

REPRO MED SYSTEMS INC
Form 10-K
May 29, 2013

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

x ANNUAL REPORT PURSUANT TO SECTION 13 or 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended
Commission File Number

FEBRUARY 28, 2013
0-12305

REPRO-MED SYSTEMS, INC.

(Exact name of registrant as specified in its charter)

NEW YORK
(State or other jurisdiction of incorporation or
organization)

13-3044880
(IRS Employer Identification No.)

24 CARPENTER ROAD, CHESTER, NY
(Address of principal executive offices)

10918
(Zip Code)

Registrant's telephone number, including area
code

(845) 469-2042

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act:

COMMON STOCK, \$.01 PAR VALUE

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(Title of Class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.
Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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 during the past 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files.)
Yes ☒ No ☐

Indicate by check mark if the disclosure of delinquent filers pursuant to Item 405 of Regulation S-K, is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this form 10-K or any amendment to this Form 10-K. ☒

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

Large accelerated filer ☐
Non-accelerated filer ☐

Accelerated filer ☐
Smaller reporting company ☒

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

Based on the closing sales price of August 31, 2012, the aggregate market value of the voting and nonvoting common equity held by non-affiliates of the registrant was \$5,363,265.

The number of issued and outstanding shares of the registrant's common stock, \$.01 par value was 36,661,667 at May 29, 2013, which excludes 2,275,000 shares of Treasury Stock.

REPRO-MED SYSTEMS, INC.

FORM 10-K

INDEX

	<u>Page</u>
PART I	
Item 1- Business	3
Item 1A- Risk Factors	9
Item 1B- Unresolved Staff Comments	9
Item 2- Property	9
Item 3- Legal Proceedings	9
Item 4- Mine Safety Disclosures	9
PART II	
Item 5- Market for the Registrant's Common Equity and Related Shareholder Matters and Issuer Purchases of Equity Securities	9
Item 6- Selected Financial Data	10
Item 7- Management's Discussion and Analysis of Financial Condition and Results of Operations	10
Item 7A- Quantitative and Qualitative Disclosures about Market Risk	12
Item 8- Financial Statements and Supplementary Data	12
Item 9- Changes in and Disagreements with Accountants on Accounting and Financial Disclosures	24
Item 9A- Controls and Procedures	25
Item 9B- Other Information	25
PART III	
Item 10-	26

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Directors, Executive Officers, and Corporate
Governance

Item 11-	Executive Compensation	26
Item 12-	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	27
Item 13-	Certain Relationships and Related Transactions and Director Independence	28
Item 14-	Principal Accountant Fees and Services	28
PART IV		
Item 15-	Exhibits and Financial Statement Schedules	29
Signatures		30

PART I

ITEM 1. BUSINESS

THE COMPANY

BUSINESS OF REGISTRANT

REPRO-MED SYSTEMS, INC., (“REPRO-MED,” or “RMS Medical Products” or the “Company”), was incorporated in the State of New York in March of 1980. The Company designs, manufactures, and markets proprietary medical devices primarily for the ambulatory infusion market and emergency medical applications. The FDA regulates these products. The Company’s development and marketing focus are primarily concentrated on the FREEDOM60(R) Syringe Infusion System and accessories, and the RES-Q-VAC(R) Emergency Medical Suction System.

CORPORATE HISTORY

REPRO-MED SYSTEMS, INC. was incorporated under the laws of the State of New York in March 1980. The corporate offices are located at 24 Carpenter Road, Chester, New York 10918. The telephone number is 845-469-2042, the fax is 845-469-5518, and the Internet site is www.rmsmedicalproducts.com.

PRODUCTS

FREEDOM60(R) SYRINGE INFUSION SYSTEM

The FREEDOM60(R) Syringe Pump uses an innovative “engine” to create a constant pressure drive system which we believe results in substantially greater safety, reliability, reduced discomfort for subcutaneous applications, and an overall higher quality infusion than other devices on the market - all at a lower cost. The basic drive mechanism used in the FREEDOM60(R) represents the first of a line of products, which we intend to develop to broaden the product applications and appeal.

FREEDOM60(R) uses precision rate-controlled tubing with standard slide clamp and luer-lock connector on the patient end. Our patented luer disc connector ensures that only the Company's FREEDOM60(R) tubing sets will function with the pump. Non-conforming tubing sets, without the patented disc connector, are ejected from the pump to prevent the danger of an overdose or runaway pump from injuring the patient. We are achieving our objective of building a product franchise with FREEDOM60(R) and the sale of patented disposable tubing sets.

Our proprietary technology employed in the FREEDOM60(R) uses constant pressure to administer drugs. FREEDOM60(R) avoids an important problem faced by electronic pumps currently on the market, which employ constant flow mechanisms that result in potentially dangerous, high pressure placed on indwelling catheters or under the skin. In order to protect the patients, these pumps must contain an overpressure sensor to shut the pump off when a potentially threatening pressure is detected. Some of these electronic pumps generate extremely high pressures exceeding 60psi before the overpressure system will activate. Also with these systems, the alarm can falsely trigger halting administration until a health professional can verify that the infusion is, in fact, safe and the pump may be reactivated. In either case, the patient is at risk from damaging pressures or not receiving the medication required.

Other unsafe conditions of conventional equipment include: runaway administrations, overdose due to programming errors or pump failure, and overpressure resulting in burst blood vessels or failed internal access devices. We believe that the increasing sales of pumps and tubing sets for the FREEDOM60(R) demonstrate that the FREEDOM60(R) eliminates these potential outcomes and ensures a safe, constant, controlled infusion. Electronic devices will increase infusion pressure while attempting to continue an infusion at the programmed rate, while the FREEDOM60(R) design maintains a safe constant pressure and thereby automatically reduces the flow rate as required, a process we refer to as "dynamic equilibrium," if any problems of administration occur.

The FREEDOM60(R) Syringe Infusion Pump is designed for ambulatory medication infusions. Ambulatory infusion pumps are most prevalent in the home care market although we believe there is potential in the hospital setting as well. Other potential applications for the FREEDOM60(R) include pain control, the infusion of specialized drugs such as IgG, and chemotherapy. The home infusion therapy market is comprised of approximately 4,500 sites of service, including local and national organizations, hospital-affiliated organizations, and national home infusion organizations, and produces approximately \$11 billion in revenue annually*. With insurance reimbursement in a severe decline, there is a tremendous need for a low-cost, effective alternative to electronic and expensive disposable IV administration devices for home care. The FREEDOM60(R) provides a high-quality delivery to the patient at costs comparable to gravity-driven infusions and is targeted for the home health care industry, patient emergency transportation, and for any time a low-cost infusion is required.

*Ref: www.nhia.org/faqs.cfm and <http://www.gao.gov/new.items/d10426.pdf>

For the home care patient, FREEDOM60(R) 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(R) delivers accurate infusion rates and uniform flow profiles providing consistent transfer of medication. The FDA approved a Form 510(k) Pre-market Notification for initial design of the FREEDOM60(R) as a Class II device in August 1994.

We have expanded the use of the FREEDOM60(R) to cover most antibiotics including the widely used and somewhat difficult to administer Vancomycin. We have also found a following for FREEDOM60(R) for use in treating thalassemia with the drug Desferal(R). In Europe, we found success in using the FREEDOM60(R) for pain control, specifically post-operative epidural pain administration. Our European market also uses the FREEDOM60(R) for chemotherapy and subcutaneous immune globulin.

The FREEDOM60(R) use for Primary Immune Deficiency by injecting immune globulin (IgG) under the skin as a subcutaneous administration (SCIG) has continued to increase during the past year. This method has provided patients with vastly improved quality of life with much fewer unpleasant side effects over the traditional intravenous route. The FREEDOM60(R) 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(R) is the lowest cost infusion system available in a heavily cost constrained market. We have begun to promote one of the main benefits of the FREEDOM60(R) for use with IgG, which is that it 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 these patients.

