ROCKWELL MEDICAL, INC.
Form 10-K
March 03, 2015

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, 2014

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, 2014 (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 $457,066,000. 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 20, 2015: 50,344,507 shares.

Documents Incorporated by Reference

Portions of the Registrant's definitive Proxy Statement pertaining to the 2015 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.

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 commercialization 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.

PART I

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 branded drug, Triferic , formerly known as Soluble Ferric Pyrophosphate or SFP, was approved by U.S. Food and Drug Administration ("FDA") in late January 2015. Triferic is a unique iron compound that is delivered to hemodialysis patients via dialysate, replacing the ongoing iron loss that occurs during their dialysis treatment. Triferic enters the blood and immediately binds to transferrin and is transported to the erythroid precursor cells to be incorporated into hemoglobin.

The Company successfully completed its Phase 3 clinical trial program SFP-3 and SFP-4 (CRUISE-1and CRUISE-2) that included an extensive long-term safety program where Triferic demonstrated a favorable safety profile similar to placebo patients. Triferic has the distinction of being the first drug in its class to be indicated for iron maintenance compared to other intravenous iron drugs that are indicated for iron repletion.

In addition, the Company completed clinical study NIH-FP-01, the PRIME study, which demonstrated that Triferic could significantly reduce the need for erythropoiesis stimulating agents ("ESA"). ESA drugs are the most expensive drugs used in dialysis.

We plan to commercialize Triferic in the U.S. market. We plan to seek foreign regulatory approval for Triferic in some countries and license the technology to partner companies who will gain regulatory approval and commercialize Triferic . Rockwell has in-licensed the exclusive right to commercialize Triferic and we hold certain other patents related to Triferic .

Rockwell's FDA approved generic drug, Calcitriol, is for treating secondary hyperparathyroidism in dialysis patients. Calcitriol (active vitamin D) injection is indicated in the management of hypocalcemia in patients undergoing chronic renal dialysis. It has been shown to significantly reduce elevated parathyroid hormone (PTH) levels. Reduction of PTH has been shown to result in an improvement in renal osteodystrophy. Rockwell has received FDA manufacturing approval and intends to market Calcitriol to hemodialysis providers in the United States dialysis market.

Rockwell is also an established manufacturer and leader in delivering high-quality hemodialysis concentrates/dialysates to dialysis providers and distributors in the United States 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 has three manufacturing and distribution facilities in the United States. Rockwell entered into an Exclusive Distribution Agreement (the "Distribution Agreement") with Baxter Healthcare Corporation ("Baxter") in October 2014 pursuant to which Baxter has become our exclusive distributor for our concentrate products in the United States and certain foreign markets. See "Item 1 Business Distribution Agreement with Baxter."

Our Business Strategy

We intend to become a leading biopharmaceutical company, leveraging our Triferic technology into other medical indications, using our operating business infrastructure to penetrate and sell approved drugs commercially into the renal market and discovering and acquiring or licensing other potential high-value drugs. The following are the key elements of our business strategy:

Commercially Launch Triferic as an Iron Maintenance Therapy for Hemodialysis Patients in the U.S.

We obtained FDA regulatory approval in January 2015 to market Triferic commercially. Triferic is a unique iron compound that is delivered to hemodialysis patients via dialysate, replacing the ongoing iron loss that occurs during their dialysis treatment. In completed clinical trials, Triferic has demonstrated that it can effectively deliver sufficient iron to the bone marrow and maintain hemoglobin, without increasing iron stores (ferritin). Rockwell intends to market Triferic to hemodialysis patients in the U.S. dialysis market in 2015.

Commercially Launch Calcitriol to Treat Secondary Hyperparathyroidism in Dialysis Patients in the U.S.

Calcitriol (active vitamin D) injection is indicated in the management of hypocalcemia in patients undergoing chronic renal dialysis. It has been shown to significantly reduce elevated parathyroid hormone levels. We expect to sell and market generic Calcitriol in 2015. Based on industry estimates, we believe the U.S. market for vitamin D therapy for ESRD patients is greater than $200 million per year. We intend to market Calcitriol to dialysis providers, many of whom we have an established commercial relationship with through our dialysis concentrate business. We estimate that there are currently over 60,000,000 vitamin D injections per year in the ESRD market in the United States.

License our Triferic Technology to Marketing Partners to Leverage Our Renal Indications and Others Globally for Commercialization.

We continue to seek commercial collaborations to license and develop our products and to realize financial benefits on a global scale. 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. We may initiate regulatory approval in select markets.

Grow Our Commercial Concentrate Business and Market Position and Leverage our Current Relationships to Sell our Renal Drugs.

We intend to continue to increase our market presence in our concentrate/dialysate products business in the United States. Through the Distribution Agreement with Baxter, we intend to expand our concentrate business operations and increase our sales domestically and internationally. We will continue to develop and offer innovative products that improve patient outcomes and lower provider costs. We intend to leverage our sales and marketing operating infrastructure to sell our renal drugs into the same market.

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 Products.

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.

The Hemodialysis Market

The great majority of hemodialysis patients receive dialysis treatment three or four times per week, or approximately 156 times per year. Most have their dialysis treatment performed at a free-standing clinic for permanent loss of kidney function; these are called "chronic" patients. Some have their treatment performed at hospitals for temporary loss of kidney function; these are called "acute" patients. A small percent of patients receive their treatment at home; these are called "home" patients. In each setting, a dialysis machine dilutes concentrated solution, such as Rockwell's 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 either citric acid or acetic 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 products such as blood tubing, fistula needles, dialyzers, drugs, 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 free standing 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 6,300 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 statistics published by USRDS, there were approximately 443,000 dialysis patients in the United States as of the end of 2012.

Based on a global market study published by a major dialysis products manufacturer, the global ESRD population receiving some form of treatment was estimated to be over 2.8 million patients at the end of 2011 with the overall global patient population growing approximately 6-7% annually. We have observed that the ESRD patient population in the United States has grown steadily over the past several decades and coupled with data provided in that report we expect the dialysis population to grow approximately 4-5% annually over the next several years. The Asia-Pacific market is projected to experience rapid growth in both the incidence of kidney disease and the total ESRD population over the decade ahead.

Drug Products

Triferic (Ferric Pyrophosphate Citrate)

Iron deficiency is pervasive in the CKD-HD patient population. Triferic is the first product approved by the FDA for iron replacement and maintenance of hemoglobin in hemodialysis patients.

We believe Triferic will become the standard of care in iron maintenance therapy for dialysis patients and address an important need in the maintenance of hemoglobin in ESRD patients.

Approved by the FDA in January 2015, Triferic is a unique iron compound that is delivered to hemodialysis patients via dialysate, replacing the ongoing iron loss that occurs during their dialysis treatment. Triferic is introduced into bicarbonate concentrate, on-site at the dialysis clinic, and subsequently mixed into dialysate. Once in dialysate, Triferic crosses the dialyzer membrane and enters the blood where it immediately binds to transferrin and is transported to the erythroid precursor cells to be incorporated into hemoglobin. In completed clinical trials, Triferic has demonstrated that it can effectively deliver sufficient iron to the bone marrow and maintain hemoglobin, without increasing iron stores (ferritin).

