UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **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 ☒

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 ☒

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 ☒ 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 ☒ 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 ☒	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 ☒

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.

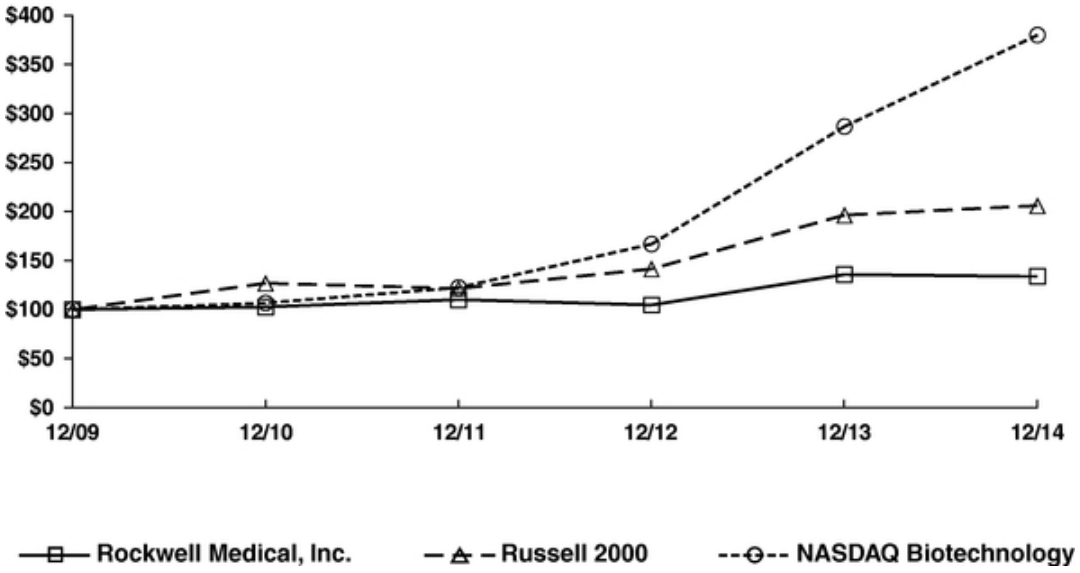
Securities Authorized for Issuance Under Equity Compensation Plans

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
Research and Product Development	7,783,594	39,382,037	48,271,649
Operating Income (Loss)	(17,559,101)	(47,059,266)	(54,262,082)
Interest and Investment Income	386,257	98,101	241,518
Interest (Expense)	(4,154,313)	(1,822,147)	(951)
Income (Loss) Before Income Taxes	(21,327,157)	(48,783,312)	(54,021,515)
Income Tax Expense	—	—	—
Net Income (Loss)	$ (21,327,157)	$ (48,783,312)	$ (54,021,515)
Basic And Diluted Earnings (Loss) Per Share	$ (0.52)	$ (1.48)	$ (2.65)

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

ROCKWELL MEDICAL, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

For The Years Ended December 31, 2014, 2013 and 2012

	2014	2013	2012
Net Income (Loss)	**$ (21,327,157)**	**$ (48,783,312)**	**$ (54,021,515)**
Reclassification of Losses Included in Net Loss	—	—	67,303
Unrealized Gain (Loss) on Available-for-Sale Investments	(230,088)	32,419	213,809
Comprehensive Income (Loss)	**$ (21,557,245)**	**$ (48,750,893)**	**$ (53,740,403)**

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

ROCKWELL MEDICAL, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY

For The Years Ended December 31, 2014, 2013 and 2012

	COMMON SHARES		PURCHASE WARRANTS		ACCUMULATED DEFICIT	ACCUMULATED OTHER COMPREHENSIVE INCOME (LOSS)	TOTAL SHAREHOLDER'S EQUITY
	SHARES	AMOUNT	WARRANTS	AMOUNT			
Balance as of December 31, 2011	18,710,002	$ 67,407,847	2,607,440	$ 7,103,975	$ (55,985,742)	$ (281,112)	$ 18,244,968
Net Loss					(54,021,515)		(54,021,515)
Reclassification of Losses Included in Net Loss						67,303	67,303
Unrealized Gain on Available-for-Sale Investments						213,809	213,809
Issuance of Common Shares	2,296,477	16,252,695					16,252,695
Shares Issued in Exchange for Services	200,000	1,854,000					1,854,000
Exercise of Purchase Warrants	288,217	2,372,192	(374,200)	(393,463)			1,978,729
Purchase Warrants Expense				468,417			468,417
Stock Option Based Expense		3,903,795					3,903,795
Restricted Stock Amortization		1,075,929					1,075,929
Balance as of December 31, 2012	21,494,696	$ 92,866,458	2,233,240	$ 7,178,929	$ (110,007,257)	$ —	$ (9,961,870)
Net Loss					(48,783,312)		(48,783,312)
Unrealized Gain on Available-for-Sale Investments						32,419	32,419
Issuance of Common Shares	18,285,132	50,431,250					50,431,250
Shares Issued in Exchange for Services	200,000	780,678					780,678
Exercise of Purchase Warrants	130,833	1,593,003	(130,833)	(428,021)			1,164,982
Expiration of Purchase Warrants		2,937,293	(1,119,336)	(2,937,293)			—
Purchase Warrants Expense				1,082,196			1,082,196
Stock Option Based Expense		3,887,695					3,887,695
Restricted Stock Amortization		1,961,501					1,961,501
Balance as of December 31, 2013	40,110,661	154,457,878	983,071	4,895,811	(158,790,569)	32,419	595,539
Net Loss					(21,327,157)		(21,327,157)
Unrealized Gain on Available-for-Sale Investments						(230,088)	(230,088)
Issuance of Common Shares	9,268,460	71,136,487					71,136,487
Exercise of Purchase Warrants	904,886	13,329,138	(983,071)	(4,895,811)			8,433,327
Stock Option Based Expense		4,597,412					4,597,412
Restricted Stock Amortization		5,497,274					5,497,274
Balance as of December 31, 2014	50,284,007	$ 249,018,189	—	$ —	$ (180,117,726)	$ (197,669)	$ 68,702,794