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(R). We believe market pressures have moved specialty pharmacies to consider alternatives to expensive electronic systems especially for new subcutaneous administrations, which usually cannot be done with gravity. For 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(R) SALES

In order to receive more favorable Medicare reimbursement for our FREEDOM60(R) 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 of the Centers for Medicare & Medicaid Services 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(R) for billable syringe pump applications approved by Medicare. Current approved uses under Medicare include among others, subcutaneous immune globulin, antivirals, antifungals, and chemotherapeutics. In June 2007, Medicare issued a letter of clarification stating in part:

“The FREEDOM60(R) Syringe Infusion Pump is the only allowable pump to be billed with the Subcutaneous Immune Globulin (SCIG). The code for this pump for dates of service 1/1/00 - 5/16/07 is E0780. For dates of service on or after 5/17/07, the correct code is E0779 per SADMERC. The items being billed must be supported by corresponding documentation. All other pumps or modifiers will result in a denial.”

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.

ECONOMIC BENEFITS OF FREEDOM60(R) PUMP AND DISPOSABLE SALES

We have shipped approximately 28,000 pumps since March 2000 including approximately 5,600 pumps in the last year. We sell directly to health care providers in the US, and to distributors in both the domestic and foreign markets. The FREEDOM60(R) pump is designed for a minimum use of 4,000 times which at our list price is amortized at \$.16 per use.

We estimate that each FREEDOM60(R) pump, when used for immune globulin administration, uses an average of four to six tubing sets per month per patient. Antibiotics may be administered much more frequently, occasionally up to four times per day. In some cases, a tubing set may be used for as long as 72 hours. We estimate tubing set usage for antibiotics to be as much as 10 sets per month per patient.

The pump has a minimum expected life of 4,000 operations. Thus, if the pump is operated up to four times per day as for some administrations of antibiotics, anticipated pump life may be more than six and one-half years. For immune globulin applications, an expected use of four to five times per month results in an anticipated life span of decades for the FREEDOM60(R) pump.

COMPETITION FOR THE FREEDOM60(R)

Competition for the FREEDOM60(R) 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, 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(R). We believe the FREEDOM60(R) 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(R), or that their policy regarding reimbursement for other infusion pumps that are currently in the market or new ones that may enter shortly will not change, 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(R). We have issued Safety Bulletins to all customers advising them that any non-RMS product used on our FREEDOM60(R) Systems may be unsafe, can create a health risk to the patient, including death and would void the warranty of the pump.

NEW PRODUCT ENHANCEMENTS FOR THE FREEDOM60(R)

During January 2010, a new subcutaneous immune globulin called Hizentra(R) with a greater concentration was approved by the FDA. We have performed significant testing of the drug with the FREEDOM60(R) and have been recognized by the drug manufacturer for use with their drug. Based on initial reactions, the new formulation appears to be an improved drug at higher concentrations, and is expected to replace the previous offerings. We believe that Hizentra(R) will continue to create additional opportunities for the FREEDOM60(R) system for our fiscal year ending 2014. There are also other IgG drugs for subcutaneous route of administration being introduced into the market, which may expand the market for the FREEDOM60(R) and its accessories.

RMS HIGH-FLO™ SAFETY NEEDLE SETS

The introduction of RMS HIgH-Flo™ Subcutaneous Safety Needle Sets allows us to offer all of the elements needed for a complete subcutaneous infusion system, when combined with our FREEDOM60(R) pump and flow rate tubing. The needle sets received FDA approval for marketing in the U.S., on May 20, 2011. They were in the overseas market at that time.

The design of RMS HIgH-Flo™ Subcutaneous Needle Sets provides maximum flow rates during the subcutaneous infusion of high viscosity immune globulin, such as the thickest 20% IgG medications, offering even flows of medication to each site. The performance of HIgH-Flo™ provides what we believe is an advantage over competitive needle sets of comparable gauges for SCIg use. In addition, our manufacturing process includes numerous quality controls, resulting in consistent needle sharpness and smooth finish.

RES-Q-VAC(R) PORTABLE MEDICAL SUCTION

The RES-Q-VAC(R) 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(R) 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, hospital crash carts and wherever portable aspiration is a necessity, including backup support for powered suction systems. The Full Stop Protection(R) filter (FSP) and disposable features of the RES-Q-VAC(R) reduce the risk of exposing the health professional to HIV or SARS when suctioning a patient or during post treatment cleanup. All of the parts that connect to the pump are disposable.

We have introduced new, updated features including the FSP filter, new pediatric connectors, new graduated canister, new adult catheters, and new convenient carry pouch. It is also available with a flexible, portable LED white light source, which is attached to the top of the canister system and provides illumination for the medical professional during nighttime or low light conditions.

A critical component and advantage of the RES-Q-VAC(R) 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 air- 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(R) with the Full Stop Protection falls under the engineering controls of the Bloodborne Pathogen regulation and that the Products 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.

On April 29, 2003, the Centers for Disease Control (CDC) issued additional guidelines for the control of SARS (Sudden Acute Respiratory Syndrome), which requires all suction systems to have filtration equivalent to a HEPA filter to prevent the spread of this disease. At the current time, we believe that the RES-Q-VAC(R) with Full Stop Protection(R) is the only portable device to comply with these CDC directives.

The new connectors added to our pediatric catheters allow them to connect directly to the adult canisters, enabling pediatric suctioning with the benefit of the Full Stop Protection(R) device as well as with sterile catheters. Many infants are born with contagious diseases and the new system eliminates this concern among paramedics during an emergency delivery.

One advantage of our RES-Q-VAC(R) airway suction system is versatility. With the addition of Full Stop Protection(R), we created specific custom RES-Q-VAC(R) 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(R). In hospitals, the RES-Q-VAC(R) 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(R) is available sterile with Full Stop Protection(R) 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(R) 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(R), which can be left by the bedside for immediate use during critical times.

Dental applications - we offer a version of the RES-Q-VAC(R), called DENTAL-EVAC(R), which addresses the needs of oral surgeons for emergency backup suction during a procedure. DENTAL-EVAC(R) 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(R) 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(R)'s compact size, powerful pump, and full protection of the user from any contamination, gives us a competitive edge in this market.

We are 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.

RES-Q-VAC(R) DISTRIBUTION

RES-Q-VAC(R) is sold domestically and internationally by emergency medical device distributors. These distributors generally sell to the end user and advertise these products in relevant publications and in their catalogs. We market the hospital RES-Q-VAC(R) system through regional distributors specializing in the hospital respiratory care market.

OSHA AND CDC REQUIREMENTS

The Full Stop Protection(R) meets the requirement of the Occupational Safety and Health Administration as described below. The Company has received a letter from OSHA confirming that the RES-Q-VAC(R) with the Full Stop Protection(R) falls under the engineering controls of the Bloodborne Pathogen regulation and that the Products use would fulfill the regulatory requirements.

OSHA 29 CFR 1910.1030 - Occupational Exposure to Bloodborne Pathogens requires that employers of "... emergency medical technicians, paramedics, and other emergency medical service providers; fire fighters, law enforcement personnel, and correctional officers ... must consider and implement devices that are appropriate [to contain blood-borne pathogens], commercially available and effective." These first responders risk exposure to serious disease, and the employers may risk OSHA violations and lawsuits if they fail to consider protective measures such as Repro-Med's Full Stop Protection(R) for RES-Q-VAC(R). The Company has received a letter from OSHA indicating the RES-Q-VAC(R) meets the intent of this regulation.