To currently address iron deficiency, patients receive intravenous (IV) 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 clinical practice for iron therapy for CKD-HD patients is provided mainly with IV iron compounds, which are approved for iron repletion, not maintenance. IV iron is 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, coupled with chronic inflammation found in ESRD patients, causes a peptide called hepcidin to mobilize and block the majority of IV iron from leaving the liver, increasing iron stores. This functional iron deficiency can reduce the effectiveness of ESA treatments. The carbohydrate moiety in IV iron compounds is also believed to be responsible for the anaphylactic reactions that may occur.

Triferic is distinctly different from IV iron compounds. Triferic is an iron salt and contains no carbohydrate. Triferic enters the bloodstream through dialysate and immediately binds to transferrin (the body's natural binding site for iron) and is carried directly to the bone marrow for the formation of new red blood cells. Triferic 's efficient binding action is similar to how a healthy human body processes dietary iron when received via food. Triferic effectively delivers iron and maintains hemoglobin without increasing iron stores. Triferic has demonstrated an excellent safety profile in its Phase 3 clinical program and has not been attributed to any anaphylaxis in over 100,000 administrations.

The PRIME study demonstrated that this more direct method of iron delivery is able to significantly reduce ESA treatment. In this study, Triferic patients used 35% less ESA than placebo patients and ESA hyporesponsive patients used 74% less ESA (see PRIME study design and results below).

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 effectively deliver iron and maintain hemoglobin without increasing iron stores, and the PRIME study has shown Triferic can lower ESA use. Triferic additionally lowers IV iron drug administration cost to dialysis providers. Along with the elimination of the needle and syringe normally used for IV iron administration, a nurse will not have to administer individual injections of IV iron, thereby reducing the amount of time required for IV iron administration, permitting nursing time to be redeployed to other patient care activities.

During 2013, Rockwell successfully completed its two pivotal Phase 3 efficacy 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). Both groups were able to have ESA doses titrated to keep hemoglobin levels within the target range, and both groups could receive IV iron if they developed absolute iron deficiency. Both groups successfully kept their hemoglobin concentrations within the target range, but the Triferic patients used 35% less ESA to do so than placebo patients. ESA hyporesponsive patients those on more than 13,000 units of epoetin per week needed 74% less ESA in the Triferic group compared to the placebo group. Hypo-responsive patients are generally estimated to represent approximately 20% of the dialysis population. According to Amgen Inc., which sells the vast majority of ESA drugs in the dialysis market, over $2.8 billion was spent on Amgen's ESA drugs in 2014 in the United States and we estimate that approximately $2.3 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 United States and Canada. This large-scale long term safety study, coupled with the successful Phase 3 CRUISE studies, dosed over 100,000 Triferic administrations and demonstrated a safety profile similar to placebo patients.

We plan to commercialize Triferic in 2015 using our current sales and marketing infrastructure. We intend to out-license the rights to Triferic for commercial development in markets outside of the United States.

Calcitriol (Active Vitamin D) Injection

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. Clinical data shows Calcitriol 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 plan to commercialize Calcitriol in 2015 using our current sales and marketing infrastructure.

Dialysis Concentrate Products

We manufacture, sell, deliver and distribute hemodialysis concentrates, along with a full line of ancillary products abroad. We use Baxter as our exclusive marketer and distributor in the U.S. and in select foreign markets. Dialysate concentrates accounted for over 89% of our 2014 revenue with ancillary products accounting for the remainder. 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 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 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 reduce the need for heparin during dialysis treatment (CitraPure® 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 Concentrate Mixer. CitraPure® contains citric acid, sodium chloride, dextrose, magnesium, potassium and calcium. CitraPure® is packaged as dry acid concentrate in 25 gallon cases and liquid acid concentrate in 55 gallon drums and four one gallon jugs to a case.

Dri-Sate® Dry Acid Concentrate

Our Dri-Sate® Concentrate is our original acetate-based product that was introduced to the market when liquid acid was the only packaging option available in the market. Dri-Sate® is packaged as a dry powder acid concentrate for use with our Dry Acid Concentrate Mixer. Dri-Sate® contains acetic acid, sodium chloride, dextrose, magnesium, potassium and calcium. Dri-Sate® is packaged as dry acid concentrate in 25 gallon cases.

Renal Pure® Liquid Acid Concentrate

Our RenalPure® Liquid Concentrate is acetate-based and contains acetic acid, sodium chloride, dextrose, magnesium, potassium and calcium and packaged in 55 gallon drums and four one gallon jugs to a case.

Dry Acid Concentrate Mixer

Our Dry Acid Concentrate Mixer 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 is a dry powder mixed on-site at the clinic and is packaged for bulk and individual treatment.

SteriLyte® Liquid Bicarbonate Concentrate

SteriLyte® bicarbonate is liquid packaged in four one gallon jugs to a case 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.

Distribution Agreement with Baxter

Pursuant to the terms of the Distribution Agreement, Baxter is now our exclusive agent for commercializing our hemodialysis concentrate and ancillary products in the United States and various foreign countries for an initial term of 10 years. We retain sales, marketing and distribution rights for our hemodialysis concentrate products for our current international customers and in those countries in which we have an established commercial presence. During the term of the Distribution Agreement, Baxter has agreed not to manufacture or sell any competitive concentrate products in the United States hemodialysis market, other than specified products. The Distribution Agreement does not include any of the Company's drug products.

Under the Distribution Agreement, Baxter will purchase concentrate-related products from us at pre-determined gross margin-based prices per unit adjusted each year during the term and subject to an annual true up. The Distribution Agreement also requires Baxter to meet minimum annual purchase levels, subject to a cure period and certain other relief, in order to maintain its exclusive distribution rights. The minimum purchase levels increase each year over the term of the Distribution Agreement. Purchases in any contract year that exceed the minimum may be carried forward and applied to future years' minimum requirements. The Distribution Agreement also contains provisions governing the operating relationship between the parties, our obligations to maintain specified manufacturing capacity and quality levels, remedies, as well as representations, warranties and indemnification obligations of the parties. We will continue to manage customer service, transportation and certain other functions for our current customers through at least December 31, 2017, for which Baxter will pay us an amount equal to our related costs plus a slight mark-up.

Following the October 2, 2014 signing of the Distribution Agreement, we received an upfront fee of $20 million and an equity investment of $15 million. Baxter also agreed to pay us $10 million during the initial term of the Distribution Agreement to build a new manufacturing facility in the Pacific time zone that will serve customers in the Western United States. The fee payable in connection with building the facility will be reduced to the extent that the facility is not operational within 12 months after the start of construction. Except for any leased components, we will own and operate the facility when completed.