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

ROCKWELL MEDICAL, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CASH FLOWS

For the years ended December 31, 2014, 2013 and 2012

	2014	2013	2012
Cash Flows From Operating Activities:			
Net (Loss)	**$ (21,327,157)**	**$ (48,783,312)**	**$ (54,021,515)**
Adjustments To Reconcile Net Loss To Net Cash Used In			
Operating Activities:			
Depreciation and Amortization	996,321	1,007,411	1,087,397
Share Based Compensation—Non-employee	—	1,862,874	2,322,417
Share Based Compensation- Employees	10,094,685	5,849,196	4,979,724
Loss (Gain) on Disposal of Assets	7,338	16,410	17,876
Loss on Sale of Investments Available for Sale	1,223	—	67,303
Amortization of Debt Issuance Costs	882,716	227,059	—
Non-Cash Interest Expense	874,942	225,059	—
Changes in Assets and Liabilities:			
(Increase) Decrease in Accounts Receivable	106,317	(146,387)	(209,116)
(Increase) in Inventory	(1,120,537)	(150,009)	(145,512)
(Increase) Decrease in Other Assets	(13,466)	669,896	1,855,787
Increase (Decrease) in Accounts Payable	(3,391,638)	(6,147,412)	9,469,028
Increase (Decrease) in Other Liabilities	(2,345,486)	(5,295,738)	3,829,767
Deferred Distribution Agreement Income	20,000,000	—	—
Recognized Distribution Agreement Income	(507,480)	—	—
Changes in Assets and Liabilities	12,727,710	(11,069,650)	14,799,954
Cash Provided By (Used In) Operating Activities	**4,257,778**	**(50,664,953)**	**(30,746,844)**
Cash Flows From Investing Activities:			
Purchase of Investments Available for Sale	(13,100,000)	(12,002,203)	(2,012,671)
Sale of Investments Available for Sale	4,976,000	—	14,037,255
Purchase of Equipment	(684,593)	(654,197)	(507,788)
Proceeds on Sale of Assets	—	6,898	1,578
Cash Provided By (Used In) Investing Activities	**(8,808,593)**	**(12,649,502)**	**11,518,374**
Cash Flows From Financing Activities:			
Proceeds from Issuance of Common Shares and Purchase Warrants	79,569,815	51,596,232	18,231,424
Proceeds from the Issuance of Notes Payable	—	20,000,000	—
Debt Issuance Costs	—	(1,109,776)	—
Payments on Notes Payable and Capital Lease Obligations	(21,100,000)	(2,280)	(6,470)
Cash Provided By Financing Activities	**58,469,815**	**70,484,176**	**18,224,954**
Increase (Decrease) In Cash	53,919,000	7,169,721	(1,003,516)
Cash At Beginning Of Period	11,881,451	4,711,730	5,715,246
Cash At End Of Period	**$ 65,800,451**	**$ 11,881,451**	**$ 4,711,730**

Supplemental Cash Flow disclosure

	2014	2013	2012
Interest Paid	$ 3,518,168	$ 1,154,752	$ 951
Non-Cash Investing and Financing Activity—			
Acquisition of Intangible Assets	$ —	$ —	$ —

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

1. DESCRIPTION OF BUSINESS

We are 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. We have obtained global licenses for certain dialysis related drugs which we are developing and planning to market.

We manufacture, sell and distribute hemodialysis concentrates and other ancillary medical products and supplies used in the treatment of patients with End Stage Renal Disease, or "ESRD". We supply our products to medical service providers who treat patients with kidney disease. Our products are used to cleanse patients' blood and replace nutrients lost during the kidney dialysis process. We primarily sell our products in the United States.

We are regulated by the Federal Food and Drug Administration ("FDA") under the Federal Drug and Cosmetics Act, as well as by other federal, state and local agencies. We obtained FDA approval of Triferic™, our branded dialysis iron maintenance therapy drug, in January 2015. We have also received 510(k) approval from the FDA to market hemodialysis solutions and powders. We also have 510(k) approval to sell our Dri-Sate Dry Acid Concentrate product line and our Dri-Sate Mixer.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

Our consolidated financial statements include our accounts and the accounts for our wholly owned subsidiary, Rockwell Transportation, Inc.

All intercompany balances and transactions have been eliminated in consolidation.

Revenue Recognition

We recognize revenue at the time we transfer title to our products to our customers consistent with generally accepted accounting principles. Generally, we recognize revenue when our products are delivered to our customer's location consistent with our terms of sale. We recognize revenue for international shipments when title has transferred consistent with standard terms of sale.

The initial payment received from our long-term distribution agreement has been deferred and classified as deferred license revenue. Deferred license revenue is being recognized based on the proportion of product shipments to Baxter in each period to total expected sales volume for the term of the agreement.

We require certain customers, mostly international customers, to pay for product prior to the transfer of title to the customer. Deposits received from customers and payments in advance for orders are recorded as liabilities under Customer Deposits until such time as orders are filled and title transfers to the customer consistent with our terms of sale. At December 31, 2014 and 2013 we had customer deposits of $183,890 and $207,545, respectively.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Shipping and Handling Revenue and Costs

Our products are generally priced on a delivered basis with the price of delivery included in the overall price of our products which is reported as sales. Separately identified freight and handling charges are also included in sales.