COMPETITION FOR THE RES-Q-VAC(R)

We believe that the RES-Q-VAC(R) is currently the performance leader for manual, portable suction instruments. In the emergency market, the primary competition is the V-Vac(TM) from Laerdal. The V-Vac(TM) 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 had more resources than REPRO-MED SYSTEMS and had begun marketing the V-Vac(TM) before RES-Q-VAC(R) 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(R) substantially separates the RES-Q-VAC(R) 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(R) provides improved protection for these users.

SALES AND DISTRIBUTION

FREEDOM60(R) systems are sold through both direct sales efforts concentrated on large national accounts and a network of medical device distributors. In recent years, our emergency medical products are sold through a wide network of domestic and international distributors in over 40 countries. Gynecological instruments are sold from the corporate offices primarily through repeat business.

The domestic emergency medical market has softened somewhat due to a decrease in Federal reimbursement to the states and cities for firefighters, police, and emergency services. We have concluded that we can have more effective market penetration with major master distributors who are able to better support our products.

For FREEDOM60(R), we have distributors in United Kingdom, Norway, Sweden, Denmark, Iceland, Finland, Estonia, Latvia, and Lithuania and are expanding into other countries. We believe that one distributor in each country will be more predisposed to advertising, promotion, and building the product franchise. We are adding distributors in other European countries to expand our sales efforts. We work closely with our distributors to promote our products in each country.

During our fiscal year, we have expanded our efforts to market both of our main product lines at national and international trade shows. We support shows attended by our primary customers such as EMS Today, National Home infusion Association Conference, Infusion Nurses Society, Immune Deficiency Foundation Annual Meeting, and MEDICA.

The table below presents the product mix for the last two fiscal years.

	FY 2013	FY 2012
	Percentage of Sales	Percentage of Sales
Infusion Therapy	90.0%	86.4%
Medical Suction	9.8%	12.3%
Other	0.2%	1.3%

MANUFACTURING AND EMPLOYEES

The Company's employees perform at the Company's facility electromechanical assembly, calibration, pre- and post-assembly quality control inspection and testing, and final packaging for all products. Products are assembled using molded plastic parts acquired from several U.S. vendors and one supplier located in Taipei, Taiwan. The availability of parts has not been a problem. The cost and time required to fabricate molds to manufacture parts can slow the development of new products and might temporarily limit supply if we determine it is advisable to seek alternate sources of supply for existing products. Our policy has been to have multiple vendors as suppliers, where practicable, that also offer mold-building capabilities as a service.

As of February 28, 2013, we had 60 employees, 40 assigned to manufacturing operations, 10 to sales and customer support, 6 to administrative functions, 2 to quality assurance functions, and 2 officers (CEO/President, CFO). The Company is dependent on the services of Andrew Sealfon who serves as President, head of Research and Development and is instrumental in sales, marketing, and finance.

While the Company did not have insurance on the life of Andrew Sealfon on February 28, 2013, a "key man" policy on the President was bound on May 17, 2013, providing a death benefit of \$3.1 Million. There is no assurance that this sum will be adequate to replace the services of Mr. Sealfon in the event of his death.

REGULATIONS GOVERNING THE MANUFACTURING OPERATIONS

The Food, Drug, and Cosmetic Act governs the development and manufacturing of all medical products. The Act requires us to register the facility, list devices, file notice of intent to market new products, track the locations of certain products and to report any incidents of death or serious injury relating to the products with the FDA. We are subject to civil and criminal penalties and/or recall seizure or injunctions if we fail to comply with regulations of the FDA.

We are required to comply with federal, state, and local environmental laws; however, there is no significant effect of compliance on capital expenditures, earnings, or competitive position. We do not use significant amounts of hazardous materials in the assembly of these products.

Periodically we are subject to inspections and audits by FDA inspectors. The last quality review by the FDA was in July 2012, which included, among others, a review of complaints, quality controls, and documentation. The primary complaints for the FREEDOM60(R) relate to a lack of training on the part of the patient and medical support staff. The FDA inspection did not find any violations and no DD483 was issued. The Company always is subject to further audits by the FDA and could be impacted by adverse findings.

PATENTS AND TRADEMARKS

We have filed and received U.S. protection for many of our products and, in some cases where it was no longer deemed economically beneficial, we have allowed certain patent protections to lapse. The RES-Q-VAC(R) is susceptible in the international market to imitation. In 2002, a competitor had introduced a competitive product to the RES-Q-VAC(R) into the market. We responded with the introduction of new innovative features for the RES-Q-VAC(R) that enhanced the product and placed it well above the competition in safety.

On June 10, 2003, we received patent #6,575,946 for our new Full Stop Protection(R). This addition to the RES-Q-VAC(R) system prevents any fluids from exiting the system. It also serves to trap airborne and fluid pathogens. We believe that the addition of the flow block design substantially separates the RES-Q-VAC(R) 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 the filtered RES-Q-VAC(R) provides improved protection for these users.

The patent position of small companies is highly uncertain and involves complex legal and factual questions. Consequently, there can be no assurance that patent applications relating to products or technology will result in patents being granted or that, if issued, the patents will afford protection against competitors with similar technology. Furthermore, some patent licenses held may be terminated upon the occurrence of certain events or become non-exclusive after a specified period. There can be no assurance that we will have the financial resources necessary to enforce any patent rights we may hold.

There can be no assurance that patents or trademarks will provide competitive advantages for the products covered or that they will not be challenged or circumvented by competitors.

We have become aware that a competitor is marketing a product in competition with our FREEDOM60(R) tubing that may infringe on one or more of our patents. At this time, it does not appear that this product is clinically acceptable for use on FREEDOM60(R) pumps. We have retained a law firm in the area of patent law and are reviewing all options, including litigation.

ITEM 1A. RISK FACTORS

Not applicable as the Company is a smaller reporting Company.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable as the Company is a smaller reporting Company.

ITEM 2. PROPERTY

We currently rent a masonry and steel frame building erected on 3.27 acres of land located at 24 Carpenter Road, Chester, New York 10918. This facility is used as our headquarters and for manufacturing operations.

Currently we are in year 14 of a 20-year lease and are responsible for all repairs, maintenance, and upkeep of the space occupied. The terms of the lease call for monthly lease payments of \$11,042, and we contribute payments of 65% of the building's annual property taxes, amounting to \$46,989 for the year ended February 28, 2013.

We also lease warehouse space in a nearby industrial park.

In August, 2012 we acquired a residence adjacent to our facility for use as additional office and R&D space.

ITEM 3. 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, breach of management contracts, and employment related claims.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY AND RELATED SHAREHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

We are authorized to issue 50,000,000 shares of Common Stock, \$.01 par value. As of February 28, 2013, 36,661,667 shares were issued and outstanding and there were approximately 1,039 shareholders of record.

Our Common Stock is traded in the over-the-counter market and is quoted through the National Daily Quotation Service. The following table sets forth the high and low closing bid quotations for the Common Stock as reported by Commodity Systems, Inc., for the periods indicated. These quotations do not include retail mark-up, markdown, or commission and may not represent actual transactions.

	High		Low	
2013 QUARTER ENDED				
February 28, 2013	\$	0.26	\$	0.19
November 30, 2012	\$	0.26	\$	0.17
August 31, 2012	\$	0.26	\$	0.17
May 31, 2012	\$	0.25	\$	0.19
2012 QUARTER ENDED				
February 29, 2012	\$	0.30	\$	0.22
November 30, 2011	\$	0.36	\$	0.20
August 31, 2011	\$	0.42	\$	0.28
May 31, 2011	\$	0.36	\$	0.15

ITEM 6. SELECTED FINANCIAL DATA

Not applicable as the Company is a smaller reporting company.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This Annual Report on Form 10-K 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 by 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, recent operating losses, 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(R), availability of sufficient capital to continue operations and dependence on key personnel. When used in this report, the words "estimate," "project," "believe," "may," "will," "anticipate," "intend," "exp" 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 market place 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. Our actual results, performance and achievements could differ materially from those expressed or implied in these forward-looking statements. 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.