Either party may terminate the Distribution Agreement upon the insolvency or material breach of the other party or in the event of a force majeure. In addition, Baxter may also terminate the Distribution Agreement at any time upon 270 days' prior written notice to us or if (1) prices increase beyond certain thresholds and notice is provided within 45 days after the true up payment is due for the year in which the price threshold is exceeded, (2) a change of control of the Company occurs and 270 days' notice is provided, or (3) upon written notice that Baxter has been enjoined by a court of competent jurisdiction from selling in the United States any product covered by the Distribution Agreement due to a claim of intellectual property infringement or misappropriation relating to such product. If Baxter terminates the Distribution Agreement under the discretionary termination or the price increase provisions, it would be subject to a limited noncompete obligation in the United States with respect to certain products for a period of two years.

If a "Refund Trigger Event" occurs, we would be obligated to repay a portion of the upfront fee and facility fee. A "Refund Trigger Event" means any of the following: (1) a change of control of the Company involving any of certain specified companies; (2) a termination by Baxter due to the Company's bankruptcy or breach, or due to price increases that exceed the stated thresholds; (3) a termination by either party due to a force majeure; (4) settlement or adjudication of any claim, action or litigation relating to a covered product that materially and adversely affects Baxter's commercialization of the product; and (5) any regulatory action or ruling relating to a covered product that materially and adversely affects Baxter's commercialization of the product. In addition, if Baxter terminates the Distribution Agreement because Baxter has been enjoined by a court of competent jurisdiction from selling in the United States any product covered by the Distribution Agreement due to a claim of intellectual property infringement or misappropriation relating to such product prior to the end of 2019, Baxter would be entitled to a partial refund. In no event would more than one refund be required to be paid.

The Distribution Agreement may be extended an additional five years by Baxter if the Company achieves a specified sales target and pays an extension fee of $7.5 million. If the first extension occurs, the Distribution Agreement term may later be extended an additional five years at Baxter's option at no additional cost.

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. Rockwell distribution and delivery will continue to operate under the Distribution Agreement on behalf of Baxter for domestic business. We perform delivery services 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 than other providers.

Sales and Marketing

The ten largest dialysis providers treat approximately 396,000 patients according to an article published by Nephrology News in 2014, which we believe constitutes over 80% of the hemodialysis patient population in the United States. Due to the concentrated nature of our customers, we will market our drug products using few salespeople. Our Chief Executive Officer leads and directs our sales effort, and handles our major accounts.

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, dialysis service providers, nephrologists, clinic administrators, nurses, medical directors and purchasing personnel.

Our dialysis concentrate products are sold to U.S. customers through Baxter in accordance with the Distribution Agreement. Our dialysis concentrate products are sold to international customers through independent sales agents, distributors and direct.

Competition

Dialysis Concentrate Solutions and Dialysis Products Market Competition

In the United States, the principal competitor for our concentrate products is 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 2,200 clinics and treats approximately 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 Delivery Market Competition

We intend to enter the iron delivery market with Triferic . We believe Triferic has potential to capture market share from the current IV iron drugs due to its unique mode of action, clinical benefits, ability to lower treatment cost for providers, ease of administration and excellent safety profile. Presently, the IV iron drug Venofer® has the majority of the market for delivering iron to CKD-HD patients in the United States. Venofer® is owned by Switzerland-based Galenica. Galenica also markets Ferinject®. Fresenius has a sublicense agreement that allows them to distribute Venofer® to the dialysis market in the United States and Canada. Other IV iron competitors include Sanofi with Ferrlecit®, Watson with a generic IV iron called Nulecit® and AMAG Pharmaceuticals, Inc. with 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 for Triferic . The bundled rate is a single payment per treatment, thereby eliminating reimbursement for individual drugs and services to providers. Regulations provide that the rate is recalculated each year. As a result, dialysis drugs are now viewed by providers as an additional cost rather than as a source of revenue. We believe Triferic , due to its potential for improved therapeutic response 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. We believe the dialysis reimbursement law that went into effect in January 2011, along with Calcitriol being the lowest dose vitamin D injection available and our relationships with many dialysis providers gives us an advantage to sell Calcitriol against 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 product quality 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 will utilize contract manufacturing organizations ("CMOs") to manufacture and package our drug products for sale. These contract manufacturers will be 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, 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 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. Our Triferic and Calcitriol products will be subject to FDA drug regulations.

Drug Approval and Regulation

The marketing of pharmaceutical products in the United States, such as Triferic , requires the approval of the FDA. We received FDA approval to market Triferic in January 2015. 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 New Drug Application ("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 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 an in-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 plus a period of ten years. Patents were issued in the United States in 2004 and extend through 2016 and may be extended thereafter under the Hatch-Waxman Act. The European patent was issued in 2005 and extends through 2017. The Japanese patent was issued in 2007 and extends through 2017. 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 and patent maintenance expenses in order to realize any benefit from commercialization of the product. In addition, we are obligated to make certain milestone payments and to pay ongoing royalties upon successful introduction of the product. As of December 31, 2014, remaining milestone payments include a payment of $100,000, which became due in January 2015 upon FDA approval of

Triferic , and a payment of $175,000 which will become due upon issuance of a reimbursement code covering Triferic .

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 United States registration of such marks. Most such applications have resulted in registration of such trademarks and servicemarks.

We were issued a United States 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, Japan and Canada. We have numerous other patents and patent applications connected to Triferic pending in various countries.

We also own patents in the United States 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. However, the lead time to bring on an additional or new CMO could be lengthy.

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, 2014, 2013 and 2012, one customer, DaVita Healthcare Partners, Inc., accounted for 49% of our sales. Our accounts receivable from this customer were $2,041,000 and $1,886,000 as of December 31, 2014 and 2013, 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. Pursuant to our Distribution Agreement, our future concentrate product sales to this customer will be through Baxter. If business with this key account were lost, it could have a material adverse effect on our business, financial condition and results of operations.

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 2014, 2013 and 2012. We have no material assets outside the United States. Our total international sales, including sales to domestic distributors for resale outside the United States, aggregated 13%, 12% and 11%, of overall sales in 2014, 2013 and 2012, respectively.

Employees

As of December 31, 2014, we had approximately 283 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 human clinical trials and other testing in 2013, and submitted our NDA for Triferic to the FDA in 2014. We received FDA approval for Triferic in January 2015.

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 $7,784,000, $39,382,000 and $48,272,000, in 2014, 2013 and 2012, respectively.

Future R&D spending on the Triferic platform may include clinical testing in connection with peritoneal dialysis, total parenteral nutrition, an orphan indication and a pediatric indication. Future spending on such indications is expected to be minor in relation to the Company's cash resources.

Where You Can Get Information We File with the SEC

Our internet address is http://www.rockwellmed.com. Our internet address is included as an inactive textual reference only and nothing on the website is incorporated by reference into this Annual Report on Form 10-K. 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 DRUG BUSINESS

Although Triferic has recently been approved by the FDA, we may not be able to commercialize it successfully.

