ROCKWELL MEDICAL, INC.
Form 10-K
March 07, 2014

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2013

OR

o **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 000-23661

ROCKWELL MEDICAL, INC.

(Exact name of registrant as specified in its charter)

Michigan	**38-3317208**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
30142 Wixom Road Wixom, Michigan	**48393**
(Address of principal executive offices)	(Zip Code)

(248) 960-9009
(Registrant's telephone number, including area code)

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

Title of Each Class:	**Name of each exchange on which registered:**
Common Stock, no par value	Nasdaq Global Market

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

(None)

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

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 o No ý

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ý No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, 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 ý No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) 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. o

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. (Check one):

Large accelerated filer o	Accelerated filer ý	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

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

The aggregate market value of the registrant's voting and non-voting common equity held by non-affiliates of the registrant on June 30, 2013 (computed by reference to the closing sales price of the registrant's Common Stock as reported on the NASDAQ Global Market on such date) was $135,645,000. For purposes of this computation, shares of common stock held by our executive officers, directors and common shareholders with 10% or more of the outstanding shares of Common Stock were excluded. Such determination should not be deemed an admission that such officers, directors and beneficial owners are, in fact, affiliates.

Number of shares outstanding of the registrant's Common Stock, no par value, as of February 28, 2014: 40,748,161 shares.

Documents Incorporated by Reference

Portions of the Registrant's definitive Proxy Statement pertaining to the 2014 Annual Meeting of Shareholders (the "Proxy Statement") to be filed pursuant to Regulation 14A are herein incorporated by reference in Part III of this Annual Report on Form 10-K.

PART I

References to "Rockwell", the "Company," "we," "us" and "our" are to Rockwell Medical, Inc. and its subsidiary unless otherwise specified or the context otherwise requires.

Forward Looking Statements

We make forward-looking statements in this report and may make such statements in future filings with the Securities and Exchange Commission, or SEC. We may also make forward-looking statements in our press releases or other public or shareholder communications. Our forward-looking statements are subject to risks and uncertainties and include information about our expectations and possible or assumed future results of our operations. When we use words such as "may," might," "will," "should," "believe," "expect," "anticipate," "estimate," "continue", "predict", "forecast", "projected," "intend" or similar expressions, or make statements regarding our intent, belief, or current expectations, we are making forward-looking statements. Our forward looking statements also include, without limitation, statements about our competitors, statements regarding the timing and costs of obtaining FDA approval of our new products, statements regarding our new products such as Triferic® and Calcitriol, and statements regarding our anticipated future financial condition, operating results, cash flows and business and financing plans.

We claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995 for all of our forward-looking statements. While we believe that our forward-looking statements are reasonable, you should not place undue reliance on any such forward-looking statements, which are based on information available to us on the date of this report or, if made elsewhere, as of the date made. Because these forward-looking statements are based on estimates and assumptions that are subject to significant business, economic and competitive uncertainties, many of which are beyond our control or are subject to change, actual results could be materially different. Factors that might cause such a difference include, without limitation, the risks and uncertainties discussed in this report, including without limitation in "Item 1A Risk Factors," and from time to time in our other reports filed with the SEC. Other factors not currently anticipated may also materially and adversely affect our results of operations, cash flows and financial position. We do not undertake, and expressly disclaim, any obligation to update or alter any statements whether as a result of new information, future events or otherwise except as required by law.

Item 1. Business.

General

Rockwell Medical, Inc., incorporated in the state of Michigan in 1996, is a fully-integrated biopharmaceutical company targeting end-stage renal disease (ESRD) and chronic kidney disease (CKD) with innovative products and services for the treatment of iron deficiency, secondary hyperparathyroidism and hemodialysis (also referred to as "dialysis").

Rockwell's lead investigational drug, Triferic®, also known as Soluble Ferric Pyrophosphate or SFP, delivers iron to the bone marrow in a non-invasive, physiologic manner to hemodialysis patients via dialysate during their regular dialysis treatment. We are preparing to submit a New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA") in the first quarter of 2014 seeking marketing approval of Triferic®. We also plan to seek foreign market approval for this product and/or license the technology to a company who will seek market approval in the licensed markets

The majority of ESRD patients receive iron on a routine basis. We believe Triferic® will substantially improve iron therapy for these patients. The Company successfully completed the two pivotal studies, CRUISE-1 and CRUISE-2, in Triferic®'s Phase 3 clinical program during 2013. Both studies met their primary efficacy endpoint and achieved statistical significance. The Company also

completed an extensive longer term safety study in early 2014 which showed that Triferic® has an exceptionally good safety profile, with over 100,000 administrations in its clinical program.

In addition, in early 2013, the Company completed its PRIME study which demonstrated that Triferic® could achieve a significant reduction in the need for erythropoiesis stimulating agents ("ESA") in CKD-HD patients who receive Triferic® during dialysis. ESA drugs are the most expensive drugs used in dialysis. We cannot, however, give any assurance that Triferic® will be approved by the FDA or, if approved, that it will be successfully marketed. See "Item 1A Risk Factors."

Rockwell is also preparing to launch an FDA approved generic drug called Calcitriol. Calcitriol is active vitamin D injection and indicated for the treatment of secondary hyperparathyroidism in dialysis patients. The majority of ESRD patients receive vitamin D on a routine basis. We are in the process of obtaining regulatory approval for a change in manufacturing location and anticipate obtaining approval to begin marketing Calcitriol in the first half of 2014. However, due to FDA's procedures for generic drugs and backlog of requests, it is uncertain as to when such approval will be granted and there is no assurance that such approval will be granted in the time frame we estimate.

Rockwell is also an established manufacturer and leader in delivering high-quality hemodialysis concentrates/dialysates to dialysis providers and distributors in the U.S. and abroad. These products are used in the hemodialysis process to maintain human life by removing toxins and replacing critical nutrients in the patient's bloodstream. Rockwell's has three manufacturing and distribution facilities in the United States and its operating infrastructure is a ready-made sales and distribution channel that will be able to provide seamless integration of Calcitriol and Triferic® into the commercial market upon FDA approval.

Our Business Strategy

We intend to become a leading biopharmaceutical company focused primarily on renal indications, while leveraging our operating business infrastructure to market and sell approved drugs commercially. The following are the key elements of our business strategy:

Obtain Regulatory Approval of our Lead Drug Candidate Triferic® for the Treatment of Iron Deficiency in Hemodialysis Patients.

We are seeking and intend to obtain FDA regulatory approval to market Triferic® commercially. Based on reports from manufacturers of intravenous ("IV") iron products and industry estimates, the market size in the United States for IV iron therapy for ESRD patients is approximately $600 million per year. We sell to and service a significant number of dialysis providers in the United States and intend to market Triferic® to those dialysis providers.

Launch Calcitriol (Active Vitamin D) Injection for the Treatment of Secondary Hyperparathyroidism in Dialysis Patients.

We expect to obtain manufacturing approval from the FDA in the first half 2014 for our FDA approved generic drug Calcitriol and begin marketing Calcitriol thereafter. Based on manufacturers' reports and industry estimates, we believe the market size in the United States for vitamin D therapy for ESRD patients is greater than $300 million per year. We intend to market Calcitriol to our existing customer base that we service via our concentrate operating business, which currently serves approximately 25% of the U.S. concentrate dialysis market.

Obtain License/Marketing Partners to Leverage Our Products Globally for Commercialization.

We seek commercial collaborations to license and develop our products and to realize financial benefits on an international basis. We intend to leverage the development, regulatory and marketing

presence and expertise of potential business partners to accelerate the development of our products throughout the world.

Continue Development of our Commercial Concentrate Business and Market Position and Leverage that Infrastructure to Sell our Renal Drugs Once Approved by the FDA.

We intend to continue to increase our market presence in our concentrate/dialysate products business in the U.S. and internationally by continuing to develop and offer innovative products that improve patient outcomes and lower provider costs. We estimate the global market for IV iron therapy is in excess of $1 billion per year. We intend to use this operating infrastructure to sell our renal drugs into the same market, with minimal additional expense.

Leverage Our Triferic® Technology to Develop Other Drugs for Other Indications in Iron Therapy Management.

We intend to pursue clinical development and or business partnerships to leverage Triferic® iron delivery technology to address other indications for treating anemia in the U.S. and globally.

Identify Novel Drugs to Address Unmet Needs and Market Opportunities.

We will pursue opportunities to secure other drugs inside and outside the renal market that we believe hold great potential to address unmet needs, and that we believe will enable us to expand our reach further into drug development.

Acquire Rights to and Commercially Implement Complementary Drug Candidates and Technologies.

We intend to continue to selectively pursue and acquire rights to drug products in various stages of development, or FDA approved drugs, with the intention to commercialize and/or realize their business potential.

Our Markets

The Hemodialysis Market

The great majority of hemodialysis patients receive dialysis treatment three times per week, or 156 times per year. Most have their dialysis treatment performed at a free-standing clinic; these are called "chronic" patients. Some have their treatment performed at hospitals; these are called "acute" patients. A small percentage receive their treatment at home; these are called "home" patients. In each setting, a dialysis machine dilutes concentrated solution, such as our concentrate products, with purified water. The resulting solution is called dialysate. Dialysate is pumped through an artificial kidney (or dialyzer) while the patient's blood is pumped through a semi-permeable membrane inside the dialyzer, in the opposite direction the dialysate is flowing. The dialysate infuses calcium and bicarbonate into the patient's blood while removing water and waste. Dialysate generally contains dextrose, sodium chloride, calcium, potassium, magnesium, sodium bicarbonate and acetic acid, or citric acid. The patient's physician chooses the proper concentrations required for each patient based on each particular patient's needs.

In addition to using reusable concentrate products, a dialysis provider also uses other ancillary products such as blood tubing, fistula needles, specialized component kits, dressings, cleaning agents, filtration salts and other supplies, many of which we sell.

Dialysis Industry Trends

Hemodialysis is the primary treatment modality employed in the United States with over 90% of all dialysis patients receiving hemodialysis. The Company does not compete in the peritoneal or home

dialysis segments. Hemodialysis treatments are generally performed in independent clinics or hospitals with the majority of dialysis services performed by national and regional for profit dialysis chains. Based on data published by the U.S. Renal Data Systems ("USRDS") we estimate that there are approximately 6,000 Medicare-certified treatment clinics in the United States. The two largest national for-profit dialysis chains service approximately 70% of the domestic hemodialysis market. According to the most recent industry statistics published by USRDS, there were approximately 430,000 dialysis patients in the United States in 2011. The U.S. patient population has grown steadily over the past several decades, and is expected to grow approximately 4-6% annually over the next several years.

Based on industry reports, the global ESRD population receiving some form of dialysis treatment is estimated to be over 2.5 million patients. Incidence rates vary by country with the overall global patient population growing approximately 6% annually. Today, the three largest dialysis markets are the United States, the European Union and Japan, which together represent approximately half of the total global treatments based on industry estimates. The Asia-Pacific market is projected to experience rapid growth in the incidence of kidney disease over the decade ahead.

Products (Operating Business)

We manufacture, sell, deliver and distribute hemodialysis concentrates, along with a full line of ancillary products, to customers in the U.S. and abroad. Dialysate concentrates account for over 93% of our revenue and consist of two products known in the industry as "acid" and "bicarbonate" and are packaged as liquid or powder. All of our products are manufactured according to Association for the Advancement of Medical Instrumentation and current good manufacturing practices ("cGMP") guidelines. Our concentrate products are used in conjunction and are diluted with clean water on-site at the clinic in the dialysis machine, creating dialysate, which works to clean the patient's blood.

CitraPure® Citric-Acid Concentrate

Our CitraPure® concentrate is 100% acetate-free, in contrast to the acetate-based products most widely used for many years. Acetate promotes inflammation so its removal is beneficial to the patient. Citrate has anticoagulant properties and has been shown in clinical studies to have the ability to reduce the need for heparin during dialysis treatment (CitraPure® however is not indicated for heparin sparing). CitraPure® is packaged as a liquid and as a dry powder acid concentrate, for use with our Dry Acid Mixing System, containing citric acid, sodium chloride, dextrose and electrolyte additives such as magnesium, potassium, and calcium. We supply dry acid in 25 gallon cases and we supply liquid acid concentrate in both 55 gallon drums and in cases containing four-one gallon containers.

Dri-Sate® Dry Acid

Dry powder acid concentrate for use with our Dry Acid Mixing System, containing acetic acid, sodium chloride, dextrose and electrolyte additives such as magnesium, potassium, and calcium. We supply dry acid in 25 gallon cases.

Renal Pure® Liquid Acid Concentrate

Liquid acid concentrate containing acetic acid, sodium chloride, dextrose and electrolyte additives such as magnesium, potassium, and calcium. We supply liquid acid concentrate in both 55 gallon drums and in cases containing four-one gallon containers.