We include shipping and handling costs, including expenses of Rockwell Transportation, Inc., in cost of sales.

Cash and Cash Equivalents

We consider cash on hand, money market funds and unrestricted certificates of deposit with an original maturity of 90 days or less as cash and cash equivalents.

Investments Available for Sale

Investments Available for Sale are short-term investments, consisting principally of investments in short term duration bond funds, and are stated at fair value based upon observed market prices (Level 1 in the fair value hierarchy). Unrealized holding gains or losses on these securities are included in accumulated other comprehensive income (loss). Realized gains and losses, including declines in value judged to be other-than-temporary on available-for-sale securities are included as a component of other income or expense.

Accounts Receivable

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 accounts 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.

Inventory

Inventory is stated at the lower of cost or net realizable value. Cost is determined on the first-in first-out (FIFO) method.

Property and Equipment

Property and equipment are recorded at cost. Expenditures for normal maintenance and repairs are charged to expense as incurred. Property and equipment are depreciated using the straight-line method over their useful lives, which range from three to ten years. Leasehold improvements are amortized using the straight-line method over the shorter of their useful lives or the related lease term.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Licensing Fees

License fees related to the technology, intellectual property and marketing rights for dialysate iron covered under certain issued patents have been capitalized and are being amortized over the life of the related patents which is generally 17 years.

Goodwill, Intangible Assets and Long Lived Assets

The recorded amounts of goodwill and other intangibles from prior business combinations are based on management's best estimates of the fair values of assets acquired and liabilities assumed at the date of acquisition. Goodwill is not amortized; however, it must be tested for impairment at least annually. Amortization continues to be recorded for other intangible assets with definite lives over their 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.

An impairment review of goodwill, intangible assets, and property and equipment 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.

The useful lives of other intangible assets are based on management's best estimates of the period over which the assets are expected to contribute directly or indirectly to our future cash flows. Management annually evaluates the remaining useful lives of intangible assets with finite useful lives to determine whether events and circumstances warrant a revision to the remaining amortization periods. It is reasonably possible that management's estimates of the carrying amount of goodwill and the remaining useful lives of other intangible assets may change in the near term.

Debt Issuance Costs

Debt issuance costs are capitalized and amortized over the term of the underlying debt instruments using the effective-interest rate method. Debt issuance costs are recorded as other assets.

Income Taxes

We account for income taxes in accordance with the provisions of ASC 740-10, *Income Taxes*. A current tax liability or asset is recognized for the estimated taxes payable or refundable on tax returns for the year. Deferred tax liabilities or assets are recognized for the estimated future tax effects of temporary differences between book and tax accounting and operating loss and tax credit carryforwards. A valuation allowance is established for deferred tax assets if we determine it to be more likely than not that the deferred tax asset will not be realized. The Company recognizes interest and penalties accrued related to unrecognized tax benefits as income tax expense.

The effects of tax positions are generally recognized in the financial statements consistent with amounts reflected in returns filed, or expected to be filed, with taxing authorities. For tax positions that the Company considers to be uncertain, current and deferred tax liabilities are recognized, or assets derecognized, when it is probable that an income tax liability has been incurred and the amount of the liability is reasonably estimable, or when it is probable that a tax benefit, such as a tax credit or loss

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

carryforward, will be disallowed by a taxing authority. The amount of unrecognized tax benefits related to current tax positions is insignificant.

Research and Product Development

We recognize research and product development costs as expenses as incurred. 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.

Share Based Compensation

We measure the cost of employee services received in exchange for equity awards, including stock options, based on the grant date fair value of the awards in accordance with ASC 718-10, *Compensation—Stock Compensation.* The cost of equity based compensation is recognized as compensation expense over the vesting period of the awards.

We estimate the fair value of compensation involving stock options utilizing the Black-Scholes option pricing model. This model requires the input of several factors such as the expected option term, expected volatility of our stock price over the expected option term, and an expected forfeiture rate, and is subject to various assumptions. We believe the valuation methodology is appropriate for estimating the fair value of stock options we grant to employees and directors which are subject to ASC 718-10 requirements. These amounts are estimates and thus may not be reflective of actual future results or amounts ultimately realized by recipients of these grants.

Employee Retirement Plans

We are the sponsor of a non-contributory 401(k) Employee Savings Plan.

Earnings per Share

We computed our basic earnings (loss) per share using weighted average shares outstanding for each respective period. Diluted earnings per share also reflect the weighted average impact from the date of issuance of all potentially dilutive securities, consisting of stock options and common share purchase warrants, unless inclusion would have had an anti-dilutive effect. Actual weighted average shares outstanding used in calculating basic and diluted earnings per share were:

	2014	2013	2012
Basic Weighted Average Shares Outstanding	41,404,999	32,882,333	20,395,889
Effect of Dilutive Securities	-0-	-0-	-0-
Diluted Weighted Average Shares Outstanding	41,404,999	32,882,333	20,395,889

For 2014, 2013 and 2012, the dilutive effect of stock options, unvested restricted share grants and common share purchase warrants have not been included in the average shares outstanding for the

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

calculation of diluted loss per share as the effect would be anti-dilutive as a result of our net loss in these periods. The table below summarizes potentially dilutive securities.

	2014	2013	2012
Stock Options	6,898,000	6,228,000	5,989,200
Range of Exercise Prices of Stock Options	$3.09 - $10.20	$2.79 - $11.44	$1.81 - $10.20
Unvested Restricted Common Shares	740,000	545,000	545,000
Common Share Purchase Warrants	None	983,071	2,233,240
Range of Exercise Prices of Warrants	n/a	$9.55 - $10.25	$6.14 - $10.25

Investments Available for Sale

Investments Available for Sale are short-term investments, consisting principally of investments in short term duration bond funds, and are stated at fair value. Unrealized holding gains or losses on these securities are included in accumulated other comprehensive income (loss). Realized gains and losses, including declines in value judged to be other-than-temporary on available-for-sale securities are included as a component of other income or expense.