The commercial success of Triferic will depend on a number of factors, including the following:

IV iron currently dominates treatment for iron deficiency and Triferic will have to compete against it and possibly other existing and future 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, cost-effectiveness, advantages over existing products, and the reimbursement policies of government and third party payers, including Medicare;

Maintaining compliance with ongoing regulatory requirements applicable to Triferic 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, and our ability to execute our marketing strategy without significant additional expenditures;

Our ability to avoid third party patent interference or patent infringement claims;

A continued acceptable safety profile of Triferic ; and

Discovery of previously unknown problems with Triferic or with any third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements.

Any of the foregoing may have a material adverse effect on our ability to manufacture and market Triferic . These factors are largely 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. Even if we were successful in commercializing Triferic , due to the highly concentrated nature of the market, our continued success may depend on adoption of Triferic by a few customers.

Triferic is currently limited to use in patients receiving hemodialysis treatments and has not been approved for other indications. Regulatory approval for any approved product is limited by the FDA to those specific indications and conditions for which clinical safety and efficacy have been demonstrated, which may limit our ability to market our drug products.

While physicians may choose to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those tested in clinical studies and approved by regulatory authorities, our ability to promote the products or encourage our customers to use the products is limited to those indications that are specifically approved by the FDA as safe and effective. Any new indication for an approved product also requires FDA approval. If we are not able to obtain FDA approval for any other indications for Triferic , our ability to effectively market and sell Triferic may be reduced and our business may be adversely affected. Moreover, if our promotional activities fail to comply with the FDA's regulations or guidelines, we may be subject to warnings from, or enforcement action by, the FDA that may include penalties, fines, injunctions, recall or seizure of products, suspension of production, denial of future regulatory approvals, withdrawal or suspension of existing regulatory approvals, operating restrictions, injunctions and criminal prosecution, any of which could materially harm our business.

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 for either of the licensed Triferic patents expiring in 2016. 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 United States 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.

Although Calcitriol has been approved by the FDA, we may not be able to commercialize it successfully.

We have received FDA approval to manufacture a generic version of Calcitriol, but we still must meet certain ongoing regulatory requirements for product testing and stability of our commercially marketed products. If our testing does not meet approvable standards, if we are unable to find one or more approved suppliers that can make the product in sufficient quantities or if we experience operational issues with our supplier, we may not be able to market Calcitriol or the launch may be delayed.

The market for generic drugs such as Calcitriol is generally very competitive, which may make it difficult for us to capture significant market share. If we have success in capturing market share with Calcitriol, it may attract other entrants to market their own Calcitriol product, 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 may not be successful in obtaining foreign regulatory approvals or in arranging an out-licensing or other venture to realize commercialization of our drug products outside of the United States. If we are successful in out-licensing our drug products, the licensee or partner may not be effective at marketing our products in certain markets or at all.

The approval procedures for marketing our new drug products, such as Triferic , outside the United States vary from country to country, can be difficult to obtain and carry the same risks as FDA approval. In particular, regulatory approval in foreign countries may require additional testing and may otherwise be expensive and time consuming to undertake. Even after foreign approvals are obtained, further delays may be encountered before products may be marketed. Many countries require additional government 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 our drugs 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 our drugs outside the United States. If we are not successful in out-licensing our drugs outside of the United States or entering into some other business development arrangement to obtain the necessary approvals to commercialize them, we may be forced to seek regulatory approval and market these products ourselves. If we elect to seek approval ourselves, it may take longer than expected to obtain regulatory approval and to market and manufacture our drugs, 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 an adverse effect on the benefits otherwise expected from marketing in foreign countries.

If we are successful in obtaining a business partner or partners to commercialize our products in foreign markets, we will be dependent upon their effectiveness in selling and marketing our products in those foreign markets. These partners may face stiff competition, government price regulations, generic versions of our drug products, violations of our intellectual property rights and other negative events or may otherwise be ineffective in commercializing our products, any of which could reduce the market potential for our products and our success in those markets.

We will rely on third party suppliers for raw materials, packaging components and manufacturing of our drug products. We may not be able to obtain the raw materials, proper components or manufacturing capacity we need, or the cost of the materials, components or 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.

We may not be able to obtain needed raw materials, packaging components and manufacturing capacity for a variety of reasons, including among others:

- We may be required to purchase certain raw materials and packaging components from unaffiliated third- party suppliers who may not be able to supply us consistently or at all;
- Regulatory requirements or action by regulatory agencies or others, including delays in receiving necessary approvals;
- 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 the desired quantities of our drug products or our expected gross profit margins may be materially adversely affected.

Before it can be marketed, an investigational drug requires FDA approval, which is a long, expensive process with no guarantee of success.

Performing clinical trials and obtaining FDA approval for any drug can take a long time. Clinical trials typically take months or years to complete. Once trials are completed and the NDA, is submitted to the FDA, 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 granting approval, which could significantly delay approval or result in us not receiving approval at all.

Clinical trials and the NDA approval process are also expensive. Any such delays, 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. If approval is not granted, our entire investment in the related products may be worthless, any licensing rights could be forfeited and the price of our common stock could substantially decline.

Our drug business will depend on government funding of health care, and changes could impact our ability to be paid in full for our products, increase prices or cause consolidation in the dialysis provider market.

Many dialysis providers receive the majority of their funding from the government and are supplemented by payments from private health care insurers. These providers 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, these providers would be severely impacted, increasing our risk of not being paid in full. An increase in our exposure to uncollectible accounts could have a material adverse effect on our financial position, results of operations and cash flows.

Since 2011, CMS has continued to modify reimbursement policies for dialysis under the ESRD prospective payment system generally resulting in lower payment to dialysis providers. 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.

CMS has also introduced a quality incentive program for dialysis facilities and posts each facility's total performance score on the CMS website. Low performance scores at our customers could result in a reduction in patient volume and a decrease in sales for those customers.

As a result of these changes to Medicare reimbursement, the dialysis provider industry may continue to consolidate. This may result in increased purchasing leverage for providers across all dialysis product categories and increased pricing pressure on all suppliers to the industry.

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 in 2010, as amended by the Health Care and Education Affordability Reconciliation Act, referred to collectively as PPACA, which has resulted in 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 through 2020. The United States 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. Our financial position, results of operations, and 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.

Device and pharmaceutical manufacturers are required to report annually 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.

RISKS RELATED TO OUR CONCENTRATE BUSINESS

The Distribution Agreement with Baxter may be terminated or Baxter may lose exclusivity, requiring us to resume commercialization, which could have a material adverse effect on our financial condition, results of operations and cash flows.

Baxter may terminate the Distribution Agreement at any time at its discretion upon 270 days' written notice to us. In addition, Baxter may terminate the Distribution Agreement if:

- We are in bankruptcy or insolvent;
- We are in breach of the agreement and have failed to cure the breach within the applicable cure period;
- Prices increase beyond certain thresholds and notice is provided within 45 days after the true up payment is due for the year in which the price threshold is exceeded;
- We have a change of control; or
- Baxter gives us written notice that it has been enjoined by a court of competent jurisdiction from selling in the United States any product covered by the Distribution Agreement due to a claim of intellectual property infringement or misappropriation relating to such product.