Dry Acid Concentrate Mixing System

Our Dry Acid Concentrate Mixing System is designed for our CitraPure® and Dri-Sate® Dry Acid product and allows a clinic to mix its acid concentrate on-site. The clinic technician, using a specially designed mixer, adds pre-measured packets of the necessary ingredients to purified water (AMII

standard). Clinics using Dry Acid Concentrate realize numerous advantages, including lower cost per treatment, reduced storage space requirements, reduced number of deliveries and more flexibility in scheduling deliveries, while enabling the Company to reduce distribution and warehousing costs.

RenalPure® Powder Bicarbonate Concentrate

RenalPure® bicarbonate sold in powder form is used mainly in chronic settings. Each clinic mixes bicarbonate on-site as required.

SteriLyte® Liquid Bicarbonate Concentrate

SteriLyte® bicarbonate is sold in liquid form and is used mainly in acute care settings.

Ancillary Products

We offer a wide range of ancillary products including blood tubing, fistula needles, specialized custom kits, dressings, cleaning agents, filtration salts and other supplies used by hemodialysis providers.

Drug Products

We are seeking FDA regulatory approval to market Triferic®, our investigational iron-delivery drug. We plan to file our NDA with the FDA in the first quarter of 2014.

We have filed an application for manufacturing approval from the FDA and expect to receive approval in the first half of 2014 for our FDA approved generic drug Calcitriol. We intend to begin marketing Calcitriol commercially upon receiving FDA approval.

Triferic® (Soluble Ferric Pyrophosphate); Investigational Drug

We have licensed the exclusive right to manufacture and sell Triferic®. If approved by the FDA, we believe Triferic® will substantially improve iron therapy treatment for dialysis patients. The treatment for iron deficiency anemia is pervasive in the CKD-HD patient population.

Triferic® is a unique iron compound that is delivered to the hemodialysis patient via dialysate, replacing the 5-7mg of iron that is lost during a dialysis treatment. Triferic® is introduced into the sodium bicarbonate concentrate that subsequently is mixed into dialysate. Once in the dialysate, Triferic® crosses the dialyzer membrane and enters the bloodstream where it immediately binds to apo-transferrin and is taken to the bone marrow. Triferic® mimics the way dietary iron is metabolized in the human body. In completed clinical trials to date with over 100,000 administrations, Triferic® has demonstrated that it can safely deliver iron and maintain hemoglobin levels, while decreasing ESA use without increasing iron stores.

To address iron deficiency, patients receive intravenous iron and ESA. ESA is an artificial hormone that acts in the bone marrow, together with iron, to increase the production of red blood cells, which carry oxygen throughout the body to nourish tissues and sustain life. Hemoglobin, an important constituent of red blood cells, is composed largely of iron and protein.

Current iron therapy for CKD-HD patients is provided mainly with IV iron compounds, which are encased by a carbohydrate shell to prevent free-iron from circulating in the bloodstream. Due to the carbohydrate shell, IV iron is taken up by the reticuloendothelial system and deposited primarily in the liver, rather than directly into blood plasma where it would be carried to the bone marrow. An increase in inflammation during dosing causes a peptide called hepcidin to mobilize and block the IV iron from effectively leaving the liver, which can reduce the effectiveness of ESA treatments. The carbohydrate moiety in IV iron compounds is also believed to be responsible for anaphylactic reactions when they occur.

Triferic® is distinctly different from IV iron compounds. Triferic® enters the bloodstream through dialysate and immediately binds to apo-transferrin (the body's natural binding site for iron) and is then carried directly to the bone marrow for the formation of new red blood cells, mimicking the way a healthy human body processes iron when received through food. Clinical data has shown that this more direct method of iron delivery is effective at maintaining a steady state of iron balance and achieves superior therapeutic response from ESA treatments, thereby lowering the need for ESA. Triferic® is an iron salt and contains no carbohydrate, and as a result has demonstrated an excellent safety profile in its recently completed Phase 3 clinical program and has not been attributed to any anaphylactic episodes in over 100,000 administrations.

ESA is administered intravenously during dialysis treatments to help maintain hemoglobin levels. Iron supplementation is required to ensure good therapeutic response from ESA treatments. Most dialysis patients receive ESA therapy coupled with iron therapy in order to maintain hemoglobin levels and to achieve the full benefit of ESA treatments. ESAs are very expensive drugs and are known to have serious risks associated with their dosing to dialysis patients.

Triferic®, in place of IV iron, has shown it can lower the drug administration cost to dialysis providers. Along with the elimination of the needle and syringe normally used for IV iron administration, and the resulting substantial nursing time gained to deliver quality patient care, Triferic® clinical data has shown that it can greatly reduce ESA use.

During 2013, Rockwell successfully completed its two pivotal Phase 3 clinical trials, called CRUISE-1 and CRUISE-2, for Triferic®. The CRUISE studies were identical single-blind, placebo controlled, parallel group, multi-center studies comparing Triferic® delivered via hemodialysate concentrate to placebo with standard hemodialysate concentrate with 600 subjects split evenly between the two studies and treatment arms. Both of the CRUISE studies successfully met their primary endpoint, demonstrating a statistically significant mean change in hemoglobin from baseline to End-of-Treatment. Triferic® also met key secondary endpoints including maintenance of hemoglobin, maintenance of reticulocyte hemoglobin and increase in serum iron pre-to-post treatment without an increase in ferritin.

A third Phase 3 trial, called the PRIME study demonstrated that Triferic® significantly reduces the need for ESA during dialysis. The PRIME study was a nine-month, prospective, randomized, placebo-controlled, double-blinded, multi-center study in the United States that randomized patients equally to dialysate containing Triferic®-iron *versus* conventional dialysate. A total of 103 patients received blinded study drug (52 Triferic®· 51 Placebo). The PRIME study data showed a statistically significant 35% reduction in ESA usage compared to the control arm. The PRIME data demonstrated that Triferic® was able to maintain hemoglobin levels in the target range over the nine month study duration while the magnitude of ESA sparing, compared to the control arm, met statistical significance. In addition, for patients that are resistant to ESA administration, referred to as hypo-responsive, these patients realized an average reduction in ESA usage of 74.4%. Hypo-responsive patients are generally estimated to represent approximately 20% of the dialysis patient population. Over $2.7 billion was spent on Amgen's ESA drugs in 2013 in the United States according to Amgen. We estimate that approximately $2.2 billion of Amgen's ESA sales were to the hemodialysis market.

In January 2014, we completed our long term safety study for Triferic® which was a prospective, randomized, double-blinded, placebo-controlled, crossover, multicenter, multinational, Phase 3 study with an enrollment of 718 CKD-HD patients in the US and Canada. This large-scale long term safety study coupled with the successful Phase 3 CRUISE studies, in which together there were over 100,000 Triferic® administrations, did not identify an acute safety signal or anaphylactic reaction, which are possible side effects of IV iron administration.

We intend to file an NDA and to seek FDA approval to market Triferic®. We intend to use our current sales and marketing infrastructure to sell and market Triferic® and other drugs to dialysis

providers in the U.S. market, once FDA approved. We intend to license the rights to Triferic® for commercial development in markets outside of the United States, such as Europe, Asia and Latin America.

Calcitriol (Active Vitamin D) Injection; FDA Approved Generic Drug

Calcitriol is a generic active vitamin D and is indicated for the treatment of secondary hyperparathyroidism in dialysis patients. The majority of ESRD patients receive vitamin D on a routine basis using one of two branded drugs. Calcitriol is the only generic vitamin D and clinical data shows it to be clinically equivalent in safety and efficacy to the two branded drugs. We believe the lower cost of Calcitriol will entice dialysis providers to purchase it over current vitamin D options. We are in the process of obtaining regulatory approval for a change in manufacturing location and anticipate obtaining approval to begin marketing Calcitriol during 2014.

Distribution and Delivery Operations

The majority of our domestic products are delivered through our subsidiary, Rockwell Transportation, Inc., which operates a fleet of trucks used to deliver products to our customers. We perform delivery services for customers that are generally not available from common carriers or our competitors, such as stock rotation, non-loading-dock delivery and drum pump-off service. As a result, we believe we offer a higher level of service to our customers.

Our Dry Acid Concentrate products require less storage space not only for our customers but for our warehousing as well. We are able to more effectively utilize warehouse and trailer space, as well transportation equipment, in our distribution process, resulting in a distribution savings.

Sales and Marketing

There are nine large dialysis providers that treat approximately 83% of the hemodialysis patient population. Due to the high level of industry concentration, we sell our products direct to domestic hemodialysis providers using a small number of salespeople. Our Chief Executive Officer leads and directs our sales effort, and handles our major accounts. Our products are sold to international customers through independent sales agents, distributors and direct.

We market and advertise through trade publications, journals, product literature, the internet and industry trade conferences. We target our sales and marketing efforts to upper management of dialysis companies, providers, nephrologists, clinic administrators, nurses, medical directors and purchasing personnel.

Competition

Dialysis Concentrate Solutions and Dialysis Products Market Competition

In the United States, we compete against Fresenius Medical Care NA, a vertically integrated manufacturer and marketer of dialysis devices, drugs and supplies and dialysis clinic operator, which has substantially greater financial, technical, manufacturing, marketing, research and development and management resources than the Company. Fresenius operates approximately 2,000 clinics and treats over 37% of the dialysis patients in the U.S. Fresenius also manufactures and sells a full range of renal products, including dialysis machines, dialyzers (artificial kidneys), concentrates and other supplies used in hemodialysis. In addition to its captive customer base, Fresenius also services clinics owned by others with its products where it commands a market leading position in its key product lines. Fresenius manufactures its concentrate in its own regional manufacturing facilities. Other than Rockwell, there are no other major dialysis concentrate suppliers in the United States.

Iron Therapy Market Competition

We intend to enter the iron delivery therapy market upon obtaining FDA approval for Triferic®. We expect Triferic® will be disruptive to the US IV iron market. Presently the IV iron drug Venofer® has the majority of the market for delivering iron to CKD-HD patients in the US. Venofer® is owned by Switzerland-based Galenica. Galenica recently received approval to market a new product called Ferinject®. Fresenius has a sublicense agreement to manufacture and distribute Venofer® to the dialysis market in the US and Canada. Sanofi-Aventis markets the IV iron drug Ferrlecit® in the United States. Watson, a large manufacturer of both generic and branded drugs, introduced a generic IV iron in 2011 called Nulecit®. AMAG Pharmaceuticals, Inc. markets Feraheme®.

The markets for drug products are highly competitive. Competition in drug delivery systems is generally based on marketing strength, product performance characteristics (i.e., reliability, safety, patient convenience) and product price. Acceptance by dialysis providers and nephrologists is also critical to the success of a product. The first product on the market in a particular therapeutic area typically is able to obtain and maintain a significant market share. In a highly competitive marketplace and with evolving technology, additional product introductions or developments by others could render our products or technologies noncompetitive or obsolete. In addition, pharmaceutical and medical device companies are largely dependent upon health care providers being reimbursed by private insurers and government payors. Drugs approved by the FDA might not receive reimbursement from private insurers or government payors.

Prior to 2011, the Centers for Medicare & Medicaid Services ("CMS") had historically paid providers for dialysis treatments under the Medicare program in two parts: the composite rate and separately reimbursed drugs and services. The composite rate is payment for the complete dialysis treatment except for physicians' professional services, separately billed laboratory services and separately billed drugs. CMS began implementation of a fully bundled reimbursement rate in 2011, which we believe will benefit our marketing efforts. The bundled rate is a single payment per treatment, thereby eliminating reimbursement for individual drugs and services to providers. As a result dialysis drugs are now viewed by providers as an additional cost rather than as a source of revenue. With FDA approval, we believe Triferic®, due to its potential for improved therapeutic response, ability to reduce the need for costly ESA and lower cost of administration, will be an attractive alternative to IV iron under this reimbursement landscape.

Vitamin D Therapy Market Competition

We intend to market Calcitriol injection against two competitors with branded vitamin D products, as well as other generic drug competitors. Abbott Laboratories markets Zemplar® and Sanofi-Aventis, through its Genzyme subsidiary, markets Hectorol®. Other companies offer oral forms of vitamin D. A handful of other companies have historically marketed generic Calcitriol. We believe the dialysis reimbursement law that went into effect in January 2011, along with our current dialysis concentrates market share position, provides us an advantage to sell Calcitriol over other competitors in the market.

Quality Assurance and Control

Dialysis Concentrate Solutions Business

We operate under FDA and cGMP guidelines and place significant emphasis on providing quality products and services to our customers. Our quality management plays an essential role in meeting customer requirements and FDA guidelines. We have implemented quality systems that involve control procedures that result in rigid conformance to specifications. Our quality systems also include assessments of suppliers of raw materials, packaging components and finished goods, and quality management reviews designed to inform management of key issues that may affect the quality of products, assess the effectiveness of our quality systems and identify areas for improvement.

Technically trained professionals at our production facilities maintain our quality system. To assure quality and consistency of our concentrates, we conduct specific analytical tests during the manufacturing process for each type of product that we manufacture. Prior to shipment, our quality control laboratory at each facility conducts analytical tests to verify that the chemical properties of the concentrates comply with the specifications required by industry standards. Each product is assigned a lot number for tracking purposes.