ACCOUNTING POLICIES

We believe that we have no critical accounting estimates or assumptions. We do not believe that any of the standards adopted by the Financial Accounting Standards Board that are not yet effective will have a material effect on our financial reporting.

RESULTS OF OPERATIONS

2013 vs. 2012

Overall sales for the year ending February 28, 2013 increased 21.5% to \$7,763,953 from \$6,390,534 for the same period last year.

We continue to focus our sales and marketing efforts mainly on our two core product lines, the FREEDOM60(R) Syringe Infusion System and the RES-Q-VAC(R) Medical Suction System.

The FREEDOM60(R) continues to lead our sales increases with an overall improvement of 29.7% going from gross sales of \$5,333,000 in 2012 to gross sales of \$6,918,000 for the current year. The increase is due to additional sales for use with immune globulin and antibiotics, and increased revenues from our line of RMS HIgH-Flo™ Subcutaneous Needle Sets. We have concentrated the majority of our efforts in the FREEDOM60(R) line, specifically towards the subcutaneous immune globulin (SCIG) market.

We anticipate these sales to continue to increase as the SCIG market continues to develop and as we work on new enhancements to the FREEDOM60(R) that we believe will expand this market even further. In addition, we expect many of the SCIG providers and others will see benefit in using the FREEDOM60(R) system for additional uses, such as antibiotics, chemotherapeutics, and pain medications.

Our net income for the year ending February 28, 2013 was \$725,763 as compared with net income of \$815,893 for the previous year, a decline of 11.0%. We increased our sales and marketing investment by 66% with expansion of our trade show schedule, stepped up advertising and an increased presence in the field. In addition, we strengthened our sales management team by hiring a Director of Sales and Marketing and a Director of National Accounts, both of whom have many years of experience in our marketplaces. We believe that these efforts are necessary to maintain our customer base and increase our sales domestically and internationally for both the FREEDOM60(R) Syringe Infusion System and HIgH-Flo™ Safety Needle Sets.

We also awarded key personnel bonuses and restricted stock grants that vest over a period of time.

RES-Q-VAC(R) Hand Held Medical Suction sales decreased by 6.3% to \$753,000 from \$803,200. Our overall sales results in the domestic market increased over the prior year; however international sales continued to decline in 2013.

RES-Q-VAC(R) is sold domestically and internationally by emergency medical device distributors. These distributors generally sell to the end user and advertise these products in relevant publications and in their catalogs. We market the hospital RES-Q-VAC(R) Hand Held Medical Suction system through regional distributors specializing in the hospital respiratory care market.

Cost of goods sold increased 25.2%, from \$2,251,398 for year ended February 29, 2012 to \$2,819,113 for the current year primarily because of increased sales. Gross profit margin for the year ended February 28, 2013 decreased 1.1% to 63.7%, as compared with 64.8% for the previous year. Raw materials costs have been increasing as have production

expenses. We also wrote-down \$129,594 in slow-moving inventory.

The Cost of Goods Sold also reflects the effects of the 2.3% Medical Device Excise Tax imposed on medical products manufacturers and importers by the 2010 Patient Protection and Affordable Care Act, effective January 1, 2013. Due to marketplace pressures, we have been forced to absorb the tax.

Selling, General & Administrative Expenses (SG&A) increased by \$888,221 year over year from \$2,655,668 to \$3,543,889, an increase of 33.4%. We increased our sales and marketing investment by 66% with expansion of our trade show schedule, stepped up advertising and an increased presence in the field. In addition, we strengthened our sales management team by hiring a Director of Sales and Marketing and a Director of National Accounts, both of whom have many years of experience in our marketplaces. We believe that these efforts are necessary to maintain our customer base and increase our sales domestically and internationally for both the FREEDOM60(R) Syringe Infusion System and HIgH-Flo™ Safety Needle Sets.

Research and development expenses increased 63.4% from \$90,329 to \$147,576 primarily due to the hiring of additional engineering staff to support development efforts. Our chief executive officer spends significant time on research and development. All of his compensation has been included in selling, general, and administrative costs.

Depreciation and amortization expense increased by 83.7% to \$190,971 during the year ended February 28, 2013 as compared with \$103,981 for the previous year 2012 as a result of increased investment in capital assets. Interest expense decreased from \$31,540 to \$28,280 due to lower debt levels.

LIQUIDITY AND CAPITAL RESOURCES

Our net operating profit for the year ended February 28, 2013 was \$1,062,404 as compared with \$1,289,158 for the previous year. For the year ended February 28, 2013 Net Cash provided from Operations was \$784,790 as compared with \$560,601 for the prior year. This increase of \$224,189 compared to the prior year was due to a small decrease in inventory (after write-down of slow-moving inventory), an increase in depreciation and amortization, an increase in various accrued expenses/taxes and an increase of deferred compensation related to the restricted stock grant program for key personnel. These were partially offset by increases in accounts receivable and a decrease in accounts payable.

In 2012, inventory had increased substantially as we ramped up for the domestic introduction of our new HIgH-Flow™ Subcutaneous Safety Needle Sets.

Accounts Receivable, net of reserves, increased at February 28, 2013 to \$1,114,847 as compared with \$884,727 for the previous year because of our increased sales. Domestic sales are made primarily on net 30-day payment terms. A variety of terms continue to be employed for export sales including cash prepayments and net 45 days to allow for increased delays due to transportation and communications. Prepaid expenses decreased slightly to \$180,651 from \$188,902.

Expenditures for capital property and equipment in 2013 were \$563,567 as compared to \$236,235 in the previous year, an increase of 139%. In 2013, we installed a new ERP system, purchased new equipment for implementation of a more efficient production process and for R&D, and acquired a residence adjacent to our facility for use as additional office and R&D space, among other capital investments.

We currently lease a masonry and steel frame building erected on 3.27 acres of land located at 24 Carpenter Road, Chester, New York 10918. This facility is used as our headquarters and for manufacturing operations. We are in year 14 of a 20-year lease and are responsible for all repairs, maintenance, and upkeep of the space occupied. The terms of the lease call for a monthly lease payment of \$11,042 per month. We also contribute payments of 65% of the building's annual property taxes, amounting to \$46,989 for the year ended February 28, 2013.

We also lease warehouse space in a nearby industrial park.

RMS HIgH-Flo™ Subcutaneous Safety Needle Sets have approval for Europe, Canada and the United States. We believe that the RMS administration sets represent an improvement in performance and safety over competitive devices on the market. We believe we have sufficient resources to continue marketing the needle sets domestically and overseas.

We believe the FREEDOM60(R) 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. We continued to experience an increase in sales during the year ending February 28, 2013. With these increases and the capital we currently have, we will continue to meet or exceed the company's liquidity needs for the next twelve months.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable as the Company is a smaller reporting Company.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

- 12 -

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders

Repro-Med Systems, Inc.

Chester, New York

We have audited the accompanying balance sheets of Repro-Med Systems, Inc. as of February 28, 2013 and February 29, 2012, and the related statements of operations, stockholders' equity and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Repro-Med Systems, Inc. as of February 28, 2013 and February 29, 2012, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

/s/ Radin, Glass & Co., LLP

New York, New York

May 29, 2013

REPRO-MED SYSTEMS, INC.**BALANCE SHEETS**

	February 28, 2013	February 29, 2012
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 1,930,321	\$ 1,757,223
Certificates of deposit	257,009	255,228
Accounts receivable less allowance for doubtful accounts of \$17,450 and \$17,718 for February 28, 2013, and February 29, 2012, respectively	1,114,847	884,727
Inventory	1,150,129	1,167,456
Prepaid expenses	180,651	188,902
Total Current Assets	4,632,957	4,253,536
PROPERTY & EQUIPMENT, net	875,986	498,940
OTHER ASSETS		
Patents, net of accumulated amortization of \$112,090 and \$107,640 at February 28, 2013 and February 29, 2012, respectively	22,913	24,513
Other	60,369	28,156
Total Other Assets	83,282	52,669
TOTAL ASSETS	\$ 5,592,225	\$ 4,805,145

The accompanying notes are an integral part of these Financial Statements.