In addition, if Baxter were to fail to purchase its minimum purchase requirement, its distribution rights may become non-exclusive. If, after December 31, 2017, the Distribution Agreement is terminated or Baxter's rights become non-exclusive, we would be required to reassume distribution of hemodialysis concentrate and ancillary products in the United States and various foreign countries and re-establish commercial arrangements with our current customers. Further, our concentrate products are distribution-intensive, resulting in a high cost to deliver relative to the selling prices of our products and we may have to re-establish, or may be unable to maintain, competitive pricing for our products in order to be profitable. If the Distribution Agreement is terminated or Baxter's distribution rights become non-exclusive, such events could have a material and adverse effect on our financial condition, results of operations and cash flows.

We may be required to repay a portion of the fees received from Baxter, which could materially and adversely affect our financial position and cash reserves.

Pursuant to the terms of the Distribution Agreement, we may be required to repay a portion of the upfront fee and a portion of the facility fee to Baxter upon the occurrence of a "Refund Trigger Event." A "Refund Trigger Event" means any of the following:

- A change of control of the Company involving any of certain specified companies;
- A termination by Baxter due to our bankruptcy, insolvency or uncured breach, or due to price increases that exceed the stated thresholds;
- A termination by either party due to a force majeure;
- The settlement or adjudication of any claim, action or litigation relating to a covered product that materially and adversely affects Baxter's commercialization of the product; and
- Any regulatory action or ruling relating to a covered product that materially and adversely affects Baxter's commercialization of the product.

Any of these events would obligate us to repay 50% of the $20 million upfront fee and 50% of the facility fee if the event occurs prior to December 31, 2016, 33% if the event occurs in 2017 or 2018, and 25% if the event occurs in 2019, 2020 or 2021. Any such repayment could result in a material negative impact on our financial condition and cash reserves.

In addition, if Baxter terminates the Distribution Agreement because it has been enjoined by a court of competent jurisdiction from selling in the United States any product covered by the Distribution Agreement due to a claim of intellectual property infringement or misappropriation relating to such product prior to the end of 2018, Baxter would be entitled to a refund of up to $10 million, or $6.6 million if the termination occurs in 2019.

If we are required to make any such refund payment, we may need to reallocate funds from other parts of our business, which could force us to change or delay plans for use of that capital. We may be forced to obtain financing or raise capital on terms that are unfavorable to us, or financing or additional capital may not be available at all. In any such event, our financial condition, results of operations and cash flows could be materially and adversely affected.

The transition to Baxter of commercialization of our concentrate and ancillary products may not be successful.

In October 2014, we entered into our Distribution Agreement with Baxter pursuant to which Baxter will become our exclusive agent for commercializing our hemodialysis concentrate and ancillary products in the United States and various foreign countries. If Baxter were to commit insufficient financial and other resources to the marketing and distribution of our products, or if our products were to lose focus within Baxter or are otherwise not being marketed as effectively as we have marketed them in the past, unit sales of our products may fall, resulting in lower revenues and gross margin for us, which could have a material adverse effect on our financial condition, results of operations and cash flows.

In addition, we may not be able to transition the sales and marketing activities of these products to Baxter successfully or Baxter could fail to price the product adequately to allow its sales of our products to be profitable to it, either of which could cause Baxter to exercise its right to terminate the Distribution Agreement or to fail to purchase the minimum requirements and allow its distribution rights to become non-exclusive. Any such termination or failure could have a material and adverse effect on our financial condition, results of operations and cash flows.

A few customers account for a substantial portion of the end user sales of our concentrate products. The loss of any of these customers could have a material adverse effect on our results of operations and cash flow from our concentrate business.

Beginning in October 2014, our concentrate and ancillary products are primarily sold to or through Baxter. Its sales of our products are highly concentrated in a few customers and Baxter's 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. If Baxter were to lose this customer or the relationship with any other major dialysis chain customers, it could have a substantial negative impact on our cash flow and operating results.

The concentrate market is very competitive and has a large competitor with substantial resources.

There is intense competition in the hemodialysis products market. The primary competitor in the market for our concentrate products is a large diversified company which has substantial financial, technical, manufacturing, marketing, research and management resources. Our distributor, Baxter, may not be able to successfully compete with them or other companies. The primary competitor has historically used product bundling and low pricing as marketing techniques to capture market share of the products we sell. Baxter may be at a disadvantage in competing against their marketing strategies to sell our products. Furthermore, the primary competitor is vertically integrated and is the largest provider of dialysis services in the United States, treating approximately 37% of all U.S. patients through its clinics. This competitor has routinely acquired smaller clinic chain operations that we

service and may acquire more of the customers we service in the future. In addition, if the Distribution Agreement were to terminate or if the distribution rights were to become non-exclusive, Baxter may be able to compete with us, which could materially and adversely affect our business.

We may be affected materially and adversely by increases in raw material costs.

A significant portion of our costs relates to chemicals and other raw materials, which are subject to price volatility based on demand and are highly influenced by the overall level of economic activity in the U.S. and abroad. These costs have tended to rise from year to year and are likely to continue to rise in the future. Under our Distribution Agreement with Baxter, such cost inflation may result in increases in the prices we charge Baxter. If these increases exceed specified levels in the Distribution Agreement, Baxter is permitted to terminate the Distribution Agreement and obtain a refund of a portion of the fees we received from Baxter. Any such termination or refund would have a material adverse effect on our business, results of operations, financial position and cash flows.

Our concentrate business is highly regulated, which increases our costs and the risk and consequence of noncompliance.

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 good manufacturing practices and quality. Our failure to comply with these regulations could result in FDA action or product liability litigation adverse to us. Any of these events could constitute a breach by us of the Distribution Agreement, providing Baxter with various remedies that would be material and adverse to us, including without limitation, termination of the Distribution Agreement. Moreover, changes in applicable regulatory requirements could significantly increase the costs of our operations and, if such higher costs result in price increases that exceed the thresholds specified in the Distribution Agreement, could give Baxter the right to terminate the Distribution Agreement and obtain a partial refund of certain fees paid to us pursuant to that agreement.

RISKS RELATED TO OUR BUSINESS AS A WHOLE

We may not be successful in expanding our product portfolio or in our business development efforts related to in-licensing, acquisitions or other business collaborations. Even if we are able to enter into business development arrangements, they could have a negative impact on our business and our profitability.

As part of our business strategy to expand our product portfolio, we are seeking to acquire or in-license other drug products that we believe are a complementary fit with our current product portfolio as well as other products that we believe have substantial development potential. Our experience with respect to these business development activities is limited. The negotiation of such arrangements can be a lengthy and complex process and there can be no assurance that any such negotiations will be completed on a timely basis or on terms that are cost-effective and acceptable to us or, if they are completed, that we will be able to effectively integrate, develop and launch such products effectively.

In addition, the market potential for new products is highly uncertain and evaluation of such potential requires significant judgment and assumptions. There is a significant risk that any new product may not be able to be brought to market as profitably as expected or at all. If the results of

any new product initiative were materially worse than expected, it could have a material adverse effect on our financial results and condition.

