October 15, 2013, 36,661,667 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**

	August 31, 2013 Unaudited	February 28, 2013
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 1,834,566	\$ 1,930,321
Certificates of deposit	257,922	257,009
Accounts receivable less allowance for doubtful accounts of \$21,950 and \$17,450 for August 31, 2013 and February 28, 2013 respectively	1,042,709	1,114,847
Inventory	1,106,832	1,150,129
Prepaid expenses	215,877	180,651
Total Current Assets	4,457,906	4,632,957
PROPERTY & EQUIPMENT, net	898,245	875,986
OTHER ASSETS		
Patents, net of accumulated amortization of \$113,880 and \$112,090 at August 31, 2013 and February 28, 2013, respectively	41,662	22,913
Other	30,969	60,369
Total Other Assets	72,631	83,282
TOTAL ASSETS	\$ 5,428,782	\$ 5,592,225
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Note payable – current portion	\$ —	1,474
Note payable to related parties - current portion	—	43,971
Deferred capital gain - current portion	22,481	22,481
Accounts payable	248,640	110,358
Accrued expenses	184,192	169,790
Accrued payroll and related taxes	58,704	50,195
Accrued tax liability	8,835	127,090

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Total Current Liabilities	522,852	525,359
OTHER LIABILITIES		
Note payable to related parties - less current portion	—	393,861
Deferred capital gain - less current portion	101,176	112,414
Deferred tax liability	204,000	204,000
Total Other Liabilities	305,176	710,275
TOTAL LIABILITIES	828,028	1,235,634
STOCKHOLDERS' EQUITY		
Common stock, \$0.01 par value, 50,000,000 shares authorized, 38,936,667 shares issued, and 36,661,667 shares outstanding	389,367	389,367
Additional paid-in capital	3,512,294	3,512,294
Retained earnings	944,593	780,530
	4,846,254	4,682,191
Less: Treasury stock, 2,275,000 shares at cost	(142,000)	(142,000)
Deferred compensation cost	(103,500)	(183,600)
Total Stockholders' Equity	4,600,754	4,356,591
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 5,428,782	\$ 5,592,225

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	
	2013	2012	2013	2012
NET SALES	\$ 2,007,958	\$ 1,951,608	\$ 3,884,344	\$ 3,695,773
COST AND EXPENSE				
Cost of goods sold	807,891	666,235	1,515,328	1,303,597
Selling, general and administrative	963,789	663,432	1,914,948	1,545,202
Research and development	43,116	37,015	80,870	75,390
Depreciation and amortization	57,590	42,933	112,527	83,470
TOTAL COSTS AND EXPENSES	1,872,386	1,409,615	3,623,673	3,007,659
NET OPERATING PROFIT	135,572	541,993	260,671	688,114
OTHER INCOME/(EXPENSES)				
Gain (Loss) currency exchange	72	(3,572)	(10,990)	(6,585)
Interest expense	(100)	(7,179)	(4,547)	(14,386)
Interest and other income	2,395	1,198	4,446	2,932
TOTAL OTHER INCOME/(EXPENSE)	2,367	(9,553)	(11,091)	(18,039)
NET PROFIT BEFORE TAXES	137,939	532,440	249,580	670,075
Provision for Income Taxes	(47,230)	(181,796)	(85,517)	(229,092)
NET INCOME	\$ 90,709	\$ 350,664	\$ 164,063	\$ 440,983
NET INCOME PER SHARE				
Basic	\$ —	0.01	\$ —	0.01
Diluted	\$ —	0.01	\$ —	0.01
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING				
Basic	36,661,667	35,546,993	36,661,667	35,371,830
Diluted	36,661,667	35,551,934	36,661,667	35,421,253

The accompanying notes are an integral part of these Financial Statements

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

	For the Six Months Ended	
	August 31, 2013	August 31, 2012
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Income	\$ 164,063	\$ 440,983
Adjustments to reconcile net income to net cash provided by operating activities:		
Amortization of deferred compensation cost	80,100	—
Depreciation and amortization	112,527	83,470
Deferred capital gain - building lease	(11,238)	(11,239)
Changes in operating assets and liabilities:		
(Increase) decrease in accounts receivable	72,138	(77,427)
(Increase) decrease in inventory	43,297	(83,929)
(Increase) decrease in prepaid expense	(35,226)	30,533
(Increase) decrease in other assets	29,400	(2,812)
Increase (decrease) in accounts payable	138,282	(87,023)
Increase in accrued payroll and related taxes	8,509	14,989
Increase (decrease) in accrued expense	14,402	(46,253)
Increase (decrease) in accrued tax liability	(118,255)	116,092
NET CASH PROVIDED BY OPERATING ACTIVITIES	497,999	377,384
CASH FLOWS FROM INVESTING ACTIVITIES		
Payments for property and equipment	(132,996)	(427,692)
Purchase of certificates of deposit	(913)	(128)
Payments for patents	(20,539)	(1,000)
NET CASH USED IN INVESTING ACTIVITIES	(154,448)	(428,820)
CASH FLOWS FROM FINANCING ACTIVITIES		
Payments on note payable to related parties	(437,832)	(20,399)
Payments on notes payable	(1,474)	(1,019)
NET CASH USED IN FINANCING ACTIVITIES	(439,306)	(21,418)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(95,755)	(72,854)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	1,930,321	1,757,223
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 1,834,566	\$ 1,684,369
Supplemental Information		
Cash paid during the period for:		
Interest	\$ 4,547	\$ 14,386
Taxes	\$ 203,773	\$ 113,000

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 August 31, 2013 have been prepared in accordance with generally accepted accounting principles in accordance with instructions to regulation S-X. Accordingly, they do not include all of the information and disclosures required by accounting principles generally accepted in the United States of America for complete financial presentation.