Drug Manufacturing

We utilize contract manufacturing organizations ("CMOs") to manufacture and package our drug products including drugs used in our clinical trials. These contract manufacturers are FDA approved drug manufacturing establishments. We follow defined procedures to qualify manufacturers of our products and to review and approve all manufactured products to ensure compliance with FDA cGMP regulations.

Government Regulation

The testing, manufacture and sale of our hemodialysis concentrates and the ancillary products we distribute are subject to regulation by numerous governmental authorities, principally the FDA and corresponding state and foreign agencies. Under the Federal Food, Drug and Cosmetic Act, as amended (the "FD&C Act"), and FDA regulations, the FDA regulates the pre-clinical and clinical testing, manufacture, labeling, distribution and marketing of medical devices. Noncompliance with applicable requirements can result in, among other things, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, failure of the government to grant pre-market clearance or pre-market approval for devices, withdrawal of marketing clearances or approvals and criminal prosecution.

We plan to develop and commercialize selected drug candidates by ourselves, such as Triferic®. The development and regulatory approval process includes preclinical testing and human clinical trials and is lengthy and uncertain. Before marketing in the United States, any pharmaceutical or therapeutic product must undergo rigorous preclinical testing and clinical trials and an extensive regulatory approval process implemented by the FDA under the FD&C Act.

Moreover, the FDA imposes substantial requirements on new product research and the clinical development, manufacture and marketing of pharmaceutical products, including testing and clinical trials to establish the safety and effectiveness of these products.

Medical Device Approval and Regulation

A medical device may be marketed in the United States only with prior authorization from the FDA unless it is subject to a specific exemption. Devices classified as Class I devices (general controls) or Class II devices (general and special controls) are eligible to seek "510(k) clearance" from the FDA. Such clearance generally is granted when submitted information establishes that a proposed device is "substantially equivalent" in terms of safety and effectiveness to a legally marketed device that is not subject to premarket approval. A legally marketed device is a "pre-amendment" device that was legally marketed prior to May 28, 1976, a device that has been reclassified from Class III to Class I or II, or a device which has been found substantially equivalent through the 510(k) process. The FDA in recent years has been requiring a more rigorous demonstration of substantial equivalence than in the past, including requiring clinical trial data in some cases. For any devices that are cleared through the 510(k) process, modifications or enhancements that could significantly affect safety or effectiveness, or constitute a major change in the intended use of the device, will require new 510(k) submissions. We have been advised that it usually takes from three to six months from the date of submission to obtain

510(k) clearance, and may take substantially longer. Our hemodialysis concentrates, liquid bicarbonate and other ancillary products are categorized as Class II devices.

A device which sustains or supports life, prevents impairment of human health or which presents a potential unreasonable risk of illness or injury is categorized as a Class III device. A Class III device generally must receive approval through a pre-market approval ("PMA") application, which requires proving the safety and effectiveness of the device to the FDA. The process of obtaining PMA approval is expensive and uncertain. We have been advised that it usually takes approximately one year to obtain approval after filing the request, and may take substantially longer.

If human clinical trials of a device are required, whether for a 510(k) submission or a PMA application, and the device presents a "significant risk," the sponsor of the trial (usually the manufacturer or the distributor of the device) will have to file an investigational device exemption ("IDE") application prior to commencing human clinical trials. The IDE application must be supported by data, typically including the results of animal and laboratory testing. If the IDE application is approved by the FDA and one or more appropriate Institutional Review Boards ("IRBs"), the device may be shipped for the purpose of conducting the investigations without compliance with all of the requirements of the FD&C Act and human clinical trials may begin. The FDA will specify the number of investigational sites and the number of patients that may be included in the investigation. If the device does not present a "significant risk" to the patient, a sponsor may begin the clinical trial after obtaining approval for the study by one or more appropriate IRBs without the need for FDA approval.

Any devices manufactured or distributed by us pursuant to FDA clearances or approvals are subject to pervasive and continuing regulation by the FDA and certain state agencies. As a manufacturer of medical devices for marketing in the United States we are required to adhere to regulations setting forth detailed cGMP requirements, which include testing, control and documentation requirements. We must also comply with medical device reporting regulations which require that we report to the FDA any incident in which our products may have caused or contributed to a death or serious injury, or in which our products malfunctioned and, if the malfunction were to recur, it would be likely to cause or contribute to a death or serious injury. Under such a scenario, our products may be subject to voluntary recall by us or by required recall by the FDA. Labeling and promotional activities are subject to scrutiny by the FDA and, in certain circumstances, by the Federal Trade Commission. The FD&C Act prohibits the marketing of approved medical devices for unapproved uses.

We are subject to routine inspection by the FDA and certain state agencies for compliance with cGMP requirements and other applicable quality system regulations. We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, transportation and disposal of hazardous or potentially hazardous substances.

We have 510(k) clearance from the FDA to market hemodialysis concentrates in both liquid and powder form. In addition, we have received 510(k) clearance for our Dry Acid Concentrate Mixer.

We must comply with the FD&C Act and related laws and regulations, including cGMP, to retain 510(k) clearances. We cannot assure you that we will be able to maintain our 510(k) clearances from the FDA to manufacture and distribute our products. If we fail to maintain our 510(k) clearances, we may be required to cease manufacturing and/or distributing our products, which would have a material adverse effect on our business, financial condition and results of operations. If any of our FDA clearances are denied or rescinded, sales of our products in the United States would be prohibited during the period we do not have such clearances.

In addition to the regulations for medical devices covering our current dialysate products, our new product development efforts will be subject to the regulations pertaining to pharmaceutical products.

We have signed a licensing agreement for Triferic®. Our Triferic® and Calcitriol products will be subject to FDA drug regulations.

Drug Approval and Regulation

The marketing of pharmaceutical products, such as Triferic® in the United States, requires the approval of the FDA. We plan to file our NDA for Triferic® in the first quarter of 2014. The FDA has established regulations, guidelines and safety standards which apply to the pre-clinical evaluation, clinical testing, manufacturing and marketing of our new iron maintenance therapy product and other pharmaceutical products. The steps required before a pharmaceutical product can be produced and marketed for human use include: (i) pre-clinical studies; (ii) submission to the FDA of an Investigational New Drug Application ("IND"), which must become effective before human clinical trials may commence in the United States; (iii) adequate and well controlled human clinical trials; (iv) submission to the FDA of a NDA or, in some cases, an Abbreviated New Drug Application ("ANDA"); and (v) review and approval of the NDA or ANDA by the FDA. An NDA generally is required for products with new active ingredients, new indications, new routes of administration, new dosage forms or new strengths. An NDA requires that complete clinical studies of a product's safety and efficacy be submitted to the FDA, the cost of which is substantial. The costs are often less, however, for new delivery systems which utilize already approved drugs than for drugs with new active ingredients.

An ANDA is a marketing application filed as part of an abbreviated approval process that is available for generic drug products that have been determined to be "bioequivalent" to an FDA-approved drug. This requires that the generic drug product have the same amount of active ingredient(s) absorbed in the same amount of time, use indication, route of administration, dosage form and dosage strength as an existing FDA-approved product. In addition the generic drug product must be manufactured in accordance with cGMP and meet requirements for batch identity, strength, purity and quality. Under applicable regulations, companies that seek to introduce an ANDA product must also certify that the product does not infringe on the approved product's patent or that such patent has expired. If the applicant certifies that its product does not infringe on the approved product's patent, the patent holder may institute legal action to determine the relative rights of the parties and the application of the patent, and the FDA may not finally approve the ANDA until a court finally determines that the applicable patent is invalid or would not be infringed by the applicant's product.

Pre-clinical studies are conducted to obtain preliminary information on a pharmaceutical product's efficacy and safety in animal or in vitro models. The results of these studies are submitted to the FDA as part of the IND and are reviewed by the FDA before human clinical trials begin. Human clinical trials may begin 30 days after receipt of the IND by the FDA unless the FDA objects to the commencement of clinical trials.

Human clinical trials are typically conducted in three sequential phases, but the phases may overlap. Phase 1 trials consist of testing the product primarily for safety, metabolism and pharmacologic action in a small number of patients or healthy volunteers at one or more doses. In Phase 2 trials, the safety and efficacy of the product are evaluated in a patient population somewhat larger than the Phase 1 trials with the primary intent of determining the effective dose range. Phase 3 trials typically involve additional testing for safety and clinical efficacy in an expanded population at a large number of test sites. A clinical plan, or protocol, accompanied by documentation from the institutions participating in the trials, must be received by the FDA prior to commencement of each of the clinical trials. The FDA may order the temporary or permanent discontinuation of a clinical trial at any time.

The results of product development and pre-clinical and clinical studies are submitted to the FDA as an NDA or an ANDA for approval. If an application is submitted, there can be no assurance that

the FDA will review and approve the NDA or an ANDA in a timely manner. The FDA may deny an NDA or an ANDA if applicable regulatory criteria are not satisfied or it may require additional testing, including pre-clinical, clinical and or product manufacturing tests. Even if such data are submitted, the FDA may ultimately deny approval of the product. Further, if there are any modifications to the drug, including changes in indication, manufacturing process, labeling, or a change in a manufacturing facility, an NDA or an ANDA supplement may be required to be submitted to the FDA. Product approvals may be withdrawn after the product reaches the market if compliance with regulatory standards is not maintained or if problems occur regarding the safety or efficacy of the product. The FDA may require testing and surveillance programs to monitor the effect of products which have been commercialized, and has the power to prevent or limit further marketing of these products based on the results of these post-marketing programs.

Manufacturing facilities are subject to periodic inspections for compliance with regulations and each domestic drug manufacturing facility must be registered with the FDA. Foreign regulatory authorities may also have similar regulations. We expend significant time, money and effort in the area of quality assurance to fully comply with all applicable requirements. FDA approval to manufacture a drug is site specific. In the event an approved manufacturing facility for a particular drug becomes inoperable, obtaining the required FDA approval to manufacture such drug at a different manufacturing site could result in production delays, which could adversely affect our business and results of operations. Manufacturers and distributors must comply with various post-market requirements, including adverse event reporting, re-evaluation of approval decisions and notices of changes in the product.

Other Government Regulations

The federal and state governments in the United States, as well as many foreign governments, from time to time explore ways to reduce medical care costs through health care reform. Due to uncertainties regarding the ultimate features of reform initiatives and their enactment and implementation, we cannot predict what impact any reform proposal ultimately adopted may have on the pharmaceutical and medical device industry or on our business or operating results. Recently enacted health reform legislation has resulted in material changes to the Medicare and Medicaid programs and levels of reimbursement, imposes excise taxes on medical devices and pharmaceutical products and requires medical device and pharmaceutical manufacturers to report certain relationships they have with physicians and teaching hospitals. Our activities are subject to various federal, state and local laws and regulations regarding occupational safety, laboratory practices, and environmental protection and may be subject to other present and possible future local, state, federal and foreign regulations.

The approval procedures for the marketing of our products in foreign countries vary from country to country, and the time required for approval may be longer or shorter than that required for FDA approval. We generally depend on our foreign distributors or marketing partners to obtain the appropriate regulatory approvals to market our products in those countries which typically do not require additional testing for products that have received FDA approval.

However, since medical practice and governmental regulations differ across regions, further testing may be needed to support market introduction in some foreign countries. Some foreign regulatory agencies may require additional studies involving patients located in their countries. Even after foreign approvals are obtained, further delays may be encountered before products may be marketed. Issues related to import and export can delay product introduction. Many countries require additional governmental approval for price reimbursement under national health insurance systems.

Product License Agreements

We are party to a license agreement for Triferic® that covers issued patents in the United States, the European Union and Japan, as well as other foreign jurisdictions. We licensed the product from a company owned by Dr. Ajay Gupta who subsequently joined us as our Chief Scientific Officer. The license agreement continues for the duration of the underlying patents in each country, or until December 30, 2017 in the United States, and may be extended thereafter under the Hatch-Waxman Act. Patents were issued in the United States in 2004. The European patent was issued in 2005 and extends through 2017. The Japanese patent was issued in 2007 and extends through 2017. If we are successful in obtaining FDA approval we may apply for an extension of our patent exclusivity for up to five years. As noted below in "Trademarks and Patents," the Company has also received patent protection on the pharmaceutical grade formulation of the active pharmaceutical ingredient in Triferic® which extends patent protection until 2029.

Our Triferic® license agreement requires us to obtain and pay the cost of obtaining FDA approval of the product in order to realize any benefit from commercialization of the product. In addition to funding safety pharmacology testing, clinical trials and patent maintenance expenses, we are obligated to make certain milestone payments and to pay ongoing royalties upon successful introduction of the product. The milestone payments include a payment of $50,000 which will become due upon completion of the last Phase 3 study report in 2014, a payment of $100,000 which will become due upon FDA approval of the product and a payment of $175,000 which will become due upon issuance of a reimbursement code covering the product.