REPRO-MED SYSTEMS, INC.**BALANCE SHEETS**

	February 28, 2013	February 29, 2012
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Note payable - current portion	\$ 1,474	\$ 2,077
Notes payable to related parties - current portion	43,971	41,417
Deferred capital gain - current portion	22,481	22,481
Accounts payable	110,358	199,527
Accrued expenses	169,790	153,800
Accrued payroll and related taxes	50,195	41,551
Accrued income tax liability	127,090	98,000
Total Current Liabilities	525,359	558,853
OTHER LIABILITIES		
Note payable - less current portion	—	1,474
Note payable to related parties - less current portion	393,861	437,832
Deferred capital gain - less current portion	112,414	134,895
Deferred tax liability	204,000	121,363
Total Other Liabilities	710,275	695,564
Total Liabilities	1,235,634	1,254,417
STOCKHOLDERS' EQUITY		
Common stock, \$0.01 par value, 50,000,000 shares authorized and 38,936,667 and 37,471,667 shares issued; 36,661,667 and 35,196,667 shares outstanding at February 28, 2013 and February 29, 2012, respectively.	389,367	374,717
Additional paid-in capital	3,512,294	3,263,244
Retained earnings	780,530	54,767
	4,682,191	3,692,728
Less: Treasury stock, 2,275,000 shares at cost	(142,000)	(142,000)
Less: Deferred compensation cost	(183,600)	—
Total Stockholders' Equity	4,356,591	3,550,728
Total Liabilities and Stockholders' Equity	\$ 5,592,225	\$ 4,805,145

The accompanying notes are an integral part of these Financial Statements.

REPRO-MED SYSTEMS, INC.
STATEMENTS OF OPERATIONS

	For the years ended	
	February 28, 2013	February 29, 2012
NET SALES	\$ 7,763,953	\$ 6,390,534
Cost and Expenses		
Cost of goods sold	2,819,113	2,251,398
Selling, general and administrative	3,543,889	2,655,668
Research and development	147,576	90,329
Depreciation and amortization	190,971	103,981
Total Costs and Expenses	6,701,549	5,101,376
Net Operating Profit	1,062,404	1,289,158
Other Income/(Expenses)		
Interest expense	(28,280)	(31,540)
Gain / (Loss) foreign currency exchange	(4,095)	10,718
Interest and other income	8,081	12,848
Total Other Expenses	(24,294)	(7,974)
INCOME BEFORE TAXES	1,038,110	1,281,184
Income Tax Expense	(312,347)	(465,291)
NET INCOME	\$ 725,763	\$ 815,893
NET INCOME PER SHARE		
Basic	\$ 0.02	\$ 0.02
Diluted	\$ 0.02	\$ 0.02
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING		
Basic	36,011,448	34,250,560
Diluted	36,036,362	35,102,446

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

REPRO-MED SYSTEMS, INC.**STATEMENT OF STOCKHOLDERS' EQUITY****FOR THE YEARS ENDED FEBRUARY 28, 2013 AND FEBRUARY 29, 2012**

	Common Stock Shares	Stock Amount	Additional Paid-in Capital	Retained Earnings (Accumulated Deficit)	Treasury Stock	Deferred Compensation Cost	Total
BALANCE, FEBRUARY 28, 2011	36,577,667	\$ 365,777	\$ 3,017,809	\$ (761,126)	\$ (142,000)	—\$	2,480,460
Issuance of common stock for exercised stock options at \$.06 per share	2,025,000	20,250	101,250	—	—	—	121,500
Excess tax benefit related to share-based compensation	—	—	132,875	—	—	—	132,875
Adjustment of shares outstanding	(1,131,000)	(11,310)	11,310	—	—	—	—
Net income for the year ended February 29, 2012,	—	—	—	815,893	—	—	815,893
BALANCE, FEBRUARY 29, 2012	37,471,667	374,717	3,263,244	54,767	(142,000)	—	3,550,728
Issuance of common stock for employee stock awards	1,465,000	14,650	249,050	—	—	(183,600)	80,100
Net income for the year ended	—	—	—	725,763	—	—	725,763

February 28,
2013

BALANCE,
FEBRUARY

28, 2013	38,936,667	\$	389,367	\$	3,512,294	\$	780,530	\$	(142,000)	\$	(183,600)	\$	4,356,591
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The accompanying notes are an integral part of these Financial Statements.

- 17 -

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

	For the Years Ended	
	February 28, 2013	February 29, 2012
CASH FLOWS FROM OPERATING ACTIVITIES		
Net income	\$ 725,763	\$ 815,893
Adjustments to reconcile net income to net cash from operating activities:		
Amortization of deferred compensation cost	80,100	—
Depreciation and amortization	190,971	103,981
Deferred capital gain - building lease	(22,481)	(22,480)
Deferred taxes	82,637	167,004
Changes in operating assets and liabilities:		
Increase in accounts receivable	(230,120)	(170,821)
Decrease (Increase) in inventory	17,327	(499,256)
Decrease (Increase) in prepaid expense	8,251	(75,965)
Increase in other assets	(32,213)	—
(Decrease) Increase in accounts payable	(89,169)	41,419
Increase in accrued payroll and related taxes	8,644	20,356
Increase in accrued expense	15,990	82,470
Increase in accrued income tax liability	29,090	98,000
NET CASH PROVIDED BY OPERATING ACTIVITIES	784,790	560,601
CASH FLOWS FROM INVESTING ACTIVITIES		
Payments for property and equipment	(563,567)	(236,235)
Payments for patents	(2,850)	—
Purchase of certificates of deposit	(1,781)	(102,829)
NET CASH USED IN INVESTING ACTIVITIES	(568,198)	(339,064)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from issuing common stock	—	121,500
Payments to note payable to related parties	(41,417)	(39,010)
Payments on note payable	(2,077)	(1,929)
Excess tax benefits from share-based payment arrangements	—	132,875
NET CASH PROVIDED BY (USED IN) FINANCING ACTIVITIES	(43,494)	213,436
NET INCREASE IN CASH AND CASH EQUIVALENTS	173,098	434,973
CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR	1,757,223	1,322,250
CASH AND CASH EQUIVALENTS, END OF YEAR	\$ 1,930,321	\$ 1,757,223
Supplemental Information		
Cash paid during the years for:		
Interest	\$ 28,280	\$ 31,540

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Taxes	\$	213,793	\$	89,644
NON-CASH FINANCING AND INVESTING ACTIVITIES				
Issuance of common stock as incentives	\$	263,700	\$	—

The accompanying notes are an integral part of these Financial Statements.

- 18 -

REPRO-MED SYSTEMS, INC.

NOTES TO FINANCIAL STATEMENTS

FEBRUARY 28, 2013 AND FEBRUARY 29, 2012

NOTE 1 NATURE OF OPERATIONS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

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. The Company is in one line of business.

CASH AND CASH EQUIVALENTS

For purposes of the statement of cash flows, the Company considers all short-term investments with an original maturity of three months or less to be cash equivalents. Occasionally, the Company has cash held in excess of \$250,000 at a single depository, which exceeds the FDIC insurance limits and is, therefore, uninsured.

At February 28, 2013, cash equivalents consisted of money market funds aggregated to \$852,977.

CERTIFICATES OF DEPOSIT

The certificates of deposit are recorded at cost plus accrued interest. The certificates of deposit earn interest at a rate of 0.4% to 0.55% and mature in July 2013 and February 2014.