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, 2013 and the results of operations and cash flow for the three-month and six-month periods ended August 31, 2013 and 2012.

The results of operations for the three months and six months ended August 31, 2013 and 2012 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, 2013, as filed with the Securities and Exchange Commission on Form 10-K.

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 will be amortized into operations over the one to two year restriction on the shares.

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.

LEGAL PROCEEDINGS

The Company has commenced a declaratory judgment action to establish the invalidity of any claim that our needle sets infringe a patent of a competitor. The defendant has recently answered the complaint and asserted various counterclaims that the Company believes are without merit. Such claims are currently being reviewed by legal counsel.

SUBSEQUENT EVENTS EVALUATION

The Company has evaluated subsequent events through October 15, 2013, 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

Management does not believe that any of the 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 August 31, 2013 and August 31, 2012 and \$10,750 for the six months ended August 31, 2013 and August 31, 2012. 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 AUGUST 31, 2013 VS. AUGUST 31, 2012

Net sales increased 2.9% overall from \$1,951,608 in the quarter ended August 31, 2012 to \$2,007,958 in the quarter ended August 31, 2013. The Company’s sales improved in both domestic and international markets. Although revenues have continued to increase, this was partially offset by the effect of lower prices that were the result of an accelerating shift from direct sales to a distributor-driven model to meet customer preferences and expand potential markets, and from introductory discounts to place our needle sets in new markets. Unit volume growth also slowed, which may be the result of reimbursement uncertainty from the implementation of the Affordable Care Act, market share saturation and increased competition. Excluding the revenue from a large one-time sale of needle sets for a drug trial in August, 2012, sales of our needle set line increased substantially and we continue to actively pursue new customer contracts for the HIgH Flo™ Subcutaneous Safety Needle sets.

Net Operating Profit was \$135,572 for the quarter ended August 31, 2013 as compared with \$541,993 during the same period last year. This change is attributable to increases in cost of goods sold, amortization of costs associated with a restricted stock grant program for key personnel authorized by the board in July 2012, expansion of sales and marketing staffs, additional advertising and promotions, legal costs associated with the engagement of Dechert LLP and other firms to review and strengthen our patent and litigation positions, and the 2.3% medical device excise tax imposed by US Public Law 111-148, The Patient Protection and Affordable Care Act (PPACA). Accordingly, net

income decreased from \$350,664 for the quarter ended August 31, 2012, to \$90,709 for the quarter ended August 31, 2013.

Selling, General and Administrative costs increased from \$663,432 in 2012 to \$963,789 in 2013 primarily as the result of amortization of costs associated with the restricted stock grant program for key employees authorized by the Board of Directors in July 2012, expansion of sales and marketing staffs, legal costs associated with the engagement of Dechert LLP and other firms to review and strengthen our patent and litigation positions, and increased marketing expenses for advertising and trade shows.

Cost of goods sold increased \$141,656, or 21%, from \$666,235 to \$807,891 due to an increase in sales, higher benefit costs, and the medical device tax imposed by PPACA. The gross profit margin decreased this quarter to 59.8% compared with 65.9% for the same quarter in 2012, due, in part, to the medical device tax which was imposed effective January 1, 2013 and price changes due to a shift in distribution channels.

Interest expense decreased to \$100 in 2013 from \$7,179 for the comparative quarter in 2012 as a result of retirement of some long-term debt.

Research and Development expenses increased \$6,101 or 16.5% from \$37,015 in 2012 to \$43,116 primarily due to R & D expenses incurred on new product development associated with the RMS HIGH-Flo™ Subcutaneous Safety Needle Sets, and research on manufacturing improvements and other new products.

Depreciation and amortization expenses increased by \$14,657 from \$42,933 in 2012 to \$57,590 in 2013 due to increased investment in capital assets.

SIX MONTHS ENDED AUGUST 31, 2013 VS. AUGUST 31, 2012

Net sales increased 5.1% overall from \$3,695,773 for the six-month period ended August 31, 2012 to \$3,884,344 in the six-month period ended August 31, 2013. The Company's sales improved in both domestic and international markets. Although revenues have continued to increase, this was partially offset by the effect of lower prices that were the result of an accelerating shift from direct sales to a distributor-driven model to meet customer preferences and expand potential markets, and from introductory discounts to place our needle sets in new markets. Unit volume growth also slowed, which may be the result of reimbursement uncertainty from the implementation of the Affordable Care Act, market share saturation and increased competition. Excluding the revenue from a large one-time sale of needle sets for a drug trial in August, 2012, sales of our needle set line increased substantially period-over-period and we continue to actively pursue new customer contracts for the HIgH Flo™ Subcutaneous Safety Needle sets.