We own an ANDA for Calcitriol. We are in the process of obtaining FDA approval to market this product following manufacturing changes relating to a CMO that we have contracted with to manufacture Calcitriol.

Trademarks and Patents

We have several trademarks and servicemarks used on our products and in our advertising and promotion of our products, and we have applied for U.S. registration of such marks. Most such applications have resulted in registration of such trademarks and servicemarks.

We were issued a U.S. patent on the synthesis and formulation of our pharmaceutical grade formulation of Triferic®. The U.S patent expires on April 17, 2029. Patents have also been granted in Europe and Canada and a patent application is pending Japan. We have numerous other patents and patent applications connected to Triferic® pending in various countries.

We also own patents in the U.S. and Canada for our Dry Acid Concentrate method and apparatus for preparing liquid dialysate which expire on September 17, 2019. Expiration of these patents is not expected to have a material impact on our business.

Suppliers

We believe the raw materials and packaging materials for our hemodialysis concentrates, the components for our hemodialysis kits and the ancillary hemodialysis products distributed by us are generally available from several potential suppliers. We intend to engage CMOs for the manufacture and packaging of our drug products. There are several potential CMOs that are able to manufacture and package our drug products and so it is unlikely we will be dependent on any particular CMO.

Customers

We operate in one market segment which involves the manufacture and distribution of hemodialysis concentrates, dialysis kits and ancillary products used in the dialysis process to hemodialysis clinics. For the years ended December 31, 2013, 2012 and 2011, one customer, DaVita

Healthcare Partners, Inc., accounted for 49%, 49% and 48% of our sales, respectively. Our accounts receivable from this customer were $1,886,000 and $2,352,000 as of December 31, 2013 and 2012, respectively. This key customer is important to our business and the loss of its business could have a material adverse effect on our business, financial condition and results of operations. No other customer accounted for more than 10% of our sales in any of the last three years.

The majority of our international sales in each of the last three years were sales to domestic distributors that were resold to end users outside the United States. Our sales to foreign customers and distributors were less than 5% of our total sales in 2013, 2012 and 2011. We have no assets outside the United States. Our total international sales, including sales to domestic distributors for resale outside the United States, aggregated 12%, 11% and 13%, of overall sales in 2013, 2012 and 2011, respectively.

Employees

As of December 31, 2013, we had approximately 286 employees, substantially all of whom are full time employees. Our arrangements with our employees are not governed by any collective bargaining agreement. Our employees are employed on an "at-will" basis.

Research & Development

Over the last several years we have invested heavily in the testing and development of Triferic®. We completed the human clinical trials and other testing required to submit an NDA in 2013 and will submit an NDA for Triferic® to the FDA in 2014. We engaged outside service providers, contract research organizations, consultants and legal counsel to assist us with clinical trials, product development and obtaining regulatory approval. We incurred product development and research costs related to the commercial development, patent approval and regulatory approval of new products, including Triferic®, aggregating approximately $39,382,000, $48,272,000, and $17,805,000 in 2013, 2012 and 2011, respectively.

Where You Can Get Information We File with the SEC

Our internet address is http://www.rockwellmed.com. You can access free of charge on our web site all of our reports filed pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, including our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports. These reports are available as soon as practicable after they are electronically filed with the SEC.

The SEC also maintains a website on the internet that contains reports, proxy and information statements and other information regarding issuers, such as us, that file electronically with the SEC. The address of the SEC's Web site is http://www.sec.gov.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below before purchasing our common stock. The risks and uncertainties described below are not the only ones facing our company. Additional risks and uncertainties may also impair our business operations. If any of the following risks actually occur, our business, financial condition or results of operations would likely suffer. In that case, the trading price of our common stock could fall, and you may lose all or part of the money you paid to buy our common stock.

RISKS RELATED TO OUR BUSINESS

Before it can be marketed, our lead drug candidate requires FDA approval, a long, expensive process with no guarantee of success.

We are seeking FDA approval for Triferic®, our lead drug candidate. Obtaining FDA approval for any drug can take a long time. The FDA may find deficiencies in our NDA, may raise safety or efficacy concerns or may otherwise require additional clinical testing or impose other requirements before approving Triferic®, which could significantly delay approval or result in us not receiving approval at all.

Clinical trials and the NDA approval process are expensive and time consuming to complete. Any such delays or additional testing or other requirements may require us to raise additional capital which may not be available when needed or may be available only on terms that are not in the best interests of the Company and its shareholders or which result in substantial dilution of shareholders' voting power and ownership.

It is possible that Triferic® may never be approved by the FDA. If we are unable to obtain FDA approval or if such approval is substantially delayed, our entire investment in new products may be worthless, our licensing rights could be forfeited and the price of our common stock could substantially decline.

Even if Triferic® is approved by the FDA, we may not be able to market it successfully.

Even if Triferic® is approved by the FDA, the commercial success of Triferic® will depend on a number of factors, including the following:

- one drug currently dominates treatment for iron deficiency and Triferic® will have to compete against it and other existing products;
- it may be difficult to gain market acceptance from dialysis chains, anemia managers and nephrologists or such acceptance may be slower than expected. Market acceptance will depend on a number of factors, such as demonstration of Triferic®'s safety and efficacy, its cost-effectiveness, its advantages over existing products, and the reimbursement policies of government and third party payors, including Medicare;
- maintaining compliance with ongoing regulatory requirements applicable to Triferic® which may be imposed by the FDA as part of the approval or which apply generally to the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping applicable to the product;
- the effectiveness of our marketing, sales and distribution strategies and operations for development and commercialization of Triferic® and our ability to execute our marketing strategy without significant additional expenditures;
- our ability to avoid third party patent interference or patent infringement claims; and
- a continued acceptable safety profile of Triferic® following approval. Later discovery of previously unknown problems with Triferic® or with any third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in regulatory action that could have a material adverse effect on our ability to manufacture and market Triferic®.

Many of these factors are beyond our control. Accordingly, we cannot assure you that we will be able to generate revenues through the sale of Triferic®. If we are not successful in commercializing Triferic®, or are significantly delayed in doing so, our entire investment in Triferic® may be worthless, our licensing rights could be forfeited and the price of our common stock could substantially decline.

If we do not obtain protection under the Hatch-Waxman Act to extend patent protection for Triferic®, our business may be harmed.

The United States Drug Price Competition and Patent Term Restoration Act of 1984, more commonly known as the "Hatch-Waxman Act," provides that patent holders may apply for an extension of patent term for drugs for a period of up to five years to compensate for time spent in development and regulatory approval. There can be no assurance that we will receive the extension of the patent term provided under the Hatch-Waxman Act. If we fail to receive such extension, our ability to prevent competitors from manufacturing, marketing and selling generic versions of Triferic® could be impaired and we would have to rely on the protection afforded us by the U.S. patent we hold on the synthesis and formulation of our pharmaceutical grade formulation of Triferic® which expires in 2029 or on other patents related to Triferic® that may be issued to us in the future.

FDA approval to manufacture Calcitriol may take longer than we anticipate and commercial launch may be delayed or may not be widely adopted when launched.

We are seeking FDA approval for a change in manufacturing location for a generic version of Calcitriol, the ANDA for which we acquired from a third party. The timing for receiving approval of this change from the FDA is not predictable. If we receive approval of this change, we must meet certain ongoing regulatory requirements for product testing and stability of our commercially marketed products. If our testing does not meet approvable standards or if we experience operational issues with our CMO we may not be able to market Calcitriol.

The market for generic drugs such as Calcitriol is generally very competitive. Even if the FDA approves our change in manufacturing location for Calcitriol so that we can begin marketing it, we may encounter a very competitive environment for Calcitriol which may make it difficult for us to capture significant market share. If we do have success in capturing market share with Calcitriol, it may attract other entrants to market their own generic version of Calcitriol, which could have a material adverse effect on our future revenues and results of operations. Branded competitors may aggressively lower their prices to maintain market share.

We could be prevented from selling products, forced to pay damages and compelled to defend against litigation if we infringe the rights of a third party.

Our success, competitive position and future revenues will depend in part on our ability to obtain and maintain patent protection for our products, methods, processes and other technologies, to preserve our trade secrets, to prevent third parties from infringing on our proprietary rights and to operate without infringing the proprietary rights of third parties.

We could incur substantial costs in seeking enforcement of our patent rights against infringement, and we cannot guarantee that such patents will successfully preclude others from using technology that we rely upon. We have no knowledge of any infringement or patent litigation, threatened or filed at this time. It is possible that we may infringe on intellectual property rights of others without being aware of the infringement. If a third party believes that one of our products infringes on the third party's patent, it may sue us even if we have received our own patent protection for the technology. If we infringe the rights of a third party, we could be prevented from selling products, forced to pay damages and compelled to defend against litigation.

We may not be successful in obtaining foreign regulatory approvals or in arranging a business development, out-licensing or other venture to realize commercialization of our drug products outside of the United States.

The approval procedures for the marketing of our new drug products, such as Triferic®, in foreign countries vary from country to country, can be difficult to obtain and carry all of the same risks as FDA approval. In particular, regulatory approval in foreign countries may require additional testing in

the applicable country, may otherwise be expensive to undertake and may take a long time to obtain. Even after foreign approvals are obtained, further delays may be encountered before products may be marketed. Many countries require additional governmental approval for price reimbursement under national health insurance systems.

Even if we obtain the necessary foreign approval in a particular market, we do not have substantial expertise selling and marketing on an international level and therefore may not be successful in realizing commercial value from our products. Our strategy for addressing the need for expertise in obtaining foreign approvals and marketing in foreign markets is to out-license rights to Triferic® in markets outside the United States. However, we may not be successful in finding a partner or partners who will be willing to invest in Triferic® outside the United States. If we are not successful in out-licensing Triferic® outside of the United States or entering into some other business development arrangement to obtain the necessary approvals and market Triferic®, we may be forced to seek regulatory approval and market the product ourselves. If we elect to seek approval ourselves in certain markets, it may take longer than expected to obtain needed regulatory approvals and to market and manufacture Triferic®, and we may decide to delay or abandon development efforts in certain markets.

Any such delay or abandonment, or any failure to receive one or more foreign approvals, may have a material adverse effect on the benefits otherwise expected from marketing in foreign countries.

Our dialysis concentrate business is substantially dependent on a few customers that account for a substantial portion of our sales. The loss of any of these customers could have a material adverse effect on our results of operations and cash flow from our dialysis business and on our ability to market our new drug products.

Our revenue is highly concentrated in a few customers and the loss of any of those customers could adversely affect our results of operations. One customer in particular accounted for nearly half of our sales in each of the last three years and for a substantial number of the clinics we serve. Our strategy is to develop new renal drugs and market them to our existing dialysis clinic customers. If we were to lose this customer or our relationship with any of our other major dialysis chain customers, it could have a substantial negative impact on the cash flow and operating results of our dialysis concentrate business and may have a detrimental impact on our ability to market our new drug products.

We operate in a very competitive market against a substantially larger competitor with greater resources.

There is intense competition in the hemodialysis product market and our primary competitor is a large diversified company which has substantially greater financial, technical, manufacturing, marketing, research and development and management resources than we do. We may not be able to successfully compete with them or other companies. Our primary competitor has historically used product bundling and low pricing as marketing techniques to capture market share of the products we sell and as we do not manufacture or sell the same breadth of products as our primary competitor, we may be at a disadvantage in competing against their marketing strategies. Furthermore, our primary competitor is vertically integrated and is the largest provider of dialysis services in the United States with approximately 37% of all U.S. patients treated by this company through its clinics. This competitor has routinely acquired smaller clinic chain operations that we served and may acquire more of our customers in the future.

We may not be successful in maintaining our gross profit margins.

A significant portion of our costs are for chemicals and fuel which are subject to pricing volatility based on demand and are highly influenced by the overall level of economic activity in the U.S. and abroad. These costs have risen each year and have had a negative effect on our gross margins. We may

realize future cost and pricing pressure which may cause our gross profit margins to decrease in the future and have a material adverse effect on our results of operations.

Our dialysis solutions products are distribution-intensive, resulting in a high cost to deliver relative to the selling prices of our products. The cost of diesel fuel represents a significant operating cost for us. If oil costs increase, we may be unable to recover those increased costs through higher pricing. Also, as we increase our business in certain markets and regions that are farther from our manufacturing facilities than we have historically served, we may incur additional costs that are greater than the additional revenue generated from these initiatives. Our customer mix may change to a less favorable customer base with lower gross profit margins.

Our competitors have often used bundling techniques to sell a broad range of products and have often offered low prices on dialysis concentrate products to induce customers to purchase their other higher margin products, such as dialysis machines and dialyzers. It may be difficult for us to raise prices due to these competitive pressures.

Our suppliers may increase their prices faster than we are able to raise our prices to offset such increases. We may have limited ability to gain a raw material pricing advantage by changing vendors for certain chemicals and packaging materials.

As we increase our manufacturing and distribution infrastructure we may incur costs for an indefinite period that are greater than the incremental revenue we derive from these expansion efforts.