Our drug and concentrate businesses are highly regulated, resulting in additional expense and risk of noncompliance that can materially and adversely affect our business, financial condition and results of operations.

Our businesses are highly regulated. The testing, manufacture and sale of the products we manufacture directly or through third party contractors are subject to extensive regulation by the FDA and by other federal, state and foreign authorities. Before drugs or medical devices, such as our concentrate products, can be commercially marketed in the United States, the FDA must give either approval or 510(k) clearance. Even after a product is approved, regulatory authorities may still impose significant restrictions on a product's indicated uses or marketing or impose requirements for potentially costly post-marketing studies. In addition, our products are subject to ongoing regulatory requirements for labeling, packaging, storage, advertising, promotion, sampling, record-keeping and reporting of safety and other post-market information, including both federal and state requirements in the United States and in other jurisdictions where they are marketed. In addition, manufacturers and their facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to current cGMP and applicable state laws. As such, we and our contract manufacturers are subject to continual review and periodic inspections to assess compliance with cGMP and state laws. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas to achieve and maintain regulatory compliance. We are also required to report certain adverse reactions and production problems, if any, to the FDA, state agencies and foreign regulatory authorities, when applicable, and to comply with requirements concerning advertising and promotion for our products.

If a regulatory agency determines that we do not comply with any applicable regulatory requirements, we may be subject to warnings from, or enforcement action by, state and federal government authorities that may include penalties, fines, injunctions, recall or seizure of products, suspension of production, denial of future regulatory approvals, withdrawal or suspension of existing regulatory approvals, operating restrictions, injunctions and criminal prosecution. If regulatory sanctions are applied, the value of our Company and our operating results could be materially and adversely affected.

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, our founder and Chief Executive Officer, Dr. Ajay Gupta, 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 have current employment agreements 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.

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. Moreover, if Baxter is prevented from selling from any of our concentrate or ancillary products due to a patent infringement or if its ability to sell any of our concentrate or ancillary products due to a patent infringement is materially and adversely affected, Baxter may be entitled to terminate our Distribution Agreement and obtain a refund of a portion of the upfront fee and facility fee.

Our products may have undesirable side effects and our product liability insurance may not be sufficient to protect us from material liability or harm to our business.

If concerns are raised regarding the safety of a new drug as a result of undesirable side effects identified during clinical testing, the FDA may decline to approve the drug at the end of the NDA review period or issue a letter requesting additional data or information prior to making a final decision regarding whether or not to approve the drug. Following FDA approval, if we or others later identify previously unknown undesirable side effects caused by our drug or concentrate products, if known side effects are more frequent or severe than in the past, or if we or others detect unexpected safety signals for such products or any products perceived to be similar to such products, the FDA or other applicable regulatory authorities may require the addition of unfavorable labeling statements, specific warnings or contraindications, may suspend or withdraw their approval of the product, may require it to be removed from the market or may impose restrictions on the distribution or use of the product. Such side effects may also result in litigation against the Company by private litigants.

We maintain products liability insurance in the amount of $5 million per occurrence and $5 million in the aggregate. We cannot be sure that such insurance would be sufficient to protect us against liabilities associated with any of these events in view of our expanding business or that such insurance will remain available at economical levels. We may have significant legal expenses that are not covered by insurance. In addition, our reputation could be damaged by such sanctions or product liability litigation and that could harm our marketing ability. Any such sanctions or litigation could also hurt our ability to retain products liability insurance or make such insurance more expensive. In any such event, our business, financial condition and results of operations could be materially adversely affected.

We may be unable to obtain certain debt financing in the future as a result of our arrangement with Baxter.

The Distribution Agreement prohibits us from entering into a contract encumbering the assets used in our concentrate business without the prior written consent of Baxter, and Baxter would be under no obligation to provide us with consent. The assets used in our concentrate business currently constitute a substantial portion of the tangible assets we own. If our development activities require substantial cash resources in the future in excess of our liquid resources on hand and if our cash flows are not sufficient to support financing through unsecured indebtedness, we may not be able to obtain debt financing and our capital financing options may become limited. If we are unable to generate, retain or obtain adequate capital, our business and our future development and expansion strategies may be adversely affected.

RISKS RELATED TO OUR COMMON STOCK

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

Any future sales by us of substantial amounts of our common shares, 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. 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, 2014, there were 4,304,583 shares issuable upon the exercise of outstanding and exercisable stock options, 2,580,500 shares issuable upon the exercise of outstanding stock options that are not yet exercisable and 733,066 additional shares available for future grant under our 2007 Long Term Incentive Plan. The market price of the common shares may be depressed by the potential exercise of these options. The holders of these options 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.

The market price for our common stock is 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 and control over our share price.

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.

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. 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 2014 and 2013.

	Price Range	
	High	Low
2014		
Fourth Quarter	$ 11.75	$ 8.10
Third Quarter	12.42	9.05
Second Quarter	13.06	9.37
First Quarter	14.80	9.49
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

As of February 24, 2015, there were 23 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.

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, 2009 with relative performance tracked through December 31, 2014. 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 12/31/09 in stock or index, including reinvestment of dividends.

Fiscal year ending December 31.

	12/31/2009	12/31/2010	12/31/2011	12/31/2012	12/31/2013	12/31/2014
Rockwell Medical, Inc.	**100.00**	**102.73**	**110.14**	**104.68**	**135.76**	**133.68**
Russell 2000	**100.00**	**126.86**	**121.56**	**141.43**	**196.34**	**205.95**
NASDAQ Biotechnology	**100.00**	**106.73**	**122.40**	**166.72**	**286.55**	**379.71**

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,				
	2014	2013	2012	2011	2010
Net sales	$ 54,188,444	$ 52,379,543	$ 49,842,392	$ 48,966,231	$ 59,554,592
Cost of sales	45,643,231	45,720,323	43,148,965	43,323,321	49,693,753
Gross profit	8,545,213	6,659,220	6,693,427	5,642,910	9,860,839
Income from continuing operations before interest expense and income taxes(1)	(17,559,101)	(47,059,266)	(54,262,082)	(21,684,757)	(2,868,916)
Interest (expense) and Investment Income, net	(3,768,056)	(1,724,046)	240,567	242,205	185,517
Income from continuing operations before income taxes	(21,327,157)	(48,783,312)	(54,021,515)	(21,442,552)	(2,683,399)
Income taxes				2,005	
Net income	(21,327,157)	(48,783,312)	(54,021,515)	(21,444,557)	(2,683,399)
Earnings per common share:					
Basic	$ (0.52)	$ (1.48)	$ (2.65)	$ (1.21)	$ (0.16)
Diluted	$ (0.52)	$ (1.48)	$ (2.65)	$ (1.21)	$ (0.16)
Weighted average number of common shares and common share equivalents					
Basic	41,404,999	32,882,333	20,395,889	17,774,865	17,111,535
Diluted	41,404,999	32,882,333	20,395,889	17,774,865	17,111,535

	2014	2013	2012	2011	2010
Total assets	$ 97,999,716	$ 36,362,124	$ 17,025,086	$ 31,939,599	$ 36,966,907
Current assets	94,707,149	31,917,774	13,149,432	25,896,529	32,666,368
Current liabilities	9,804,402	17,849,671	26,986,956	13,692,351	6,420,220
Working capital	84,902,747	14,068,103	(13,837,524)	12,204,178	26,246,148
Long-term debt and capitalized lease obligations		17,916,914		2,280	8,750
Stockholders' equity(2)	68,702,794	595,539	(9,961,870)	18,244,968	30,537,937
Book value per outstanding common share	$ 1.37	$ 0.01	$ (0.46)	$ 0.98	$ 1.74
Common shares outstanding	50,284,007	40,110,661	21,494,696	18,710,002	17,513,608

(1) Decrease in loss in 2014 reflects significant decrease in research and development expenses associated with completion of Phase 3 clinical trials for Triferic .