Management evaluates securities for other-than-temporary impairment ("OTTI") on a quarterly basis, and more frequently when conditions warrant such an evaluation. When evaluating investment securities, consideration is given to the length of time and the extent to which the fair value has been less than cost, the financial condition and near-term prospects of the issuer, and whether the Company has the intent to sell the security or more likely than not will be required to sell the security before its anticipated recovery. The assessment of whether an OTTI exists involves a high degree of subjectivity and judgment and is based on the information available to management at a point in time.

Other Comprehensive Income (Loss)

Accounting principles generally require that recognized revenue, expenses, gains, and losses be included in net income. Certain changes in assets and liabilities, however, such as unrealized gains and losses on available for sale securities, are reported as a direct adjustment to the equity section of the balance sheet. Such items, along with net income (loss), are considered components of comprehensive income (loss). Accumulated Other Comprehensive Income (Loss) consists solely of unrealized gains and losses on available-for-sale investment securities.

Estimates in Preparation of Financial Statements

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of revenues and expenses during the period. Actual results could differ from those estimates.

3. FAIR MARKET VALUE MEASUREMENTS

Accounting standards require certain assets and liabilities be reported at fair value in the financial statements and provides a framework for establishing that fair value. The framework for determining fair value is based on a hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described below:

Level 1:	Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.
Level 2:	Observable prices that are based on inputs not quoted in active markets, but corroborated by market data.
Level 3:	Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

In determining fair value, we utilize valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible as well as considering counterparty credit risk in its assessment of fair value. The following methods, assumptions, and valuation techniques were used to measure different financial assets and liabilities at fair value and in estimating its fair value disclosures for financial instruments.

Cash and Cash Equivalents: The carrying amounts reported in the consolidated statements of financial condition for cash and cash equivalents is deemed to approximate fair value

Investment Securities: Fair values for investment securities are determined by quoted market prices if available.

Notes Payable: The fair value of notes payable is based on the discounted value of contractual cash flows using rates currently offered for similar maturities.

Accounts receivable, Accounts Payable and Accrued Liabilities: The fair value of trade receivables and payables approximate their carrying amounts due to the short duration before collection or payment.

3. FAIR MARKET VALUE MEASUREMENTS (Continued)

Based on the foregoing methods and assumptions, the carrying value and fair value of the Company's financial instruments other than trade receivables and payables are as follows (in thousands):

	Carrying value	Fair value	Level 1	Level 2	Level 3
As of December 31, 2014					
Financial assets					
Cash and cash equivalents	$ 65,800	$ 65,800	$ 65,800	$ —	$ —
Investment securities available for sale	19,927	19,927	19,927	—	—
As of December 31, 2013					
Financial assets					
Cash and cash equivalents	11,881	11,881	11,881	—	—
Investment securities available for sale	12,035	12,035	12,035	—	—
Financial liabilities					
Notes Payable	20,000	20,000	—	20,000	—

The Company also has certain non-financial assets that under certain conditions are subject to measurement at fair value on a non-recurring basis. No such measurements were required in 2014 or 2013.

4. INVESTMENTS IN AVAILABLE FOR SALE SECURITIES

As of December 31, 2014, we held investments in available for sale securities in several short term bond funds. These funds generally held high credit quality short term debt instruments. These debt instruments were subject to changes in fair market value due to changes in interest rates. The market value of these investments was $19,927,310 as of December 31, 2014. In 2014, we purchased securities with a market value of $13,100,000 and had unrealized gains of $7,161 and unrealized losses of $204,830 as of December 31, 2014. In 2014, we sold securities with a market value of $4,976,000 with an average cost basis of $4,977,223. We realized gains of $28,430 and losses of $29,653 from sales of available for sale securities.

As of December 31, 2013, we held investments in available for sale securities in several short term bond funds. These funds generally held high credit quality short term debt instruments. These debt instruments were subject to changes in fair market value due to changes in interest rates. The market value of these investments was $12,034,622 as of December 31, 2013. In 2013 we purchased securities with a market value of $12,002,203 and had unrealized gains of $44,070 and unrealized losses of $11,652 as of December 31, 2013.

5. SIGNIFICANT MARKET SEGMENTS

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

5. SIGNIFICANT MARKET SEGMENTS (Continued)

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.

6. DISTRIBUTION AGREEMENT

As of October 2, 2014, we entered into the Distribution Agreement with Baxter, pursuant to which Baxter became the Company's exclusive agent for sales, marketing and distribution activities for the Company's hemodialysis concentrate and ancillary products in the United States and various foreign countries for an initial term of 10 years. The Distribution Agreement does not include any of the Company's drug products. The Company will retain sales, marketing and distribution rights for its hemodialysis concentrate products in specified foreign countries in which the Company has 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.

Pursuant to the Distribution Agreement, Baxter paid the Company $20 million in cash in early October (the "Upfront Fee"). The Upfront Fee has been deferred and will be recognized as revenue based on the proportion of product shipments to Baxter in each period to total expected sales volume over the term of the Distribution Agreement. The Company recognized revenue associated with the Upfront Fee totaling $507,480 for the year ended December 31, 2014.

Under the Distribution Agreement, Baxter will purchase products from the Company at established gross margin-based prices per unit, adjusted each year during the term. The Company will continue to manage customer service, transportation and certain other functions for its current customers on Baxter's behalf through at least December 31, 2017, in exchange for which Baxter will pay the Company an amount equal to the Company's related costs to provide such functions plus a slight mark-up.