INVENTORY

Inventories of raw materials are stated at the lower of standard cost, which approximates average cost, or market value including allocable overhead. Work-in-process and finished goods are stated at the lower of standard cost or market value and include direct labor and allocable overhead.

PATENTS

Costs incurred in obtaining patents have been capitalized and are being amortized over seventeen years.

INCOME TAXES

Deferred income taxes are provided using the liability method whereby deferred tax assets are recognized for deductible temporary differences and operating loss and tax credit carry forwards and deferred tax liabilities are recognized for taxable temporary differences.

The Company believes that it has no uncertain tax positions requiring disclosure or adjustment. Generally, tax years starting with 2009 are subject to examination by income tax authorities.

PROPERTY, EQUIPMENT, AND DEPRECIATION

Property and equipment is stated at cost and is depreciated using the straight-line method over the estimated useful lives of the respective assets.

STOCK-BASED COMPENSATION

The Company accounts for stock issued for services using the fair value method. The measurement date of shares issued for service is the date when the counterparty's performance is complete.

NET INCOME PER COMMON SHARE

Basic earnings per share are computed on the weighted average of common shares outstanding during each year. Diluted earnings per share include only an increase in the weighted average shares by the common shares issuable upon exercise of employee and director stock options (Note 7).

	Fiscal Year Ended	
	February 28, 2013	February 29, 2012
Net income	\$ 725,763	\$ 815,893
Weighted Average Outstanding Shares:		
Outstanding shares	36,011,448	34,250,560
Option shares includable	24,914	851,886
	36,036,362	35,102,446
Net income per share		
Basic	\$ 0.02	\$ 0.02
Diluted	\$ 0.02	\$ 0.02

USE OF ESTIMATES IN THE FINANCIAL STATEMENTS

The preparation of financial statements in conformity with U.S. generally accepted accounting principles 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.

SUBSEQUENT EVENTS EVALUATION

The Company has evaluated subsequent events through May 29, 2013, the date on which the financial statements were issued. With the exception of those matters discussed in Note 11, there were no material subsequent events that required recognition or additional disclosure in these financial statements.

REVENUE RECOGNITION

Sales of manufactured products are recorded when shipment occurs. The Company's revenue stream is derived from the sale of an assembled product. Other service revenues are recorded as the service is performed. Shipping and handling costs generally are billed to customers and are included in sales. The Company does not accept return of goods shipped unless it is a Company error. The only credits provided to customers are for defective merchandise.

EMERGING ACCOUNTING STANDARDS

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

FAIR VALUE OF FINANCIAL INSTRUMENTS

The carrying amounts reported in the balance sheet for cash, trade receivables, accounts payable and accrued expenses approximate fair value based on the short-term maturity of these instruments.

ACCOUNTING FOR LONG-LIVED ASSETS

The Company reviews its long-lived assets for impairment at least annually or whenever the circumstances and situations change such that there is an indication that the carrying amounts may not be recoverable. As of February 28, 2013 the Company does not believe that any of its assets are impaired.

NOTE 2 INVENTORY

Inventory consists of:

		February 28, 2013		February 29, 2012
Raw materials	\$	625,934	\$	788,092
Work in progress		45,820		55,067
Finished goods		478,375		324,297
	\$	1,150,129	\$	1,167,456

NOTE 3 PROPERTY AND EQUIPMENT

Property and equipment consists of the following at:

		February 28, 2013		February 29, 2012	Estimated Useful Lives
Land	\$	54,030	\$	—	
Building		171,094		—	20 years
Furniture, office equipment, and leasehold improvements		844,747		636,159	3-10 years
Manufacturing equipment and tooling		1,408,113		1,278,258	3-12 years
		2,477,984		1,914,417	
Less: accumulated depreciation		1,601,998		1,415,477	
Property and equipment, net	\$	875,986	\$	498,940	

Depreciation expense was \$186,521 and \$98,655 for the years ended February 28, 2013 and February 29, 2012, respectively.

NOTE 4 RELATED PARTY TRANSACTIONS**LEASED AIRCRAFT**

The Company leases an aircraft from a Company controlled by the President. The lease payments aggregated \$21,500 for both the years ended February 28, 2013 and February 29, 2012. The original lease agreement has expired and the

Company is currently on a month-to-month basis for rental payments.

BUILDING LEASE

In February 2011, the Company elected Mr. Mark Pastreich as a Director. Mr. Pastreich is a principal in the entity that owns the building leased by REPRO-MED SYSTEMS, INC. The Company is in year fourteen 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.

NOTE 5 LONG-TERM DEBT

Long-term debt consists of the following at February 28, 2013 and February 29, 2012:

	February 28, 2013	February 29, 2012
In February 2009, the Company was granted a loan from a director of the Company for \$672,663, payable in 144 monthly installments of \$5,754 at a rate of 6.00% interest. The Company issued the director 755,000 shares of common stock at the price of \$0.11 per share in June 2009 further to reduce the debt. The loan will mature in February 2021.	437,832	479,249
Other	1,474	3,551
	439,306	482,800
Less current portion	45,445	43,494
Long-term portion	\$ 393,861	\$ 439,306

Aggregate maturities as required on long-term debt at February 28, 2013 are:

2014	\$	45,445
2015		46,683
2016		49,562
2017		52,619
2018		55,865
Thereafter		189,132
Total	\$	439,306

NOTE 6 STOCKHOLDERS' EQUITY

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. Amortization amounted to \$80,100 for the year ended February 28, 2013.

NOTE 7 STOCK OPTIONS

On June 6, 2007, the Board of Directors approved the issuance of 4,360,000 stock options to key employees and directors of the Company. The options had an expiration date of 5 years from the date of grant and an exercise price of \$0.06 per share.

The fair value of each option grant was calculated to be \$.0272 on the date of grant using the Black-Schole Option pricing model with the following assumption used for grants during the applicable period.

Risk free rate	2.4%
Volatility	96.16%
Expected life	1.5 years
Dividend yield	0%

The following table summarizes the Company's stock options.

Options	Shares	Weighted-Average	Weighted-Average
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			Exercise Price	Remaining Contractual Term	
Outstanding at March 1, 2012	125,000	\$	0.06	0.3	
Granted	—		—	—	
Exercised	—		—	—	
Forfeited or expired	(125,000)	\$	0.06	—	
Outstanding at February 28, 2013	—		—	—	
Exercisable at February 28, 2013	—		—	—	

In August 2011, the president and one director exercised stock options. Total intrinsic value of options exercised during the period ended August 31, 2011 was \$400,000. The Company recorded an excess tax benefit to APIC related to share-based compensation in the amount of \$136,000 at August 31, 2011.

There are no outstanding options as of February 28, 2013.

NOTE 8 SALE-LEASEBACK TRANSACTION - OPERATING LEASE

On February 25, 1999, the Company entered into a sale-leaseback arrangement whereby the Company sold its land and building at 24 Carpenter Road in Chester, New York and leased it back for a period of 20 years. The leaseback is accounted for as an operating lease. The gain of \$449,617 realized in this transaction has been deferred and is amortized to income in proportion to rental expense over the term of the related lease.

At February 28, 2013 minimum future rental payments are:

Year	Minimum Rental Payments
2014	\$ 132,504
2015	132,504
2016	132,504
2017	132,504
2018	132,504
2019	132,504
	\$ 795,024

Rent expense for the years ended February 28, 2013 and February 29, 2012 aggregated \$132,504.

NOTE 9 FEDERAL AND STATE INCOME TAXES

The provision for income taxes consisted of at February 28, 2013 and February 29, 2012:

	2013	2012
State income tax:		
Deferred	\$ —	\$ —
Current, net of refund in 2013	(11,173)	2,000
Federal income tax:		
Deferred	82,637	167,004
Current, including credit to additional paid-in capital in 2012	240,883	296,287
Total	\$ 312,347	\$ 465,291

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The Company had operating loss carry forwards, all of which were fully utilized by February 29, 2012.