(2) There were no cash dividends paid during the periods presented. Stockholders' equity reflects the proceeds of public and private offerings in 2014, 2013 and 2012.

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 United States 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 January 2015, we received FDA approval to market Triferic our lead branded drug. Based on our clinical trial results, we believe Triferic has the potential to capture significant market share due to its unique attributes and clinical benefits, including savings on nursing administration time, potential to reduce expensive ESA treatments and excellent safety profile. We also received FDA approval to manufacture Calcitriol an injectable generic vitamin D analogue. We plan to launch both of these drugs in 2015.

In 2014, our dialysis concentrate business had revenue of $54.2 million, an increase of 3.5% or $1.8 million while our gross profit increased by 28% or $1.9 million. We supply approximately 25% of the United States domestic market with dialysis concentrates and we also supply dialysis concentrates to distributors serving a number of foreign countries, primarily in the Americas as well as the Pacific Rim.

In October 2014, we entered into the Distribution Agreement with Baxter, a leading global dialysis products supplier, to exclusively distribute our dialysis concentrates in the United States and certain foreign markets. Under the Distribution Agreement, we are the exclusive third party supplier of dialysis concentrates to Baxter in the United States. Rockwell receives a pre-defined gross profit margin on its products sold through Baxter which adjusts each year over the ten year term of the agreement and is subject to an annual true-up. Baxter must achieve certain growth targets to maintain its exclusivity under the agreement. This Distribution Agreement relates solely to our dialysis concentrate business and excludes any future drug related business. For a more detailed description of the Distribution Agreement, see "Item 1 Business Distribution Agreement with Baxter. We expect the distribution relationship with Baxter under the Distribution Agreement to have a generally positive impact on our operating profit. Our operating costs are expected to decrease and operating income should improve. Initially, our sales will decrease, partially offset by the portion of the $20 million license fee received from Baxter that is being recognized as revenue over the term of the Distribution Agreement. Going forward over time, we expect our overall domestic and global concentrate sales to increase as a result of Baxter's expanded marketing reach, coupled with the anticipated expansion of our manufacturing operations in the Western United States.

In the fourth quarter of 2014, we strengthened our balance sheet to position the Company for future growth and development. We raised net proceeds of approximately $55 million in a public offering of our common shares and sold $15 million of common shares to Baxter in a private offering. We also received $20 million in cash from Baxter related to the Distribution Agreement related to our concentrate products. We fully paid off our high interest rate long term debt and we have no debt on our balance sheet. Overall, we had cash and investments of $85.7 million as of December 31, 2014.

We expect to achieve profitability following the launch of our drug products and to generate positive cash flow from our business operations as a result.

Results of Operations

For the year ended December 31, 2014 compared to the year ended December 31, 2013

Sales

In 2014, our sales were $54.2 million compared to $52.4 million in 2013 an increase of $1.8 million or 3.5%. Domestic sales increased $1.1 million or 2.5% and international sales increased $0.7 million or 10.4%.

The growth in and conversion to our higher margin CitraPure dry acid concentrate product line contributed to improving gross profit margin while moderating the sales increase. CitraPure products represented 63.5% of gallons sold in 2014 compared to 32.5% in 2013.

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

Gross Profit

Our gross profit was $8.5 million in 2014, an increase of $1.9 million or 28.3% compared to 2013. Gross profit margins were 15.8% in 2014 compared to 12.7% in 2013. The increase in gross profit was primarily due to the favorable impact of higher sales of our higher margin CitraPure product lines, strong sales of other higher margin products, a more favorable customer profile and our efforts to reduce operating and distribution costs. We also realized approximately $0.3 million in additional gross profit as a result of the execution of the Distribution Agreement with Baxter in the fourth quarter of 2014.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $18.3 million in 2014 compared to $14.3 million in 2013. The increase of $4.0 million was primarily due to an increase of $2.4 million in non-cash equity compensation expenses, increased cash compensation of $0.6 million and increased marketing, legal and regulatory expenses related to Triferic of $0.6 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 $7.8 million and $39.4 million in 2014 and 2013, respectively. Costs incurred in 2014 were mostly related to Triferic and primarily for regulatory approval of Triferic , which the FDA approved in January 2015. Spending in 2014 also included costs for the completion of the Triferic clinical program. Costs incurred in 2013 were primarily for conducting human clinical trials of Triferic and other Triferic testing and development activities.

Future R&D spending on the Triferic platform is expected to include clinical testing in connection with peritoneal dialysis, total parenteral nutrition, an orphan indication and a pediatric indication. Spending on product development and research activities is not expected to be significant in 2015.

Interest Expense, Net

Our net interest expense was $3.8 million in 2014 compared to $1.7 million in 2013. The increase in net interest expense was due to the loan agreement entered into in June 2013. We fully paid off that loan in the fourth quarter of 2014, which included a $1.1 million end of term fee and have no remaining debt as of December 31, 2014. The end of term fee was being recognized over the term of

the loan and the remaining unamortized portion was recognized as interest expense upon termination of the loan.

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, 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.

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.

Interest Expense, Net

Our net interest expense was $1.7 million in 2013 compared to net interest and investment income of $0.2 million 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.

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

In May 2014, the Financial Accounting Standards Board issued Accounting Standards Update No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which will supersede the current revenue recognition requirements in Topic 605, *Revenue Recognition*. The ASU is based on the principle that revenue is recognized to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The ASU also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. The new guidance will be effective for the Company's year ending December 31, 2017, including interim periods within that reporting period. The ASU permits the new revenue recognition guidance to be applied using one of two retrospective application methods. The Company has not yet determined which application method it will use or the potential effects of the new standard on the financial statements, if any.

Liquidity and Capital Resources

We have adequate capital resources and substantial liquidity to pursue our business strategy. Our strategy is centered on developing and licensing high potential drug candidates including Triferic , for which we received FDA approval to market in late January 2015. We intend to commercialize Triferic using Rockwell's sales and marketing infrastructure with minor additional resources added to support commercialization.