The Distribution Agreement also requires Baxter to meet minimum annual gallon-equivalent 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. Orders in any contract year that exceed the minimum will be carried forward and applied to future years' minimum requirements. The Distribution Agreement also contains provisions governing the operating relationship between the parties, the Company's obligations to maintain specified manufacturing capacity and quality levels, remedies, as well as representations, warranties and indemnification obligations of the parties.

6. DISTRIBUTION AGREEMENT (Continued)

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 the Company 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 non-compete obligation in the United States with respect to certain products for a period of two years.

If a "Refund Trigger Event" occurs, the Company would be obligated to repay a portion of the Upfront Fee and Facility Fee (described below) as follows: 50% 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. 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 2018, Baxter would be entitled to a refund of up to $10 million, or $6.6 million if the termination occurs in 2019. In no event would Baxter be entitled to more than one refund payment.

The Distribution Agreement also required the Company to prepay its outstanding secured long-term indebtedness within 180 days and prohibits the Company from entering into a subsequent contract encumbering the assets used in the Company's concentrate business without the prior written consent of Baxter.

Baxter has also agreed to pay the Company $10 million (the "Facility Fee") to build and operate a new manufacturing facility located in the Pacific time zone to service customers in the Western United States. The Facility Fee 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, the Company will own the facility when completed.

The Distribution Agreement may be extended an additional five years by Baxter if Baxter 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.

7. INVENTORY

Components of inventory as of December 31, 2014 and 2013 are as follows:

	2014	2013
Raw Materials	$ 2,197,143	$ 1,142,776
Work in Process	197,106	254,714
Finished Goods	1,525,936	1,402,158
Total	$ 3,920,185	$ 2,799,648

8. PROPERTY AND EQUIPMENT

Major classes of property and equipment, stated at cost, as of December 31, 2014 and 2013 are as follows:

	2014	2013
Leasehold Improvements	$ 581,990	$ 517,907
Machinery and Equipment	6,635,380	6,398,396
Information Technology & Office Equipment	2,163,945	1,961,968
Laboratory Equipment	594,946	513,616
Transportation Equipment	319,209	374,035
	10,295,470	9,765,922
Accumulated Depreciation	(8,798,558)	(8,116,973)
Net Property and Equipment	$ 1,496,912	$ 1,648,949

Below is a summary of depreciation expense by period:

	2014	2013	2012
Depreciation expense	$ 829,292	$ 840,382	$ 920,368

9. GOODWILL AND INTANGIBLE ASSETS

Total goodwill was $920,745 at December 31, 2014 and 2013. We completed our annual impairment tests as of November 30, 2014 and 2013, and determined that no adjustment for impairment of goodwill was required.

We have entered into a global licensing agreement for certain patents covering Triferic™, a therapeutic drug compound to be delivered using our dialysate product lines. We received FDA approval for this product in January 2015. We have capitalized the licensing fees paid for the rights to use this patented technology as an intangible asset.

9. GOODWILL AND INTANGIBLE ASSETS (Continued)

During 2011, we acquired an abbreviated new drug application ("ANDA") for a generic version of an intravenous vitamin-D analogue, Calcitriol. Total capitalized costs related to this ANDA were approximately $695,000. These costs are being amortized over a five year period.

	2014	2013	2012
Capitalized Licensing Fees	$ 1,070,126	$ 1,070,126	$ 1,070,126
Accumulated Amortization	(737,440)	(570,411)	(403,382)
Capitalized Licensing Fees, Net of Amortization	$ 332,686	$ 499,715	$ 666,744
Amortization Expense	$ 167,029	$ 167,029	$ 167,029

Our policy is to amortize licensing fees over the life of the patents pertaining to certain licensing agreements. Estimated amortization expense for licensing fees for 2015 through 2016 is approximately $167,000 per year. Our Triferic™ licensing agreement, which is with a company owned by our chief scientific officer, requires additional payments by the Company upon achievement of certain milestones.

10. NOTES PAYABLE

In 2013, the Company entered into a loan and security agreement (the "Loan Agreement") with Hercules Technology III, L.P. ("Hercules") pursuant to which the Company received a loan in the aggregate principal amount of $20.0 million. On December 19, 2014, the Company paid off and terminated the loan agreement in accordance with its loan agreement. The payoff amount of $18,902,434 included principal, accrued and unpaid interest, fees, costs and expenses payable under the Loan Agreement, including an end of term fee of $1.1 million. In connection with such repayment, Hercules terminated its security interest in the assets of the Company subject to the Loan Agreement.

The loan under the Loan Agreement was due on March 1, 2017, and bore interest at the greater of (i) 12.50% plus the prime rate as reported in The Wall Street Journal minus 3.25%, or (ii) 12.50%. Amounts outstanding under the Loan Agreement bore interest at 12.50%. Monthly principal and interest payments were due on the loan following August 31, 2014 through the maturity date.

11. ACCRUED LIABILITIES

We had the following accrued liabilities as of December 31, 2014 and 2013:

	2014	2013
Accrued Research & Development Expense	$ 747,488	$ 3,237,093
Accrued Compensation and Benefits	1,359,659	1,490,953
Other Accrued Liabilities	2,218,850	1,919,782
Total Accrued Liabilities	$ 4,325,997	$ 6,647,828

12. OPERATING LEASES

We lease our production facilities and administrative offices as well as certain equipment used in our operations including leases on transportation equipment used in the delivery of our products. The lease terms range from monthly to seven years. 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 February 2016.