We depend on government funding of health care, changes in which could impact our ability to be paid in full for our products, increase pricing pressures or cause consolidation in the dialysis provider market.

Many of our customers receive the majority of their funding from the government and are supplemented by payments from private health care insurers. Our customers depend on Medicare and Medicaid funding to be viable businesses. A variety of changes to health insurance and reimbursement are included in health reform legislation enacted by Congress in recent years. Some of these changes could have a negative impact on Medicare and Medicaid funding, which fund the majority of dialysis costs in the United States, and on reimbursement protocols. If Medicare and Medicaid funding were to be materially decreased, our customers would be severely impacted, increasing our risk of not being paid in full by our customers. An increase in our exposure to uncollectible accounts could have a material adverse effect on our financial position, results of operations and cash flows.

In the United States, the Medicare Improvements for Patients and Providers Act of 2008 or "MIPPA" changed the dialysis reimbursement method from the prior practice of separately billed services and medications to a single bundled prospective rate for Medicare outpatient ESRD facilities beginning January 1, 2011, with full implementation by January 1, 2012. Most dialysis providers have adopted this method of reimbursement, which provides for a single payment per dialysis treatment compared to the current method consisting of a composite rate payment and separately billed drugs and services. We anticipate that dialysis providers will continue to seek ways to reduce their costs per treatment due to this change in reimbursement practice which could reduce our sales and profitability and have a material adverse effect on our business, financial condition and results of operations.

As a result of these changes to Medicare reimbursement, industry observers also anticipate increased consolidation in the dialysis provider market which has been largely unchecked by the Federal Trade Commission to date. Continued consolidation in providers will likely result in increased purchasing leverage for providers across all dialysis product categories and increased pricing pressure on all suppliers to the industry.

We will rely on third party suppliers for raw materials, packaging components and manufacturing of our drug products for our commercially marketed drug products once they are approved. We may not be able to obtain the raw materials, components and manufacturing capacity we need, or the cost of the materials, components and manufacturing capacity may be higher than expected, any of which could have a material adverse effect on our expected results of operations, financial position and cash flows.

For our drug products, we will rely on unaffiliated third-party suppliers for raw materials, packaging components and manufacturing of our finished drug products. Certain of those raw materials and packaging components may be the proprietary products of those unaffiliated third-party suppliers and are specifically cited in our drug application with regulatory agencies so that they must be obtained from that specific source or sources and could not be obtained from another supplier unless and until the regulatory agency has approved such supplier. We may not be able to obtain needed raw materials, packaging components and manufacturing capacity for a variety of reasons, including among others:

regulatory requirements or action by regulatory agencies or others;

adverse financial or other strategic developments at or affecting the supplier or contract manufacturer;

unexpected demand for or shortage of raw materials or packaging components;

failure to comply with cGMP standards which results in quality or product failures, adulteration, contamination and/or recall;

limitations in capacity of contract manufacturers; and,

changes in product demand.

If we are unable to obtain the raw materials, components and manufacturing capacity we require, or if we are charged more than expected for these items, we may not be able to produce our drug products or our gross profit margins may be materially adversely affected.

Health care reform could adversely affect our business.

The federal and state governments in the United States, as well as many foreign governments, from time to time explore ways to reduce medical care costs through health care reform. The federal Medicare and Medicaid programs are facing financial challenges and are looking at ways to reduce the costs of the Medicare and Medicaid programs. Similarly, many states have large deficits which may prove unsustainable, resulting in defaults on state debt obligations which may ultimately result in the reduction or curtailment of health care benefits or state Medicaid reimbursement.

In the United States, Congress enacted the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, referred to collectively as PPACA, in 2010 that has made significant changes to the health care payment and delivery system. The PPACA requires employers to provide employees with insurance coverage that meets minimum eligibility and coverage requirements or face penalties. The PPACA also includes provisions that impact the number of individuals with insurance coverage, including expansion of those eligible for Medicaid in some states, the types of coverage and level of health benefits that are required and the amount of payment providers performing health care services receive. The PPACA imposes implementation effective dates beginning in 2010 and extending through 2020. In addition, the PPACA imposes fees or excise taxes on pharmaceutical and device manufacturers based on their sales results. As a result, the Company was required to pay $0.8 million in excise taxes in 2013. The U.S. government faces structural deficits that may require changes to government funded healthcare programs such as Medicare and Medicaid which may negatively impact customers of our products. On March 1, 2013, President Obama issued a sequestration order that imposed a 2% "across the board" reduction in Medicare reimbursement. Our sales, results of operations, cash flows and ability to commercialize our drug

products could be materially impacted by the PPACA, future health care reform or reduced Medicare and Medicaid spending by the federal government.

Beginning in early 2014 and annually thereafter, device and pharmaceutical manufacturers are required to report to the FDA regarding certain financial relationships they have with physicians and teaching hospitals. This reporting requirement will increase governmental scrutiny on our contractual relationships with physicians and teaching hospitals and will increase the risk that inadvertent violations result in liability under the federal fraud and abuse laws, which could have a material adverse effect on our results of operations, financial position and cash flows.

We depend on key personnel, the loss of which could harm our ability to operate.

Our success depends heavily on the efforts of Robert L. Chioini, a founder and our President and Chief Executive Officer, Dr. Ajay Gupta MD, our Chief Scientific Officer, Dr. Raymond D. Pratt, our Chief Medical Officer and Thomas E. Klema, our Chief Financial Officer, Secretary and Treasurer. Mr. Chioini is primarily responsible for the strategic direction of the Company and for managing our sales and marketing efforts. Dr. Gupta is primarily responsible for discovery and development of new technologies. Dr. Pratt is primarily responsible for the clinical development, testing and regulatory approval of our products. None of our executive management are parties to a current employment agreement with the Company. If we lose the services of Mr. Chioini, Dr. Gupta, Dr. Pratt or Mr. Klema, our business, product development efforts, financial condition and results of operations could be adversely affected.

Our business is highly regulated, which increases our costs and results in risks relating to potential noncompliance.

The testing, manufacture and sale of the products we manufacture and distribute are subject to extensive regulation by the FDA and by other federal, state and foreign authorities. Before medical devices can be commercially marketed in the United States, the FDA must give either 510(k) clearance or pre-market approval for the devices. If we do not comply with these requirements, we may be subject to a variety of sanctions, including fines, injunctions, seizure of products, suspension of production, denial of future regulatory approvals, withdrawal of existing regulatory approvals and criminal prosecution. Our business could be adversely affected by any of these actions.

Although our hemodialysis concentrates have been cleared by the FDA, it could rescind these clearances and any new products or modifications to our current products that we develop could fail to receive FDA clearance. If the FDA rescinds or denies any current or future clearances or approvals for our products, we would be prohibited from selling those products in the United States until we obtain such clearances or approvals. Our business would be adversely affected by any such prohibition, any delay in obtaining necessary regulatory approvals, and any limits placed by the FDA on our intended use. Our products are also subject to federal regulations regarding manufacturing quality. In addition, our new products will be subject to review and approval by the FDA. The process of obtaining such approval is time-consuming and expensive. In addition, changes in applicable regulatory requirements could significantly increase the costs of our operations and may reduce our profitability if we are unable to recover any such cost increases through higher prices.

We may not have sufficient products liability insurance.

As a supplier of medical products, we may face potential liability from a person who claims that he or she suffered harm as a result of using our products. We maintain products liability insurance in the amount of $5 million per occurrence and $5 million in the aggregate. We cannot be sure that it will remain economical to retain our current level of insurance, that our current insurance will remain available or that such insurance would be sufficient to protect us against liabilities associated with our

business, particularly if it expands substantially in the wake of the potential FDA approval of Triferic®. We may be sued, and we may have significant legal expenses that are not covered by insurance. In addition, our reputation could be damaged by product liability litigation and that could harm our marketing ability. Any litigation could also hurt our ability to retain products liability insurance or make such insurance more expensive. Our business, financial condition and results of operations could be adversely affected by an uninsured or inadequately insured product liability claim in the future.

RISKS RELATED TO OUR COMMON STOCK

Shares eligible for future sale may negatively affect the market price of our common shares.

Any additional future sales of common shares by us may have a negative effect on the market price of our common shares. Sales of substantial amounts of our common shares (including shares issued upon the exercise of stock options or warrants), or the possibility of such sales, could adversely affect the market price of our common shares and also impair our ability to raise capital through an offering of our equity securities in the future. As of December 31, 2013, an additional 983,071 shares may be issued upon exercise of outstanding warrants. In the future, we may issue additional shares or warrants in connection with investments or for other purposes considered advisable by our Board of Directors. Any substantial sale of our common shares may have an adverse effect on the market price of our common shares and may dilute the economic value and voting rights of existing shareholders.

In addition, as of December 31, 2013, there were 4,513,567 shares issuable upon the exercise of outstanding and exercisable stock options, 1,714,433 shares issuable upon the exercise of outstanding stock options that are not yet exercisable and 1,409,165 additional shares available for grant under our 2007 Long Term Incentive Plan. Additional grants have been made in 2014. The market price of the common shares may be depressed by the potential exercise of these options or warrants. The holders of these options and warrants are likely to exercise them when we would otherwise be able to obtain additional capital on more favorable terms than those provided by the options.

Our stock price could be volatile.

Our stock price, like the market price of many stocks in the biotechnology and pharmaceutical industries, is volatile. Events such as announcements around clinical testing results or regulatory approval of a product, as well as the reporting of sales, operating results and cash resources, may cause significant fluctuations in our share price. In addition, third parties may engage in trading strategies that result in intentional volatility to our share price, given our relatively small public market float.

We could have a material weakness in our internal control over financial reporting, which, until remedied, could result in errors in our financial statements requiring restatement of our financial statements. As a result, investors may lose confidence in our reported financial information, which could lead to a decline in our stock price.

SEC rules require us to evaluate the effectiveness of our internal control over financial reporting as of the end of each year, and to include a management report assessing the effectiveness of our internal control over financial reporting in each Annual Report on Form 10-K. It is possible, due to the small size of our accounting staff, that we may identify control deficiencies in the future that constitute one or more material weaknesses. If our internal control over financial reporting or disclosure controls and procedures are not effective, there may be errors in our financial statements and in our disclosure that could require restatements. Investors may lose confidence in our reported financial information and in our disclosure, which could lead to a decline in our stock price.

No system of internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Further, the design of a control system must

reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. Over time, controls may become inadequate because changes in conditions or deterioration in the degree of compliance with policies or procedures may occur. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. As a result, we cannot assure you that significant deficiencies or material weaknesses in our internal control over financial reporting will not be identified in the future.

Structural and anti-takeover provisions reduce the likelihood that you will receive a takeover premium.

The Board of Directors has the authority, without shareholder approval, to issue shares of preferred stock having such rights, preferences and privileges as the Board of Directors may determine. Any such issuance of preferred stock could, under certain circumstances, have the effect of delaying or preventing a change in control and may adversely affect the rights of holders of common shares, including by decreasing the amount of earnings and assets available for distribution to holders of common shares and adversely affect the relative voting power or other rights of the holders of the common shares. In addition, we may become subject to Michigan statutes regulating business combinations which might also hinder or delay a change in control. Anti-takeover provisions that could be included in the preferred stock when issued and the Michigan statutes regulating business combinations can have a depressive effect on the market price of our common shares and can limit shareholders' ability to receive a premium on their shares by discouraging takeover and tender offers. In addition, amounts outstanding under our secured loan agreement must be prepaid in the event of a change in control of the Company.

Our shareholders do not have the right to cumulative voting in the election of directors. Moreover, our directors serve staggered three-year terms, and directors may not be removed without cause. These provisions could have an anti-takeover effect by making it more difficult to acquire us by means of a tender offer, a proxy contest or otherwise, or to remove incumbent directors. These provisions could delay, deter or prevent a tender offer or takeover attempt that a shareholder might consider in his or her best interests, including those attempts that might result in a premium over the market price for the common shares.

We do not anticipate paying dividends in the foreseeable future.

Since inception, we have not paid any cash dividend on our common shares and do not anticipate paying such dividends in the foreseeable future. The payment of dividends is within the discretion of our Board of Directors and depends upon our earnings, capital requirements, financial condition and requirements, future prospects, restrictions in future financing agreements, business conditions and other factors deemed relevant by the Board. We intend to retain earnings and any cash resources to finance our operations. Moreover, our secured loan agreement prohibits the payment of dividends. Therefore, it is highly unlikely we will pay cash dividends.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

We occupy a 51,000 square foot facility and a 17,500 square foot facility in Wixom, Michigan under a lease expiring in August 2015. We also occupy a 51,000 square foot facility in Grapevine, Texas under a lease expiring in December 2015. In addition, we lease a 57,000 square foot facility in Greer, South Carolina under a lease expiring in February 2016.

We intend to use each of our facilities to manufacture and warehouse our products. All such facilities and their contents are covered under various insurance policies which management believes provide adequate coverage. We also use the office space in Wixom, Michigan as our principal administrative office. With our continued growth we expect that we will require additional office space, manufacturing capacity and distribution facilities to meet our business requirements.