As of December 31, 2014, we had current assets of $94.7 million and net working capital of $84.9 million. We have over $85.7 million in cash and investments with over $65 million of that total in cash. Our cash resources include cash generated from our business operations, $55 million we raised from an equity offering, $20 million from Baxter related to the Distribution Agreement, and

$15 million from a private placement of common shares to Baxter. We also received $8.4 million from the exercise of expiring warrants during 2014. We expect cash flow from operations to be positive following the launch of our drug products in 2015. Cash flow from operations improved to $4.3 million in 2014 from ($50.7 million) in 2013 due largely to the decrease in research and development expense and the $20 million upfront payment from Baxter.

We have no long term debt as of December 31, 2014 and do not expect to incur interest expense in 2015, the sum of which aggregated $4.2 million of interest expense in 2014.

We intend to expand our plant operations during 2015. Under the terms of our Distribution Agreement, capital spending related to such an expansion will be funded through payments by Baxter of $5 million upon commencement of construction and up to $5 million following completion. Other capital expenditures on our current facilities are not expected to materially exceed depreciation expense. We intend to source our drug products from contract manufacturing organizations.

Our research and development expenses were reduced significantly following the completion of the clinical program for Triferic and FDA approval of Triferic . Future R&D spending on the Triferic platform is expected to include clinical testing in connection with peritoneal dialysis, total parenteral nutrition and pediatric indications. Future spending on such indications is expected to be minor in relation to the Company's cash resources. Our expected future cash investment for product launches is expected to be primarily related to working capital for inventory and accounts receivables in the near term.

The Company is in discussions with multiple potential business development partners to out-license rights to Rockwell's products outside the United States. We are considering other business development arrangements including joint ventures, partnerships and other transactions related to our products or other future products that we may develop or license.

Contractual Obligations

The following table details our contractual obligations as of December 31, 2014:

		Payments due by period			
Contractual Obligations	**Total**	**Less than 1 year**	**1 - 3 years**	**3 - 5 years**	**More than 5 years**
Operating leases	$ 5,314,131	1,658,737	1,988,268	1,583,835	83,291
Purchase obligations					
All other long term liabilities					
Total	$ 5,314,131	$ 1,658,737	$ 1,988,268	$ 1,583,835	$ 83,291

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

We have invested $19.9 million in available for sale securities that 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-28 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, 2014. In making its assessment of internal control over financial reporting, management used the criteria described in the 2013 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, 2014.

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, 2014. 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, 2014 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, 2014:

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	6,885,083	$ 7.41	733,066
Equity compensation plans not approved by security holders			
Total	6,885,083	$ 7.41	733,066

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).
*10.43	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).
*10.46	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).
*10.54	Form of Restricted Stock Award Agreement June 2013 (Executive Version) (Company's Form 10-Q filed May 12, 2014).

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).
10.56	Rockwell Medical, Inc. Amended and Restated 2007 Long Term Incentive Plan, as amended effective May 22, 2014 (appendix to Company's Proxy Statement for the 2014 Annual Meeting of Shareholders filed April 14, 2014).
10.57	Exclusive Distribution Agreement, dated as of October 2, 2014, between the Company and Baxter Healthcare Corporation (with certain portions redacted pursuant to a confidential treatment order).
10.58	Investment Agreement, dated as of October 2, 2014, between the Company and Baxter Healthcare Corporation.
*10.59	Amendment to October 1, 2014 Stock Option Agreement with Robert L. Chioini.
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 3, 2015

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 3, 2015
/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 3, 2015
/s/ KENNETH L. HOLT Kenneth L. Holt	Director	March 3, 2015
/s/ RONALD D. BOYD Ronald D. Boyd	Director	March 3, 2015
/s/ PATRICK J. BAGLEY Patrick J. Bagley	Director	March 3, 2015

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, 2014 and 2013, 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, 2014. 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, 2014 and 2013, and the consolidated results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2014, in conformity with U.S. generally accepted accounting principles.

The financial statement schedule has been subjected to audit procedures performed in conjunction with the audit of the Company's financial statements. The financial statement schedule is the responsibility of the Company's management. Our audit procedures included determining whether the financial statement schedule reconciles to the financial statements or the underlying accounting and other records, as applicable, and performing procedures to test the completeness and accuracy of the information presented in the financial statement schedule. In forming our opinion on the financial statement schedule, we evaluated whether the financial statement schedule, including its form and content, is presented in conformity with generally accepted accounting principles. In our opinion, the financial statement schedule is fairly stated, in all material respects, in relation to the financial statements as a whole.

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, 2014, based on criteria established in the 2013 Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 3, 2015 expressed an unqualified opinion on the effectiveness of internal control over financial reporting.

/s/ Plante & Moran, PLLC

Clinton Township, Michigan
March 3, 2015

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, 2014, based on criteria established in the 2013 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, 2014, based on criteria established in the 2013 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, 2014 and 2013, 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, 2014 and related financial statement schedule and our report dated March 3, 2015 expressed an unqualified opinion thereon.

/s/ Plante & Moran, PLLC

Clinton Township, Michigan
March 3, 2015

ROCKWELL MEDICAL, INC. AND SUBSIDIARY

CONSOLIDATED BALANCE SHEETS

As of December 31, 2014 and 2013

	December 31, 2014	December 31, 2013
ASSETS		
Cash and Cash Equivalents	$ 65,800,451	$ 11,881,451
Investments Available for Sale	19,927,310	12,034,622
Accounts Receivable, net of a reserve of $52,000 in 2014 and $37,000 in 2013	4,472,002	4,578,319
Inventory	3,920,185	2,799,648
Other Current Assets	587,201	623,734
Total Current Assets	94,707,149	31,917,774
Property and Equipment, net	1,496,912	1,648,949
Intangible Assets	332,686	499,715
Goodwill	920,745	920,745
Other Non-current Assets	542,224	1,374,941
Total Assets	$ 97,999,716	$ 36,362,124
LIABILITIES AND SHAREHOLDERS' EQUITY		
Note Payable	$	$ 2,308,145
Accounts Payable	5,294,515	8,686,153
Accrued Liabilities	4,325,997	6,647,828
Customer Deposits	183,890	207,545
Total Current Liabilities	9,804,402	17,849,671
Deferred License Revenue	19,492,520	
Long Term Debt		17,916,914
Shareholders' Equity:		
Common Shares, no par value, 50,284,007 and 40,110,661 shares issued and outstanding	249,018,189	154,457,878
Common Share Purchase Warrants, none and 983,071 warrants issued and outstanding		4,895,811
Accumulated Deficit	(180,117,726)	(158,790,569)
Accumulated Other Comprehensive Income	(197,669)	32,419
Total Shareholders' Equity	68,702,794	595,539
Total Liabilities And Shareholders' Equity	$ 97,999,716	$ 36,362,124

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, 2014, 2013 and 2012

	2014	2013	2012
Sales	$ 54,188,444	$ 52,379,543	$ 49,842,392
Cost of Sales	45,643,231	45,720,323	43,148,965
Gross Profit	8,545,213	6,659,220	6,693,427
Selling, General and Administrative	18,320,720	14,336,449	12,683,860