	2014	2013	2012
Rent Expense Recognized Under Operating Leases	$ 2,075,919	$ 2,163,281	$ 1,955,626

Future minimum rental payments under operating lease agreements are as follows:

Year ending December 31, 2015	$ 1,658,737
Year ending December 31, 2016	1,073,187
Year ending December 31, 2017	915,081
Year ending December 31, 2018	885,008
Year ending December 31, 2019	698,827
Year ending December 31, 2020 and thereafter	83,291
Total	$ 5,314,131

13. INCOME TAXES

A reconciliation of income tax expense at the statutory rate to income tax expense at our effective tax rate is as follows:

	2014	2013	2012
Tax Expense Computed at 34% of Pretax Income	$ (7,251,000)	$ (16,583,000)	$ (18,367,000)
State Income Taxes	—	—	—
Effect of Change in Valuation Allowance	(7,251,000)	(16,583,000)	(18,367,000)
Total Income Tax Expense	$ -0-	$ -0-	$ -0-

13. INCOME TAXES (Continued)

The details of the net deferred tax asset are as follows:

	December 31,	
	2014	2013
Deferred tax assets:		
Net Operating Loss Carryforward	$ 49,463,000	$ 49,426,000
Stock Based Compensation	7,673,000	6,839,000
Deferred Revenue	6,627,000	—
General Business Credit	5,293,000	—
Accrued Expenses	345,000	334,000
Inventories	77,000	65,000
Book over Tax Depreciation	19,000	—
Workers' Compensation Reserve	48,000	60,000
Accounts Receivable	18,000	13,000
Total Deferred Tax Assets	69,563,000	56,737,000
Deferred Tax Liabilities:		
Tax over Book Depreciation	—	118,000
Goodwill & Intangible Assets	196,000	225,000
Prepaid Expenses	60,000	122,000
Total Deferred Tax Liabilities	256,000	465,000
Subtotal	69,307,000	56,272,000
Valuation Allowance	(69,307,000)	(56,272,000)
Net Deferred Tax Asset	$ -0-	$ -0-

Deferred tax assets result primarily from net operating loss carryforwards. For tax purposes, we have net operating loss carryforwards of approximately $145,479,000 that expire between 2018 and 2034.

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will be realized upon the generation of future taxable income during the periods in which those temporary differences become deductible. We recognized no income tax expense or benefit for the years ended December 31, 2014, 2013 and 2012. While we anticipate generating income within the next year or two, we expect to incur operating losses until our drug products are manufactured and marketed following FDA approval. Considered together with our limited history of operating income and our net losses in 2014, 2013 and 2012, management has placed a full valuation allowance against the net deferred tax assets as of December 31, 2014 and 2013. The portion of the valuation allowance resulting from excess tax benefits on share based compensation that would be credited directly to contributed capital if recognized in subsequent periods is $7.3 million.

The Company accounts for its uncertain tax positions in accordance with ASC 740-10, *Income Taxes* and the amount of unrecognized tax benefits related to tax positions is not significant at December 31, 2014 and 2013.

14. CAPITAL STOCK

Our authorized capital stock consists of 2,000,000 preferred shares, none of which were issued or outstanding at December 31, 2014, 2013 and 2012, and 120,000,000 common shares, no par value per share, of which the following shares were outstanding:

	2014	2013	2012
Shares outstanding as of December 31,	50,284,007	40,110,661	21,494,696
Summary of Share Issuances:			
Shares Issuances related to Equity Compensation:			
Shares issued upon exercise of stock options by employees	711,516	478,411	216,477
Proceeds realized from stock option exercises	$ 2,964,445	$ 766,926	$ 132,026
Average exercise price of options exercised	$ 4.17	$ 1.60	$ 0.61
Restricted Stock Grants	740,000	310,000	235,000
Share issuances related to Warrant Exercises			
Shares issued upon the exercise of warrants	904,886	130,833	288,217
Proceeds realized from warrant exercises	$ 8,433,045	$ 1,164,982	$ 1,982,720
Share issuances related to Equity Offerings			
Shares issued pursuant to equity offerings	7,816,944	17,496,721	1,845,000
Proceeds realized from equity offerings	$ 69,780,967	$ 49,664,324	$ 16,120,669
Share issuances in Exchange for Services			
Share issuances in Exchange for Services	—	200,000	200,000
Value of Shares issued in Exchange for Services	—	$ 780,678	$ 1,854,000

Common Shares

Holders of the common shares are entitled to one vote per share on all matters submitted to a vote of our shareholders and are entitled to receive dividends when and if declared by the Board of Directors. The Board is authorized to issue additional common shares within the limits of the Company's Articles of Incorporation without further shareholder action, subject to applicable stock exchange rules.

Warrants

As of December 31, 2014, we had no outstanding warrants. During 2014, we realized $8,433,045 in net proceeds from the exercise of 904,886 warrants at an average exercise price of $9.32.

We had 983,071 common share purchase warrants outstanding at December 31, 2013, all of which were exercisable as of December 31, 2013. During 2013, we agreed to extend the term of 1,008,336 common share purchase warrants until July 31, 2013 and incurred an expense of $927,669 related to the extension of these warrants. Outstanding warrants as of December 31, 2013 consisted of 883,071 warrants with an exercise price of $9.55 expiring on October 5, 2014 and 100,000 warrants with an exercise price of $10.25 expiring on March 31, 2014.

We had 2,233,240 common share purchase warrants outstanding at December 31, 2012, of which 2,133,240 were exercisable as of December 31, 2012. During 2012, we agreed to extend the term of

14. CAPITAL STOCK (Continued)

1,079,169 common share purchase warrants until January 28, 2013 and incurred an expense of $280,600 related to the extension of these warrants. We also extended the term of 80,000 common share purchase warrants until November 28, 2013 and incurred an expense of $33,600 related to the extension of the term of these warrants.

Warrants were valued using the Black Scholes model. In 2013 and 2012, we recognized $1,082,196 and $468,417, respectively, in expense related to services and consideration provided in exchange for warrants.