Item 3. Legal Proceedings.

We are involved in certain legal proceedings before various courts and governmental agencies concerning matters arising in the ordinary course of business. We cannot predict the final disposition of such proceedings. We regularly review legal matters and record provisions for claims that are considered probable of loss. The resolution of pending proceedings is not expected to have a material effect on our operations or consolidated financial statements in the period in which they are resolved.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Our common shares trade on the Nasdaq Global Market under the trading symbol "RMTI". The prices below are the high and low sale prices as reported by the Nasdaq Global Market in each quarter during 2013 and 2012.

	Price Range	
	High	Low
2013		
Fourth Quarter	$ 15.85	$ 9.51
Third Quarter	12.25	3.40
Second Quarter	4.41	3.25
First Quarter	8.40	3.16
2012		
Fourth Quarter	$ 8.38	$ 5.18
Third Quarter	9.60	7.64
Second Quarter	10.70	7.37
First Quarter	11.75	8.08

As of February 14, 2014, there were 24 holders of record of our common shares.

Dividends

Our Board of Directors has discretion whether or not to pay dividends. Among the factors our Board of Directors considers when determining whether or not to pay dividends are our earnings, capital requirements, financial condition, future business prospects and business conditions. We have never paid any cash dividends on our common shares and do not anticipate paying dividends in the foreseeable future. We intend to retain earnings, if any, to finance the development and expansion of our operations. Our secured loan agreement prohibits us from paying dividends while the loan is outstanding.

Securities Authorized for Issuance Under Equity Compensation Plans

The information contained under "Item 12 Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters" of this Annual Report on Form 10-K under the heading "Securities Authorized for Issuance Under Equity Compensation Plans" is incorporated herein by reference.

Performance Graph

The following graph compares the cumulative 5-year total return of holders of the Company's common stock with the cumulative total returns of the Russell 2000 index and the Nasdaq Biotechnology index. The graph tracks the performance of a $100 investment in our common stock and in each of the indexes (with reinvestment of all dividends, if any) on December 31, 2008 with relative performance tracked through December 31, 2013. The stock price performance included in this graph is not necessarily indicative of future stock price performance.

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*
Among Rockwell Medical, Inc., the Russell 2000 Index,
and the NASDAQ Biotechnology Index

*

$100 invested on 12/31/08 in stock or index, including reinvestment of dividends. Fiscal year ending December 31.

	12/31/2008	12/31/2009	12/31/2010	12/31/2011	12/31/2012	12/31/2013
Rockwell Medical	**100.00**	**183.53**	**188.54**	**202.15**	**192.12**	**249.16**
Russell 2000	**100.00**	**127.17**	**161.32**	**154.59**	**179.86**	**249.69**
NASDAQ Biotechnology	**100.00**	**104.67**	**112.89**	**127.04**	**169.50**	**288.38**

The information furnished under the heading "Stock Performance Graph" shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section, and such information shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended.

Item 6. Selected Financial Data.

The financial data in the following tables should be read in conjunction with the consolidated financial statements and notes thereto and Management's Discussion and Analysis of Financial Condition and Results of Operations included in this Form 10-K.

	For the Year Ended December 31,				
	2013	2012	2011	2010	2009
Net sales	$ 52,379,543	$ 49,842,392	$ 48,966,231	$ 59,554,592	$ 54,729,505
Cost of sales	45,720,323	43,148,965	43,323,321	49,693,753	46,842,334
Gross profit	6,659,220	6,693,427	5,642,910	9,860,839	7,887,171
Income from continuing operations before interest expense and income taxes(1)	(47,059,266)	(54,262,082)	(21,684,757)	(2,868,916)	(5,481,379)
Interest (expense) and Investment Income, net	(1,724,046)	240,567	242,205	185,517	(19,859)
Income from continuing operations before income taxes	(48,783,312)	(54,021,515)	(21,442,552)	(2,683,399)	(5,501,238)
Income taxes			2,005		
Net income	(48,783,312)	(54,021,515)	(21,444,557)	(2,683,399)	(5,501,238)
Earnings per common share:					
Basic	$ (1.48)	$ (2.65)	$ (1.21)	$ (0.16)	$ (0.37)
Diluted	$ (1.48)	$ (2.65)	$ (1.21)	$ (0.16)	$ (0.37)
Weighted average number of common shares and common share equivalents					
Basic	32,882,333	20,395,889	17,774,865	17,111,535	14,709,016
Diluted	32,882,333	20,395,889	17,774,865	17,111,535	14,709,016

	2013	2012	2011	2010	2009
Total assets	$ 36,362,124	$ 17,025,086	$ 31,939,599	$ 36,966,907	$ 34,879,221
Current assets	31,917,774	13,149,432	25,896,529	32,666,368	29,948,945
Current liabilities	17,849,671	26,986,956	13,692,351	6,420,220	5,536,957
Working capital	14,068,103	(13,837,524)	12,204,178	26,246,148	24,411,988
Long-term debt and capitalized lease obligations	17,916,914		2,280	8,750	19,062
Stockholders' equity(2)	595,539	(9,961,870)	18,244,968	30,537,937	29,323,202
Book value per outstanding common share	$ 0.01	$ (0.46)	$ 0.98	$ 1.74	$ 1.70
Common shares outstanding	40,110,661	21,494,696	18,710,002	17,513,608	17,200,442

(1) Increase in loss reflects significant increase in research and development expenses associated with Phase 3 clinical trials for Triferic®.

(2) There were no cash dividends paid during the periods presented. Stockholders' equity reflects the proceeds of public offerings in 2009, 2012 and 2013.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Overview and Recent Developments

Rockwell is a fully-integrated pharmaceutical company targeting end-stage renal disease and chronic kidney disease with innovative products and services for the treatment of iron deficiency, secondary hyperparathyroidism and hemodialysis. We are also an established manufacturer and leader in delivering high-quality hemodialysis concentrates/dialysates to dialysis providers and distributors in the U.S. and abroad.

We are currently developing unique, proprietary renal drug therapies. These novel renal drug therapies support disease management initiatives to improve the quality of life and care of dialysis patients and are designed to deliver safe and effective therapy, while decreasing drug administration costs and improving patient convenience and outcome.

Our strategy is to develop high potential drugs while expanding our dialysis products business. In 2013, our sales increased 5.1% to $52.4 million. The increase in sales was primarily a result of increased business with current customers. We signed a multi-year contract extension through 2018 with our largest customer, which increased the number of committed clinics purchasing from us, but we do not expect a material increase in gross profit to result from the increase. Most of our total sales are to domestic clinics that order routinely. From time to time, we have experienced volatility in international sales.

Our product development costs were primarily related to completing the Phase 3 clinical trials for Triferic®, our lead drug candidate. We believe our Triferic® product has unique and substantive benefits compared to current treatment options and has the potential to compete in the iron maintenance therapy market. We successfully completed the Phase 3 clinical trial program for Triferic® in early 2014 and we are preparing to file our NDA for Triferic® in the first quarter of 2014.

In 2011, we acquired the right to manufacture the generic version of Calcitriol, a vitamin D analogue, indicated in the treatment of secondary hyperparathyroidism, which is common in ESRD patients. We are in the process of obtaining FDA approval to make a change in manufacturing locations and we expect to receive such approval during the first half of 2014. We anticipate that our gross profit margins and operating cash flows will improve once we begin marketing Calcitriol.

In March and May 2013, we completed common stock offerings for a total of approximately $50.4 million in net proceeds. In June 2013, we entered into a secured loan agreement and borrowed $20.0 million.

As of December 31, 2013, we had $23.9 million in cash, cash equivalents and short term investments. We have completed the major spending on Triferic® development and future spending on Triferic® R&D and commercial launch is not expected to require additional cash resources to complete. We believe we have adequate cash resources to fund our business development and drug launch efforts for Triferic® and Calcitriol.

Results of Operations

For the year ended December 31, 2013 compared to the year ended December 31, 2012

Sales

In 2013, our sales were $52.4 million compared to $49.9 million in 2012. Sales increased $2.5 million or 5.1% in 2013 compared to 2012. Domestic sales increased $1.8 million or 4.0% to $46.0 million while international sales increased by $0.8 million or 14% to $6.4 million.

Domestic sales increased due to new business additions, including the renewal and expansion of the supply agreement with our largest customer, as well as conversions to our CitraPure and dry acid concentrate product lines.

Dry acid concentrate lowers providers' cost per treatment and reduces our sales, but improves our gross profit margins due to a reduction in shipping costs.

International sales and domestic sales shipped internationally increased due to increased demand in international markets for dialysis products.

Gross Profit

Our gross profit was $6.7 million in both 2013 and 2012. Gross profit margins were 12.7% in 2013 compared to 13.4% in 2012. Favorable product mix changes from CitraPure growth were offset by higher costs for material, shipping and operating costs, as well as growth in lower margin sales and higher regulatory compliance costs.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $14.3 million in 2013 compared to $12.7 million in 2012. The increase of $1.6 million was primarily due to an increase of $1.3 million in compensation expense, an increase of $0.6 million in non-cash charges relating to extending the expiration date of outstanding warrants and an increase in other expense of $0.8 million attributable to the medical device excise tax imposed on us beginning in 2013. These increases were partially offset by a reduction in non-cash equity compensation for services of $1.1 million.

The increase in compensation costs included an increase in non-cash charges for equity compensation of $0.9 million while cash compensation and benefit costs increased $0.4 million.

Research and Development

We incurred product development and research costs related to the commercial development, patent approval and regulatory approval of new products, primarily Triferic®, aggregating approximately $39.4 million and $48.3 million in 2013 and 2012, respectively. Costs incurred in 2013 and 2012 were primarily for conducting human clinical trials of Triferic® and other Triferic® testing and development activities. We have now completed the clinical testing for Triferic® and incurred the majority of Triferic® development expenses by the end of 2013.

Interest Expense, Net

Our net interest expense was $1,724,000 in 2013 compared to net interest and investment income of $242,000 in 2012. The increase in net interest expense was due to the loan agreement entered into in June 2013 coupled with reduced net interest and investment income due to lower funds available for investment in 2013 compared to 2012.

Income Tax Expense

We have substantial tax loss carryforwards from our earlier losses. We have not recorded a federal income tax benefit from either our prior losses or our current year losses because we might not realize the carryforward benefit of the remaining losses.

For the year ended December 31, 2012 compared to the year ended December 31, 2011

Sales

In 2012, our sales were $49.9 million compared to $49.0 million in 2011. Sales increased $0.9 million or 1.8% in 2012 compared to 2011. Domestic sales increased $1.7 million or 3.9% to $44.2 million while international sales decreased by $0.8 million or 12.1% to $5.6 million. International sales to a single international distributor decreased $1.4 million while all other international sales increased $0.6 million.

Domestic sales increased due to new business additions as well as changes in product mix to higher margin products including our CitraPure product lines and due to higher volume of our dry acid concentrate product lines.

Gross Profit

Our gross profit in 2012 was $6.7 million an increase of $1.1 million or 18.6% compared to 2011. Gross profit margins were 13.4% in 2012 compared to 11.5% in 2011. The increase in gross profit margins was due to increased sales of higher margin products and product lines including our CitraPure product lines along with conversions to dry acid concentrates. Margins also benefited from efforts to control operating costs in the face of inflationary cost increases for material, transportation operating costs and diesel fuel.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $12.7 million in 2012 compared to $9.5 million in 2011. The increase of $3.2 million was primarily due to an increase in non-cash charges for equity compensation of $2.9 million. Employee non-cash equity compensation aggregated $5.0 million in 2012 compared to $4.1 million in 2011. In addition, share based compensation for services increased $2.0 million to $2.3 million in 2012.

Research and Development

We incurred product development and research costs related to the commercial development, patent approval and regulatory approval of new products, primarily Triferic®, aggregating approximately $48.3 million and $17.8 million in 2012 and 2011, respectively. Costs incurred in both 2012 and 2011 were primarily for conducting human clinical trials of Triferic® and other Triferic® testing and development activities. Our spending increased considerably in 2012 for our Phase 3 clinical program as enrollment efforts and related testing activities increased dramatically and were in effect for the full year.

Interest and Investment Income, Net

Net interest and investment income in 2012 was $242,000 compared to $244,000 in 2011. We earned higher rates of return on investable funds in 2012 compared to 2011 while overall investable funds were reduced throughout 2012 to fund our clinical development program.

Income Tax Expense

We have substantial tax loss carryforwards from our earlier losses. We have not recorded a federal income tax benefit from either our prior losses or our current year losses because we might not realize the carryforward benefit of the remaining losses.

Critical Accounting Estimates and Judgments

Our consolidated financial statements and accompanying notes are prepared in accordance with accounting principles generally accepted in the United States of America. These accounting principles require us to make estimates, judgments and assumptions that affect the reported amounts of revenues, expenses, assets, liabilities, and contingencies. All significant estimates, judgments and assumptions are developed based on the best information available to us at the time made and are regularly reviewed and updated when necessary. Actual results will generally differ from these estimates. Changes in estimates are reflected in our financial statements in the period of change based upon on-going actual experience, trends, or subsequent realization depending on the nature and predictability of the estimates and contingencies.