The reconciliation of income taxes shown in the financial statements and amounts computed by applying the Federal expected tax rate of 34% is as follows:

	2013	2012
Income before tax	\$ 1,038,110	\$ 1,281,184
Computed expected tax	\$ 352,957	\$ 435,603
State income and franchise tax/(refund)	(11,173)	2,000
Other	(29,437)	27,688
Provision for taxes	\$ 312,347	\$ 465,291

- 23 -

The components of deferred tax liabilities at February 28, 2013 and February 29, 2012, respectively, are as follows:

	2013		2012
Deferred compensation cost	(62,424)	\$	—
Depreciation and amortization	(141,576)		(121,363)
Deferred tax liabilities	\$ (204,000)	\$	(121,363)

NOTE 10 MAJOR CUSTOMERS

For the year ended February 28, 2013, approximately, 27.4% and 12.2% of the Company's revenue were derived from two major customers. At February 28, 2013, accounts receivable due from these customers were \$366,890 and \$82,368, respectively.

For the year ended February 29, 2012, approximately, 19.2% and 17.6% of the Company's revenue were derived from two major customers. At February 29, 2012, accounts receivable due from these customers were \$160,470 and \$98,185, respectively.

The largest customer in both years is a medical products and supplies distributor. Although a number of larger FREEDOM60(R) users have elected to consolidate their purchases through one or more distributors in recent years, we continue to maintain a strong direct relationship with them. We do not believe that their continued purchases of FREEDOM60 pumps, tubing, needle sets and related supplies is contingent upon the distributor.

NOTE 11 SUBSEQUENT EVENTS

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 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 Director loan with a balance of \$437,832 as of February 28, 2013 was fully paid on May 17, 2013 as we concluded that the cash on hand was not earning the cost of the interest.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

On October 20, 2011 McGrail Merkel Quinn & Associates, P.C., was dismissed as REPRO-MED SYSTEMS, INC.'s (the "Company") independent registered public accounting firm, as approved by the Board of Directors. McGrail Merkel Quinn & Associates, P.C.'s, report on the Company's financial statements for the two fiscal years ended February 28, 2011 and 2010 did not contain an adverse opinion or disclaimer of opinion, and was not qualified or modified as to uncertainty, audit scope or accounting principles.

During the fiscal years ended February 28, 2011 and 2010, as well as the interim period preceding the dismissal of McGrail Merkel Quinn & Associates, P.C., there were no disagreements or reportable events of the kind described in Item 304(a)(1)(v) of Regulation S-K of the Securities and Exchange Commission (the "Commission") between the Company and McGrail Merkel Quinn & Associates, P.C., on any matters of accounting principles or practices, financial statement disclosure, or auditing scope or procedure which, if not resolved to the satisfaction of McGrail Merkel Quinn & Associates, P.C., would have caused McGrail Merkel Quinn & Associates, P.C., to make a reference to the subject matter of the disagreement or reportable event in connection with the issuance of its audit reports.

On October 20, 2011, the Board of Directors of REPRO-MED SYSTEMS, INC. approved the engagement of Radin, Glass & Co., LLP as the Company's independent registered public accounting firm for the year ending February 29, 2012. Radin Glass & Co., LLP's engagement as the Company's independent registered public accounting firm commenced on October 20, 2011.

During the years ended February 28, 2010 and February 28, 2011, and through October 20, 2011, neither the Company nor anyone on its behalf has consulted with Radin Glass & Co., LLP with respect to either (i) the application of accounting principles to a specified transaction, either completed or proposed, or the type of audit opinion that might be rendered on the Company's financial statements, and neither a written report nor oral advice was provided to the Company that Radin Glass & Co., LLP concluded was an important factor considered by the Company in reaching a decision as to any accounting, auditing or financial reporting issue; or (ii) any matter that was either the subject of a disagreement (as defined in Item 304(a)(1)(iv) of Regulation S-K and the related instructions to Item 304 of Regulation S-K) or a reportable event (as defined in Item 304(a)(1)(v) of Regulation S-K).

ITEM 9A CONTROLS AND PROCEDURES

EVALUATION OF DISCLOSURE CONTROLS AND PROCEDURES

An evaluation was performed under the supervision and with the participation of our management, including our Chief Executive Officer or CEO, and Chief Financial Officer or CFO, of the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act) as of February 28, 2013. Based on that evaluation, our management, including our CEO and CFO, concluded that our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and is accumulated and communicated to our management, including our CEO and CFO, to allow timely decisions regarding required disclosure.

MANAGEMENT'S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting. The Company's internal control over financial reporting is a process designed under the supervision of the Company's Chief Executive Officer and Chief Financial Officer, and implemented in conjunction with management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the Company's financial statements for external purposes in accordance with generally accepted accounting principles.

There are inherent limitations in the effectiveness of any internal control, including the possibility of human error and the circumvention or overriding of controls. Accordingly, even effective internal control can provide only reasonable assurance with respect to financial statement preparation. Further, because of changes in conditions, the effectiveness of internal control may vary over time.

Management assessed the effectiveness of the Company's internal control over financial reporting as of February 28, 2013. This assessment was based on criteria for effective internal control over financial reporting described in "Internal Control - Integrated Framework," issued by the Committee of Sponsoring Organization of the Treadway Commission (COSO). Based on this assessment, management determined that, as of February 28, 2013, the Company maintained effective internal control over financial reporting.

This annual report does not include an attestation report of the Company's registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's

registered public accounting firm pursuant to the Dodd-Frank Act that permits the Company to provide only management's report in the annual report.

CHANGES IN INTERNAL CONTROL OVER FINANCIAL REPORTING

There has been no change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) during the fiscal year ended February 28, 2013 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE

The following table sets forth-certain information with respect to the Executive Officers and Directors:

Name	Age	Position / Held Since
Andrew I. Sealfon	67	President 1980, Chairman 1989, Director 1980, CEO 1986
Michael R. Boscher	48	Treasurer 2012, CFO 2012
Paul Mark Baker	62	Director 1991
Remo Spagnoli	83	Director 1993
Mark Pastreich	83	Director 2011

Mr. Sealfon is deemed a “parent” and “promoter” as those terms are defined under the Securities Act of 1933 as amended.

All directors hold offices until the next annual meeting of shareholders or until their successors are elected. Executive Officers hold office at the discretion of the Board of Directors.

Mr. Sealfon co-founded REPRO-MED SYSTEMS, INC., in 1980. He is an electrical engineer and inventor and has been granted numerous United States patents. Mr. Sealfon is a graduate of Lafayette College.

Mr. Boscher, master in business administration from Durham University, United Kingdom, joined the company in 2011 as director of operations. Effective February 2012, he is Treasurer and Chief Financial Officer.

Dr. Baker earned a medical degree from Cornell University Medical College. He is a practicing pediatrician and is attending at Department of Pediatrics Horton Memorial Hospital, Middletown, New York, and attending at New York Hospital-Cornell Medical Center in New York City. Dr. Baker assisted us in the development of the RES-Q-VAC(R) Suction System. In addition, Dr. Baker has published results of use of the RES-Q-VAC(R) in a letter to LANCET, a medical journal.

Mr. Spagnoli is a principal founder and past President and Chairman of CRS, Inc., Newburgh, NY, a manufacturer of proprietary inventory control and point of sale software and distributor of computer equipment.

Mr. Pastreich is a businessman, and a longtime real estate investor and broker. He has served on numerous for-profit and not-for-profit boards. Among his other various real estate holdings, he is presently a partner in Casper Creek LLC, which owns the building leased by REPRO-MED SYSTEMS, INC.