15. LONG TERM INCENTIVE PLAN & STOCK OPTIONS

Long Term Incentive Plan & Stock Options

The Board of Directors adopted the Rockwell Medical, Inc., 2007 Long Term Incentive Plan ("LTIP") on April 11, 2007 as a replacement for the 1997 Stock Option Plan (the "Old Plan") which was terminated as to future grants. No options were granted under the Old Plan after 2006. There are 9,500,000 common shares reserved for issuance under the LTIP. The Compensation Committee of the Board of Directors (the "Committee") is responsible for the administration of the LTIP including the grant of stock based awards and other financial incentives including performance based incentives to employees, non-employee directors and consultants.

The Committee determines the terms and conditions of options and other equity based incentives including, but not limited to, the number of shares, the exercise price, term of option and vesting requirements. The Committee approved stock option grants and restricted stock grants during 2014, 2013 and 2012. The stock option awards were granted with an exercise price equal to the market price of the Company's stock on the date of the grant. The options expire 10 years from the date of grant or upon termination of employment and generally vest in three equal annual installments beginning on the first anniversary of the date of grant.

Restricted Stock Grants

We granted 740,000, 310,000 and 235,000 restricted shares in 2014, 2013 and 2012, respectively under the LTIP. These restricted stock grants were valued at the market price on the date of grant.

During 2014, restricted stock grants aggregating 320,000 shares were granted in January 2014 with a vesting date of approximately fourteen months after the grant date and an additional 420,000 common shares were granted in October 2014 with a vesting date of approximately seven months following the grant date. Vesting is conditioned upon continued employment with the Company.

15. LONG TERM INCENTIVE PLAN & STOCK OPTIONS (Continued)

The 2013 grant vested on the fourteenth month anniversary of the grant with vesting conditioned upon continued employment with the Company. The 2012 grant vested two years after the date of grant with vesting conditioned upon continued employment with the Company.

	2014	2013	2012
Restricted Shares Granted	740,000	310,000	235,000
Average Market Value Per Share on Grant Date	$ 9.42	$ 3.94	$ 9.45
Expense related to All Restricted Shares	$ 5,497,274	$ 1,961,501	$ 1,075,929
Unearned Stock Based Compensation for All Restricted Stock Awards Attributable to Future Periods.	$ 2,580,634		

Stock Option Grants

Our standard stock option agreement in the 2007 Plan allows for the payment of the exercise price of vested stock options either through cash remittance in exchange for newly issued shares, or through non-cash exchange of previously issued shares held by the recipient for at least six months in exchange for our newly issued shares. The 1997 Plan also allows for the retention of shares in payment of the exercise price and income tax withholding. The latter method results in no cash being received by us, but also results in a lower number of total shares being outstanding subsequently as a direct result of this exchange of shares. Shares returned to us in this manner would be retired.

In 2014, 2013 and 2012, the Company received cash proceeds of $2,964,445, $766,926 and $132,026, respectively, in exchange for shares issued upon the exercise of options during the year. No income tax benefits were recognized during 2014, 2013 and 2012 related to stock option activity as the Company has a full valuation allowance recorded against its deferred tax assets. However, tax benefits for the excess of the value of the shares issued over the price paid of $3,228,000, $609,000 and $494,000, were created in 2014, 2013, and 2012. The cumulative excess tax benefit at December 31, 2014 is $7.3 million, which when realized, will be credited directly to stockholders' equity.

15. LONG TERM INCENTIVE PLAN & STOCK OPTIONS (Continued)

A summary of the status of the LTIP and the Old Plan is as follows:

	SHARES	WEIGHTED AVERAGE EXERCISE PRICE	AGGREGATE INTRINSIC VALUE
Outstanding at December 31, 2011	5,482,135	5.23	$ 17,761,008
Granted	871,000	9.62	
Exercised	(223,601)	0.59	$ 1,486,470
Forfeited	(140,334)	8.66	
Outstanding at December 31, 2012	5,989,200	5.95	$ 12,559,074
Granted	920,500	5.74	
Exercised	(623,700)	1.23	$ 1,920,557
Forfeited	(58,000)	8.31	
Outstanding at December 31, 2013	6,228,000	6.27	$ 25,956,880
Granted	1,731,500	9.43	
Exercised	(1,029,016)	2.88	$ 2,964,445
Forfeited	(45,401)	6.19	
Outstanding at December 31, 2014	6,885,083	7.41	$ 19,730,211

	OPTIONS OUTSTANDING			OPTIONS EXERCISABLE	
RANGE OF EXERCISE PRICES	NUMBER OF OPTIONS	REMAINING CONTRACTUAL LIFE	WEIGHTED EXERCISE PRICE	NUMBER OF OPTIONS	WEIGHTED AVERAGE EXERCISE PRICE
$3.09 to $4.93	1,010,916	1.1 - 8.5 yrs.	$ 4.00	934,805	$ 4.04
$5.34 to $7.13	2,638,000	2.8 - 8.7 yrs.	$ 6.42	2,134,667	$ 6.49
$8.35 to 10.20	3,236,167	4.8 - 9.8 yrs.	$ 9.29	1,235,111	$ 9.01
Total	6,885,083	6.3 yrs.	$ 7.41	4,304,583	$ 6.68
Intrinsic Value	$ 19,730,211			$ 15,477,857	