Interim changes in estimates are generally applied prospectively within annual periods. Certain accounting estimates, including those concerning revenue recognition, allowance for doubtful accounts, impairments of long-lived assets, and accounting for income taxes, are considered to be critical in evaluating and understanding our financial results because they involve inherently uncertain matters and their application requires the most difficult and complex judgments and estimates. These are described below. For further information on our accounting policies, see Note 2 to our Consolidated Financial Statements.

Revenue recognition

We recognize revenue at the time we transfer title to our products to our customers consistent with generally accepted accounting principles. Our products are generally sold domestically on a delivered basis and as a result we do not recognize revenue until delivered to the customer with title transferring upon completion of the delivery. For our international sales, we recognize revenue upon the transfer of title as defined by standard shipping terms and conventions uniformly recognized in international trade.

Allowance for doubtful accounts

Accounts receivable are stated at invoice amounts. The carrying amount of trade accounts receivable is reduced by an allowance for doubtful accounts that reflects our best estimate of accounts that may not be collected. We review outstanding trade account receivable balances and based on our assessment of expected collections, we estimate the portion, if any, of the balance that may not be collected as well as a general valuation allowance for other accounts receivable based primarily on historical experience. All accounts or portions thereof deemed to be uncollectible are written off to the allowance for doubtful accounts. If we underestimate the allowance, we would incur a current period expense which could have a material adverse effect on earnings.

Impairments of long-lived assets

We account for impairment of long-lived assets, which include property and equipment, amortizable and non-amortizable intangible assets and goodwill, in accordance with authoritative accounting pronouncements. An impairment review is performed annually or whenever a change in condition occurs which indicates that the carrying amounts of assets may not be recoverable. Such changes may include changes in our business strategies and plans, changes to our customer contracts, changes to our product lines and changes in our operating practices. We use a variety of factors to assess the realizable value of long-lived assets depending on their nature and use.

Goodwill is not amortized; however, it must be tested for impairment at least annually. The goodwill impairment analysis is based on the fair market value of our common shares. Amortization continues to be recorded for other intangible assets with definite lives over the estimated useful lives. Intangible assets subject to amortization are reviewed for potential impairment whenever events or

circumstances indicate that carrying amounts may not be recoverable based on future cash flows. If we determine that goodwill has been impaired, the change in value will be accounted for as a current period expense and could have a material adverse effect on earnings.

Accounting for income taxes

We estimate our income tax provision to recognize our tax expense and our deferred tax liabilities and assets for future tax consequences of events that have been recognized in our financial statements using current enacted tax laws. Deferred tax assets must be assessed based upon the likelihood of recoverability from future taxable income and to the extent that recovery is not likely, a valuation allowance is established. The allowance is regularly reviewed and updated for changes in circumstances that would cause a change in judgment about whether the related deferred tax asset may be realized. These calculations and assessments involve complex estimates and judgments because the ultimate tax outcome can be uncertain and future events unpredictable. If we determine that the deferred tax asset will be realized in the future, it may result in a material beneficial effect on earnings.

New Accounting Pronouncements

No new accounting pronouncements that were issued or became effective during the year have had or are expected to have a material impact on our Consolidated Financial Statements.

Liquidity and Capital Resources

Our strategy is centered on obtaining regulatory approval to market Triferic® and developing other high potential drug candidates, while also expanding our dialysis products business. We have completed the clinical trials required for the submission of our NDA for Triferic®. Our future spending on research and development for Triferic® is not expected to be material in future periods. We believe we have adequate cash resources to launch Triferic® once approved by the FDA and to fund other business development opportunities we may elect to pursue.

Our cash resources include cash generated from our business operations, the $50.4 million in net proceeds generated from equity offerings during 2013 and the $20.0 million borrowed under the secured loan agreement executed in June 2013. The repayment and other terms of the loan are described in Note 10 to our Consolidated Financial Statements. We were in compliance with the terms of the loan agreement and there was no event of default as of December 31, 2013. As of December 31, 2013, our cash and investments were $23.9 million and our current assets exceeded our current liabilities by $14.1 million.

We expect to generate positive cash flow from operations in 2014, excluding research and development related expenditures. The Company intends to expand its customer relationships and to introduce Calcitriol in 2014 which we anticipate will result in increased cash availability and higher future cash flows if successful. We believe that cash flow from operations will increase substantially when sales of Calcitriol commence.

The Company is in discussion with potential business development partners to license rights to its products outside the United States and to partner its dialysis business with interested parties including joint ventures, partnerships and other arrangements. We do not expect to require additional cash resources to execute our business plan.

Contractual Obligations

The following table details our contractual obligations as of December 31, 2013:

	Payments due by period				
Contractual Obligations	**Total**	**Less than 1 year**	**1 - 3 years**	**3 - 5 years**	**More than 5 years**
Long term debt	$ 21,100,000	$ 2,308,145	$ 18,791,855		
Capital leases					
Operating leases	5,501,726	1,500,697	1,929,332	1,472,137	599,560
Purchase obligations					
All other long term liabilities					
Total	$ 26,601,726	$ 3,808,842	$ 20,721,187	$ 1,472,137	$ 599.560

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that have or are reasonably likely to have a material effect on our financial condition.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk.

Interest Rate Risk

Our current exposure to interest rate risk is primarily on our long term debt. As of December 31, 2013 we owed $20,000,000 in current and long term debt related to a loan we entered into in June 2013. The loan bears interest at the greater of (i) 12.50% plus the prime rate as reported in The Wall Street Journal minus 3.25%, or (ii) 12.50%.

We are exposed to interest rate risk on this loan to the extent the prime rate rises above 3.25%. If the prime rate were to increase to 3.25%, a hypothetical 100 basis point increase above that rate would increase interest expense by $200,000.

We have invested $12.0 million in available for sale securities which are invested in short term bond funds which typically yield higher returns than the interest realized in money market funds. While these funds hold bonds of short term duration, their market value is affected by changes in interest rates. Increases in interest rates will reduce the market value of bonds held in these funds and we may incur unrealized losses from the reduction in market value of the fund. If we liquidate our position in these funds, those unrealized losses may result in realized losses which may or may not exceed the interest and dividends earned from those funds. However, due to the short duration of these short term bond fund portfolios, we do not believe that a hypothetical 100 basis point increase or decrease in interest rates will have a material impact on the value of our investment portfolio.

Foreign Currency Exchange Rate Risk

Our international business is conducted in U.S. dollars. It has not been our practice to hedge the risk of appreciation of the U.S. dollar against the predominant currencies of our trading partners. We have no significant foreign currency exposure to foreign supplied materials, and an immediate 10% strengthening or weakening of the U.S. dollar would not have a material impact on our shareholders' equity or net income.

Item 8. Financial Statements.

The Consolidated Financial Statements of the Registrant and other information required by this item are set forth on pages F-1 through F-19 and incorporated herein by reference.

Item 9. Changes In and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure material information required to be disclosed in our 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 that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required financial disclosure. In designing and evaluating the disclosure controls and procedures, we recognized that a control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected. Management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As of the end of the period covered by this report, we carried out an evaluation under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting. We maintain internal control over financial reporting designed to provide reasonable, but not absolute, assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Therefore, internal control over financial reporting determined to be effective provides only reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

Under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, management evaluated the effectiveness of our internal control over financial reporting as of December 31, 2013. In making its assessment of internal control over financial reporting, management used the criteria described in the 1992 Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Our evaluation included documenting, evaluating and testing of the design and operating effectiveness of our internal control over financial reporting. Based on this evaluation, we concluded that the Company's internal control over financial reporting was effective as of December 31, 2013.

Plante & Moran, PLLC, an independent registered public accounting firm, as auditors of our consolidated financial statements, has issued an attestation report on the effectiveness of our internal control over financial reporting as of December 31, 2013. Plante & Moran, PLLC's report, which

expresses an unqualified opinion on the effectiveness of our internal control over financial reporting, is included herein.

Changes in Internal Controls

There was no change in our internal control over financial reporting identified in connection with the Company's evaluation of such internal controls that occurred during our fiscal quarter ended December 31, 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 required information will be contained in the Proxy Statement under the captions "Election of Directors" and "Section 16(a) Beneficial Ownership Reporting Compliance" and (excluding the Report of the Audit Committee) is incorporated herein by reference.

Item 11. Executive Compensation.

The required information will be contained in the Proxy Statement under the captions "Compensation of Executive Officers and Directors," and "Compensation Committee" and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The required information will be contained in the Proxy Statement under the caption "Voting Securities and Principal Holders" and is incorporated herein by reference.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table summarizes our compensation plans, including individual compensation arrangements, under which our equity securities are authorized for issuance as of December 31, 2013:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	6,228,000	$ 6.27	1,409,165
Equity compensation plans not approved by security holders			
Total	6,228,000	$ 6.27	1,409,165

Item 13. Certain Relationships and Related Transactions and Director Independence.

The required information will be contained in the Proxy Statement under the captions "Independence" and "Related Party Transactions" and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services.

The required information will be contained in the Proxy Statement under the caption "Independent Accountants" and is incorporated herein by reference.

Item 15. Exhibits and Financial Statement Schedules.

(a) The financial statements and schedule filed herewith are set forth on the Index to Financial Statements and Schedule of the separate financial section of this annual report, which is incorporated herein by reference.

(b) Exhibits

The following documents are filed as part of this report or were previously filed and incorporated herein by reference to the filing indicated. Exhibits not required for this report have been omitted. Our Commission file number is 000-23661.

3.1	Restated Articles of Incorporation, as amended as of May 1, 2013. (Company's Form 10-Q filed May 8, 2013).
3.2	Amended and Restated Bylaws (Company's Form 8-K filed November 25, 2008).
4.3	Form of Investor Warrant to Purchase Common Stock issuable by the Company to the investor signatories to the Subscription Agreement, filed as exhibit F to the Placement Agency Agreement (Company's Form 8-K filed September 30, 2009).
4.13	Warrant issued to DaVita Inc.(n/k/a DaVita Healthcare Partners, Inc.) as of February 16, 2011 (Company's Form 8-K filed February 23, 2011).
4.18	Loan and Security Agreement, dated as of June 14, 2013, among Rockwell Medical, Inc., Rockwell Transportation, Inc. and Hercules Technology III, L.P. (Company's Form 8-K filed June 20, 2013).
*10.1	Rockwell Medical, Inc. 1997 Stock Option Plan (Company's Proxy Statement filed April 17, 2006).
10.4	Licensing Agreement between the Company and Charak LLC and Dr. Ajay Gupta dated January 7, 2002 (with certain portions of the exhibit redacted pursuant to a confidential treatment order) (Company's Form 10-KSB filed April 1, 2002).
10.11	Amending Agreement made the 16th day of January, 2006, by and between Dr. Ajay Gupta, Charak LLC and Rockwell Medical, Inc. (Company's Form 10-KSB filed March 31, 2006).
*10.20	Form of Nonqualified Stock Option Agreement (Director Version) (Company's Form 8-K filed December 20, 2007).
*10.21	Form of Nonqualified Stock Option Agreement (Employee Version) (Company's Form 8-K filed December 20, 2007).
*10.36	Amendment No. 3 to Rockwell Medical, Inc. 2007 Long Term Incentive Plan (Company's Proxy Statement filed April 15, 2010).
*10.43	Form of Amendment to 2010 Restricted Stock Award Agreement as of March 7, 2012 with Robert L. Chioini, Thomas E. Klema, and Dr. Ajay Gupta (Company's Current Report on Form 8-K dated March 7, 2012)
*10.44	Form of Amendment to 2008 Restricted Stock Award Agreement as of May 14, 2012 with Robert L. Chioini and Thomas E. Klema (Company's Current Report on Form 8-K dated May16, 2012)

*10.45	Rockwell Medical, Inc. Amended and Restated 2007 Long Term Incentive Plan, as amended effective May 24, 2012 (incorporated by reference to the Company's Proxy Statement for the 2012 Annual Meeting of Shareholders filed on April 13, 2012).
*10.46	Form of restricted stock award agreement (Company's Current Report on Form 8-K dated June 14, 2012).
*10.47	Form of Amendment to 2010 Restricted Stock Award Agreement as of August 3, 2012 with Robert L. Chioini, Thomas E. Klema, and Dr. Ajay Gupta (Company's Current Report on Form 8-K filed August 3, 2012).
10.50	Common Stock Purchase Agreement, dated March 20, 2013, between the Company and the investors party thereto (Company's Form 8-K filed March 20, 2013).
10.51	Placement Agency Agreement, dated March 20, 2013, among the Company, Chardan Capital Markets, LLC and Newbridge Securities Corporation (Company's Form 8-K filed March 20, 2013).
10.52	Form of Subscription Agreement, dated March 20, 2013 (Company's Form 8-K filed March 20, 2013).
*10.53	Rockwell Medical, Inc. Amended and Restated 2007 Long Term Incentive Plan, as amended effective April 30, 2013 (appendix to Company's Proxy Statement for the 2013 Annual Meeting of Shareholders filed March 29, 2013).
*10.54	Form of Restricted Stock Award Agreement June 2013 (Executive Version) (Company's Form 8-K filed June 19, 2013).
10.55	First Amended and Restated Products Purchase Agreement dated May 8, 2013, by and between Rockwell Medical, Inc. and DaVita Healthcare Partners, Inc. (with certain portions redacted pursuant to a confidential treatment order) (Company's Form 10-Q filed August 1, 2013).
14.1	Rockwell Medical, Inc. Code of Ethics (Company's Proxy Statement filed April 23, 2004).
21.1	List of Subsidiaries (Company's Form SB-2 (file No. 333-31991)).
23.1	Consent of Plante & Moran, PLLC.
31.1	Certification of Chief Executive Officer Pursuant to Rule 13a-14(a).
31.2	Certification of Chief Financial Officer Pursuant to Rule 13a-14(a).
32.1	Certification of the Chief Executive Officer and Chief Financial Officer, Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Database
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase

* Current management contracts or compensatory plans or arrangements.