ITEM 11. EXECUTIVE COMPENSATION

Andrew I. Sealfon, President, received \$304,166 in salary, \$348,218 in bonus and a restricted stock grant valued at \$180,000 for a total compensation of \$832,384 during the fiscal year ended February 28, 2013. The bonus payments were awarded by the Board of Directors for exceptional performance in recent years and intended to cover taxes on stock options and grants. The restricted stock vests over a two-year period.

Mike R. Boscher, CFO, received \$178,288 in salary, bonus and restricted stock awards from Repro-Med during the fiscal year ended February 28, 2013.

The officers are reimbursed for travel and other expenses incurred on behalf of REPRO-MED SYSTEMS, INC. We do not have pension or profit sharing plans, but do offer an optional 401(k) savings plan with a company matching component to all full-time employees with 90 days of service.

Name & Position	Summary Compensation		
	Year	Salary	Other *
Andrew I. Sealfon, President & CEO	2013	\$ 832,384	—
	2012	\$ 443,194	—
	2011	\$ 163,917	—
	2010	\$ 155,007	—
	2009	\$ 122,499	—
	2008	\$ 109,347	—
Michael R. Boscher, Treasurer & CFO	2013	\$ 178,288	—
	2012	\$ 103,175	—

* Other compensation for Mr. Sealfon includes car allowance (not itemized here).

Table of aggregate options exercised during the fiscal year ended February, 2012 and option values at year-end February 2012:

Name of Individual	Shares Acquired On Exercise	Value Realized	Number of Unexercised Options at Year-end Exercisable/ Un-exercisable	Value of Unexercised In-the-money Options at Year-end Exercisable/ Un-exercisable
A. I. Sealfon				
Exercisable	2,000,000	\$ 400,000	0	\$ 0
Un-exercisable	0	\$ 0	0	\$ 0

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth, as of May 29, 2013, the number of shares of Common Stock beneficially owned by each person owning more than 5% of the outstanding shares, by each officer and director, and by all officers and directors as a group:

Name of Principal Shareholders and Identity of Group	Number of Shares Owned	Percent of Class	Notes:
Andrew I. Sealfon*	8,267,250	23%	(1)
Dr. Paul Mark Baker	1,381,180	4%	(2)

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Remo Spagnoli	1,009,381	3%	—
Mark Pastreich	376,500	1%	—
Mike R. Boscher	75,000	—	—
All Directors and Officers as a Group	11,109,311	31 %	—

*Andrew I. Sealfon is deemed a “parent” and a “promoter” of REPRO-MED SYSTEMS, INC., as those terms are defined under the Securities Act of 1933, as amended.

(1) Does not include 690,000 shares of common stock owned by members of Mr. Sealfon’s family, as to which Mr. Sealfon disclaims beneficial ownership.

(2) Includes beneficial shares owned by Andrea Baker.

Certain shares and/or options, which have been disclosed above, were issued to officers, directors, or 10% shareholders. The Company has reminded each of said directors to file an SEC Form 3, 4, or 5 as applicable, with respect to such stock issuances or option grants.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

To reduce corporate travel expenses, we maintain and operate a corporate aircraft. Since 1992, the aircraft has been leased from AMI Aviation, Inc. Mr. Sealfon is a majority shareholder in AMI Aviation. The lease expenses paid were \$21,500 in each of 2013 and 2012. We believe the AMI lease is on terms competitive with those that could be obtained from unaffiliated third parties.

In February 2009, the Company borrowed \$672,663 from a Director of the company, at 6% interest per annum. In June 2009, 755,000 shares of stock were issued to the director at \$0.11 per share to reduce the debt. The remaining debt matures in February 2021.

In February 2011, the company added Mr. Mark Pastreich as a director. Mr. Pastreich is a principal in the company that owns the building leased by REPRO-MED SYSTEMS, INC. The Company is in year fourteen of a twenty-year lease. No changes have been made to the lease terms as a result of his directorship, and none are anticipated before the end of the lease.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The following is a summary of the fees billed to us by Radin, Glass & Co., LLP, an independent registered public accounting firm, for professional services rendered for the fiscal years ended February 28, 2013 and February 29, 2012, respectively.

Fee Category	Fiscal 2013 Fees	Fiscal 2012 Fees
Audit Fees (1)	\$40,000	\$38,500
Tax Returns & Consulting Services	\$18,000	\$10,000

- (1) Audit fees consist of aggregate fees billed for professional services rendered for the audit of our annual financial statements and review of the interim financial statements included in quarterly reports or services that are normally provided by the independent auditors in connection with statutory and regulatory filings or engagements for the fiscal years ended February 28, 2013 and February 29, 2012, respectively.

The Board of Directors is responsible for the appointment, compensation, and oversight of the work of the independent auditors and approves in advance any services to be performed by the independent auditors, whether audit-related or not. The Board of Directors reviews each proposed engagement to determine whether the provision of services is compatible with maintaining the independence of the independent auditors. All of the fees shown above

were pre-approved by the Board of Directors.

- 28 -

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)

- (1) Financial Statements - The following financial statements are incorporated by reference in Part II, Item 8 hereof:

Report of Independent Registered Public Accounting Firm
Balance Sheets
Statements of Operations
Statements of Stockholders' Equity
Statements of Cash Flows
Notes to Financial Statements

- (2) Financial Statement Schedules - The Financial Statement Schedules are incorporated by reference in Part II, Item 8 hereof.

- (3) Exhibits

The following exhibits are filed herewith or incorporated by reference as part of this Annual Report.

Exhibit No.	Description
3(i)	Articles of Incorporation, by reference from the Regulation and Offering Statement of REPRO-MED SYSTEMS, INC., dated November 12, 1982 (previously filed and incorporated by reference).
3(ii)	By-Laws, by reference from the Annual Report on Form 10-K of REPRO-MED SYSTEMS, INC., for the fiscal year ended February 1987 (previously filed and incorporated by reference).
14.1	Acknowledgement of Receipt and Understanding of Code of Ethics for Officers, Directors, and Employees of REPRO-MED SYSTEMS, INC., and Federal Securities Law Prohibitions as to use of Insider Information (previously filed and incorporated by reference).
14.2	Code of Ethics for Officers, Directors, and Employees of REPRO-MED SYSTEMS, INC. (previously filed and incorporated by reference).
14.3	Federal Securities Law Considerations for Management of REPRO-MED SYSTEMS, INC. (previously filed and incorporated by reference).
31.1	Certification of the Principal Executive Officer of registrant required under Section 302 of the Sarbanes-Oxley Act of 2002, filed herewith.
31.2	

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Certification of the Treasurer and Chief Financial Officer of registrant required under Section 302 of the Sarbanes-Oxley Act of 2002, filed herewith.

32.1 Certification of the Principal Executive Officer of registrant required under Section 906 of the Sarbanes-Oxley Act of 2002, filed herewith.

32.2 Certification of the Treasurer and Chief Financial Officer of registrant required under Section 906 of the Sarbanes-Oxley Act of 202, filed herewith.

101 Interactive Data File (Annual Report on Form 10-K, for the fiscal year ended February 28, 2013), furnished in XBRL (eXtensible Business Reporting Language).

- 29 -

SIGNATURES

Pursuant to the requirements of Section 13 or 15 (d) 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 on May 29, 2013.

REPRO-MED SYSTEMS, INC.

/s/ Andrew I. Sealfon

Andrew I. Sealfon, President

/s/ Michael R. Boscher

Michael R. Boscher, Treasurer & CFO

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities indicated on May 29, 2013.

/s/ Andrew I. Sealfon

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

/s/ Dr. Paul Mark Baker

Dr. Paul Mark Baker, Director

/s/ Remo Spagnoli

Remo Spagnoli, Director

/s/ Mark Pastreich

Mark Pastreich, Director

- 30 -