Net Operating Profit was \$260,671 for the six months ended August 31, 2013 as compared with \$688,114 during the same period last year. This change is attributable to increases in cost of goods sold, amortization of costs associated with a restricted stock grant program for key personnel authorized by the board in July 2012, expansion of sales and marketing staffs, additional advertising and promotions, legal costs associated with the engagement of Dechert LLP and other firms to review and strengthen our patent and litigation positions, and the 2.3% medical device excise tax imposed by US Public Law 111-148, The Patient Protection and Affordable Care Act (PPACA). Accordingly, net income decreased from \$440,983 to \$164,063 in the six-month period ended August 31, 2013.

Selling, General and Administrative costs increased from \$1,545,202 in 2012 to \$1,914,948 in 2013 primarily as the result of amortization of costs associated with the restricted stock grant program for key employees authorized by the Board of Directors in July 2012, expansion of sales and marketing staffs, legal costs associated with the engagement of Dechert LLP and other firms to review and strengthen our patent and litigation positions, and increased marketing expenses for advertising and promotions.

Cost of goods sold increased \$211,731, or 16%, from \$1,303,597 to \$1,515,328 due to an increase in sales, higher benefit costs, and the medical device tax imposed by PPACA. The gross profit margin decreased for the six-month period ended August 31, 2013 to 61.0% compared to 64.7% from the same period in 2012, due, in part, to the medical device tax which was imposed effective January 1, 2013, and price changes due to a shift in distribution channels.

Interest expense decreased by 68.4% to \$4,547 in 2013 from \$14,386 for the comparative six-month period in 2012 as a result of retirement of some long-term debt.

Research and Development expenses increased \$5,480 or 7% from \$75,390 in 2012 to \$80,870 primarily due to R & D expenses incurred on new product development associated with the RMS HIgH-Flo™ Subcutaneous Safety Needle Sets, and research on manufacturing improvements and other new products.

Depreciation and amortization expenses increased by \$29,057 from \$83,470 in 2012 to \$112,527 in 2013 due to increased investment in capital assets.

LIQUIDITY AND CAPITAL RESOURCES

Net Cash provided from Operations was \$497,999 for the six months ended August 31, 2013 as compared with net cash provided by operations of \$377,384 for the previous six months ended August 31, 2012. This change is primarily due to a decrease in accounts receivables, an increase in and amortization of stock awarded under the restricted stock grant program for key personnel authorized by the Board of Directors in July 2012.

Net cash decreased by \$95,755 as the result of a decision to pay off a note to a related party. In the current interest rate environment, we believe that retiring higher interest debt is a more efficient use of funds than keeping them in low-yield accounts or certificates of deposit.

In August 2012, we acquired a residence adjacent to our facility for use as additional office and R&D space. We continue to invest in new equipment and facility improvements to accommodate our sales growth.

We continue to experience an increase in sales. With these increases and the capital we currently have at the end of this period, we will continue to meet or exceed the Company's liquidity needs for the next twelve months.

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®

The FREEDOM60® Syringe Infusion Pump is designed for ambulatory medication infusions. For the home care patient, FREEDOM60® is an easy-to-use lightweight mechanical pump using a 60cc 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 ADDITION TO FREEDOM60® PRODUCT LINE

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, and quadruple 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 is 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 with greater resources will not enter the market with competitive products that will have an adverse effect on our sales.

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®. We believe the principle behind the FREEDOM60® is ideal for all 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 have become aware of a new mechanical pump entry on the market which we do not believe to have FDA approval. The new pump uses a prior design of a simple coil spring which does not create a constant pressure and which had been removed from the market several years ago. The company offering this product is also representing that it is capable of manufacturing lower cost accessories which can be used with the FREEDOM60®. We have issued Safety Bulletins to all customers advising them that any non-RMS product used on our FREEDOM60® Systems may be unsafe, can create a health risk to the patient, including death, and would void the warranty of the pump.

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 and continue our effort into nursing homes 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.

As part of our sales efforts in the emergency medicine field, we exhibited at the EMS Today Show in Washington, DC, March 7-9, 2013. This offered emergency medicine technicians, paramedics, firefighting and police professionals, and others the opportunity to test RES-Q-VAC® for themselves and helped to support the efforts of RES-Q-VAC distributors.

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 August 31, 2013 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 are, from time to time, subject to claims and suits arising in the ordinary course of business, including claims for damages for personal injuries and employment related claims.

We have commenced a declaratory judgment action to establish the invalidity of any claim that our needle sets infringe a patent of a competitor. The defendant has recently answered our complaint and asserted various counterclaims that we believe are without merit. Such claims are currently being reviewed by legal counsel.

ITEM 1A. RISK FACTORS.

Not required for smaller reporting companies.

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

None.

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.

October 15, 2013

/s/ Andrew I. Sealfon

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

October 15, 2013

/s/ Michael R. Boscher

Michael R. Boscher, Treasurer and Chief Financial Officer