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.

ROCKWELL MEDICAL, INC. (Registrant)

By: /s/ ROBERT L. CHIOINI

Robert L. Chioini
President and Chief Executive Officer

Date: March 7, 2014

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons on behalf of registrant and in the capacities and on the dates indicated.

SIGNATURE	TITLE	DATE
/s/ ROBERT L. CHIOINI Robert L. Chioini	President, Chief Executive Officer and Director (Principal Executive Officer)	March 7, 2014
/s/ THOMAS E. KLEMA Thomas E. Klema	Vice President of Finance, Chief Financial Officer, Treasurer and Secretary (Principal Financial Officer and Principal Accounting Officer)	March 7, 2014
/s/ KENNETH L. HOLT Kenneth L. Holt	Director	March 7, 2014
/s/ RONALD D. BOYD Ronald D. Boyd	Director	March 7, 2014
/s/ PATRICK J. BAGLEY Patrick J. Bagley	Director	March 7, 2014

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders
Rockwell Medical, Inc. and Subsidiary

We have audited the accompanying consolidated balance sheets of Rockwell Medical, Inc. and Subsidiary (the Company) as of December 31, 2013 and 2012, and the related consolidated statements of income, comprehensive income, changes in shareholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2013. Our audits also included the financial statement schedule listed in the Index at Item 15. These financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and financial statement schedule 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 audit 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 consolidated financial position of Rockwell Medical, Inc. and Subsidiary at December 31, 2013 and 2012, and the consolidated results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2013, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, such financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Rockwell Medical, Inc. and Subsidiary's internal control over financial reporting as of December 31, 2013, based on criteria established in the 1992 Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 7, 2014 expressed an unqualified opinion on the effectiveness of internal control over financial reporting.

/s/ Plante & Moran, PLLC

Clinton Township, Michigan
March 7, 2014

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders
Rockwell Medical, Inc. and Subsidiary

We have audited Rockwell Medical, Inc. and Subsidiary's internal control over financial reporting as of December 31, 2013, based on criteria established in the 1992 Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Rockwell Medical, Inc. and Subsidiary maintained, in all material respects, effective internal control over financial reporting as of December 31, 2013, based on criteria established in the 1992 Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Rockwell Medical, Inc. and Subsidiary (the Company) as of December 31, 2013 and 2012, and the related consolidated statements of income, comprehensive income, changes in shareholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2013 and related financial statement schedule and our report dated March 7, 2014 expressed an unqualified opinion thereon.

/s/ Plante & Moran, PLLC

Clinton Township, Michigan
March 7, 2014

ROCKWELL MEDICAL, INC. AND SUBSIDIARY

CONSOLIDATED BALANCE SHEETS

As of December 31, 2013 and 2012

	December 31, 2013	December 31, 2012
ASSETS		
Cash and Cash Equivalents	$ 11,881,451	$ 4,711,730
Investments Available for Sale	12,034,622	
Accounts Receivable, net of a reserve of $37,000 in 2013 and $26,000 in 2012	4,578,319	4,431,932
Inventory	2,799,648	2,649,639
Other Current Assets	623,734	1,356,131
Total Current Assets	31,917,774	13,149,432
Property and Equipment, net	1,648,949	1,858,442
Intangible Assets	499,715	666,744
Goodwill	920,745	920,745
Other Non-current Assets	1,374,941	429,723
Total Assets	$ 36,362,124	$ 17,025,086
LIABILITIES AND SHAREHOLDERS' EQUITY		
Note Payable Capitalized Lease Obligations	$ 2,308,145	$
Capitalized Lease Obligations Capitalized Lease Obligations		2,280
Accounts Payable	8,686,153	14,833,565
Accrued Liabilities	6,647,828	12,015,978
Customer Deposits	207,545	135,133
Total Current Liabilities	17,849,671	26,986,956
Long Term Debt	17,916,914	
Shareholders' Equity:		
Common Shares, no par value, 40,110,661 and 21,494,696 shares issued and outstanding	154,457,878	92,866,458
Common Share Purchase Warrants, 983,071 and 2,233,240 warrants issued and outstanding	4,895,811	7,178,929
Accumulated Deficit	(158,790,569)	(110,007,257)
Accumulated Other Comprehensive Income	32,419	
Total Shareholders' Equity (Deficit)	595,539	(9,961,870)
Total Liabilities And Shareholders' Equity	$ 36,362,124	$ 17,025,086

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

ROCKWELL MEDICAL, INC. AND SUBSIDIARY

CONSOLIDATED INCOME STATEMENTS

For The Years Ended December 31, 2013, 2012 and 2011

	2013	2012	2011
Sales	$ 52,379,543	$ 49,842,392	$ 48,966,231
Cost of Sales	45,720,323	43,148,965	43,323,321
Gross Profit	6,659,220	6,693,427	5,642,910
Selling, General and Administrative	14,336,449	12,683,860	9,522,305
Research and Product Development	39,382,037	48,271,649	17,805,362
Operating Income (Loss)	(47,059,266)	(54,262,082)	(21,684,757)
Interest and Investment Income	98,101	241,518	244,049
Interest (Expense)	(1,822,147)	(951)	(1,844)
Income (Loss) Before Income Taxes	(48,783,312)	(54,021,515)	(21,442,552)
Income Tax Expense			2,005
Net Income (Loss)	$ (48,783,312)	$ (54,021,515)	$ (21,444,557)
Basic And Diluted Earnings (Loss) Per Share	$ (1.48)	$ (2.65)	$ (1.21)

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

ROCKWELL MEDICAL, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

For The Years Ended December 31, 2013, 2012 and 2011

	2013	2012	2011
Net Income (Loss)	**$ (48,783,312)**	**$ (54,021,515)**	**$ (21,444,557)**
Reclassification of Losses Included in Net Loss		67,303	84,590
Unrealized Gain (Loss) on Available-for-Sale Investments	32,419	213,809	(152,079)
Comprehensive Income (Loss)	**$ (48,750,893)**	**$ (53,740,403)**	**$ (21,512,046)**

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

ROCKWELL MEDICAL, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY

For The Years Ended December 31, 2013, 2012 and 2011

	COMMON SHARES		PURCHASE WARRANTS			ACCUMULATED OTHER COMPREHENSIVE	TOTAL
	SHARES	AMOUNT	WARRANTS	AMOUNT	ACCUMULATED DEFICIT	INCOME (LOSS)	SHAREHOLDER'S EQUITY
Balance as of December 31, 2010	17,513,608	$ 57,017,236	3,338,569	$ 8,275,509	$ (34,541,185)	$ (213,623)	$ 30,537,937
Net Loss					(21,444,557)		(21,444,557)
Reclassification of Losses Included in Net Loss						84,590	84,590
Unrealized (Loss) on Available-for-Sale Investments						(152,079)	(152,079)
Issuance of Common Shares	397,054	719,484					719,484
Issuance of Purchase Warrants			100,000	312,325			312,325
Exercise of Purchase Warrants	799,340	5,361,135	(831,129)	(1,483,859)			3,877,276
Additional Paid In Capital		244,289					244,289
Stock Option Based Expense		3,469,703					3,469,703
Restricted Stock Amortization		596,000					596,000
Balance as of December 31, 2011	18,710,002	$ 67,407,847	2,607,440	$ 7,103,975	$ (55,985,742)	$ (281,112)	$ 18,244,968
Net Loss					(54,021,515)		(54,021,515)
Reclassification of Losses Included in Net Loss						67,303	67,303
Unrealized Gain on Available-for-Sale Investments						213,809	213,809
Issuance of Common Shares	2,296,477	16,252,695					16,252,695
Shares Issued in Exchange for Services	200,000	1,854,000					1,854,000
Exercise of Purchase Warrants	288,217	2,372,192	(374,200)	(393,463)			1,978,729
Purchase Warrants Expense				468,417			468,417
Stock Option Based Expense		3,903,795					3,903,795
Restricted Stock Amortization		1,075,929					1,075,929
Balance as of December 31, 2012	21,494,696	$ 92,866,458	2,233,240	$ 7,178,929	$ (110,007,257)	$	$ (9,961,870)
Net Loss					(48,783,312)		(48,783,312)
Unrealized Gain on Available-for-Sale Investments						32,419	32,419
Issuance of Common Shares	18,285,132	50,431,250					50,431,250
Shares Issued in Exchange for Services	200,000	780,678					780,678
Exercise of Purchase Warrants	130,833	1,593,003	(130,833)	(428,021)			1,164,982
Expiration of Purchase Warrants		2,937,293	(1,119,336)	(2,937,293)			
Purchase Warrants Expense				1,082,196			1,082,196
Stock Option Based Expense		3,887,695					3,887,695
Restricted Stock Amortization		1,961,501					1,961,501
Balance as of December 31, 2013	40,110,661	$ 154,457,878	983,071	$ 4,895,811	$ (158,790,569)	$ 32,419	$ 595,539

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

ROCKWELL MEDICAL, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CASH FLOWS

For the years ended December 31, 2013, 2012 and 2011

	2013	2012	2011
Cash Flows From Operating Activities:			
Net (Loss)	**$ (48,783,312)**	**$ (54,021,515)**	**$ (21,444,557)**
Adjustments To Reconcile Net Loss To Net Cash Used In Operating Activities:			
Depreciation and Amortization	1,007,411	1,087,397	1,176,007
Share Based Compensation Non-employee	1,862,874	2,322,417	312,325
Share Based Compensation Employees	5,849,196	4,979,724	4,065,703
Loss (Gain) on Disposal of Assets	16,410	17,876	29,093
Loss on Sale of Investments Available for Sale		67,303	84,590
Amortization of Debt Issuance Costs	227,059		
Non-Cash Interest Expense	225,059		
Changes in Assets and Liabilities:			
(Increase) Decrease in Accounts Receivable	(146,387)	(209,116)	284,480
(Increase) Decrease in Inventory	(150,009)	(145,512)	432,751
(Increase) Decrease in Other Assets	669,896	1,855,787	(2,457,370)
Increase (Decrease) in Accounts Payable	(6,147,412)	9,469,028	1,705,030
Increase (Decrease) in Other Liabilities	(5,295,738)	3,829,767	5,028,846
Changes in Assets and Liabilities	(11,069,650)	14,799,954	4,993,737
Cash (Used In) Operating Activities	**(50,664,953)**	**(30,746,844)**	**(10,783,102)**
Cash Flows From Investing Activities:			
Purchase of Investments Available for Sale	(12,002,203)	(2,012,671)	(2,000,000)
Sale of Investments Available for Sale		14,037,255	1,975,244
Purchase of Equipment	(654,197)	(507,788)	(421,043)
Proceeds on Sale of Assets	6,898	1,578	2,985
Purchase of Intangible Assets			(145,121)
Cash Provided By (Used In) Investing Activities	**(12,649,502)**	**11,518,374**	**(587,935)**
Cash Flows From Financing Activities:			
Proceeds from Issuance of Common Shares and Purchase Warrants	51,596,232	18,231,424	4,841,049
Proceeds from the Issuance of Notes Payable	20,000,000		
Debt Issuance Costs	(1,109,776)		
Payments on Notes Payable and Capital Lease Obligations	(2,280)	(6,470)	(18,215)
Cash Provided By Financing Activities	**70,484,176**	**18,224,954**	**4,822,834**
Increase (Decrease) In Cash	7,169,721	(1,003,516)	(6,548,203)
Cash At Beginning Of Period	4,711,730	5,715,246	12,263,449
Cash At End Of Period	**$ 11,881,451**	**$ 4,711,730**	**$ 5,715,246**

Supplemental Cash Flow disclosure

	2013	2012	2011
Interest Paid	$ 1,154,752	$ 951	$ 1,844
Non-Cash Investing and Financing Activity			
Acquisition of Intangible Assets			