15. LONG TERM INCENTIVE PLAN & STOCK OPTIONS (Continued)

	NUMBER OF UNVESTED OPTIONS	WEIGHTED AVERAGE FAIR MARKET VALUE AT GRANT DATE
As of December 31, 2011	1,529,333	
Granted	871,000	$ 5.93
Forfeited	(140,334)	
Vested	(680,999)	
As of December 31, 2012	1,579,000	
Granted	920,500	$ 3.33
Forfeited	(58,000)	
Vested	(727,067)	
As of December 31, 2013	1,714,433	
Granted	1,731,500	$ 5.91
Forfeited	(45,401)	
Vested	(820,032)	
As of December 31, 2014	2,580,500	

The Company values stock options awarded using the Black-Scholes method. Assumptions used in the stock option valuations were:

	2014	2013	2012
Volatility of share price	69 - 70%	59 - 67%	64 - 65%
Risk free interest rate	1.9 - 2.0%	0.1 - 2.0%	0.8 - 1.2%
Expected option life	6 yrs.	1 - 6 yrs.	6 yrs.
Dividend Yield	0.0%	0.0%	0.0%

We believe this valuation methodology is appropriate for estimating the fair value of stock options we grant to employees and directors which are subject to ASC 718-10 requirements. We primarily base our determination of expected volatility through our assessment of the historical volatility of our common shares. We do not believe that we are able to rely on our historical stock option exercise and post-vested termination activity to provide accurate data for estimating our expected term for use in determining the fair value of these options. Therefore, as allowed by Staff Accounting Bulletin (SAB) No. 107, *Share-Based Payment*, we have opted to use the simplified method for estimating the expected option term equal to the midpoint between the vesting period and the contractual term. The contractual term of the option is 10 years from the date of grant and the vesting term of the option is three years from date of grant. Risk free interest rates utilized are based upon published U.S. Treasury yield curves at the date of the grant for the expected option term.

For the years ended December 31, 2014, 2013 and 2012, we recognized compensation expense of $4,597,412, $3,877,695, and $3,903,795, respectively related to options granted to employees under the LTIP with a corresponding credit to common stock. At December 31, 2014, the amount of unrecorded stock-based compensation expense for stock options attributable to future periods was approximately $9,517,328 which is expected to be amortized to expense over the remaining vesting periods of the options of 1 to 33 months.

15. LONG TERM INCENTIVE PLAN & STOCK OPTIONS (Continued)

As of December 31, 2014, the remaining number of common shares available for equity awards under the LTIP was 733,066.

16. RISK MANAGEMENT

Insurance

We evaluate various kinds of risk that we are exposed to in our business. In our evaluation of risk, we evaluate options and alternatives to mitigating such risks. For certain insurable risks we may acquire insurance policies to protect against potential losses or to partially insure against certain risks. For our subsidiary, Rockwell Transportation, Inc., we maintain a partially uninsured workers' compensation plan. Under the policy, the Company's self-insurance retention is $350,000 per occurrence and $747,619 in aggregate coverage for the policy year ending July 1, 2015. The total amount at December 31, 2014 by which retention limits exceed the claims paid and accrued is approximately $747,000 for the policy year ending July 1, 2015. Estimated additional future claims subject to payment by the Company of approximately $133,608 has been accrued for the year ended December 31, 2014.

At December 31, 2014, approximately $400,000 was held in cash collateral and escrow by the insurance carrier for workers' compensation insurance. At December 31, 2014 amounts held in cash collateral and escrow are included in prepaid expenses and other non-current assets in the consolidated financial statements.

17. QUARTERLY RESULTS OF OPERATIONS

The following is a summary of the quarterly results of operations for the years ended December 31, 2014 and 2013.

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
2014				
Sales	$ 12,963,652	$ 13,033,361	$ 13,743,778	$ 14,447,653
Cost of Sales	11,283,694	11,014,469	11,473,961	11,871,106
Gross Profit	1,679,958	2,018,892	2,269,817	2,576,547
Selling, General and Administrative	4,090,199	4,214,205	4,098,835	5,917,480
Research and Product Development	4,615,197	186,695	1,301,824	1,679,878
Operating Income (Loss)	(7,025,438)	(2,382,008)	(3,130,842)	(5,020,811)
Interest and Investment Income, net	74,215	69,633	55,263	187,144
Interest Expense	854,303	858,003	892,027	1,549,980
Income (Loss) Before Income Taxes	(7,805,526)	(3,170,378)	(3,967,606)	(6,383,647)
Income Tax Expense	—	—	—	—
Net Income (Loss)	$ (7,805,526)	$ (3,170,378)	$ (3,967,606)	$ (6,383,647)
Basic And Diluted Earnings (Loss) Per Share	$ (.20)	$ (.08)	$ (.10)	$ (.14)

17. QUARTERLY RESULTS OF OPERATIONS (Continued)

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
2013				
Sales	$ 12,336,374	$ 12,984,164	$ 13,094,381	$ 13,964,624
Cost of Sales	11,055,394	11,299,099	11,461,100	11,904,730
Gross Profit	1,280,980	1,685,065	1,633,281	2,059,894
Selling, General and Administrative	3,916,783	3,237,974	3,386,367	3,795,325
Research and Product Development	12,754,518	10,222,721	10,611,219	5,793,579
Operating Income (Loss)	(15,390,321)	(11,775,630)	(12,364,305)	(7,529,010)
Interest and Investment Income, net	10,672	4,566	13,546	69,317
Interest Expense	75	92,155	857,505	872,412
Income (Loss) Before Income Taxes	(15,379,724)	(11,863,219)	(13,208,264)	(8,332,105)
Income Tax Expense	—	—	—	—
Net Income (Loss)	$ (15,379,724)	$ (11,863,219)	$ (13,208,264)	$ (8,332,105)
Basic And Diluted Earnings (Loss) Per Share	$ (.72)	$ (.38)	$ (.34)	$ (.21)

SCHEDULE II—VALUATION AND QUALIFYING ACCOUNTS

	Balance at Beginning of Period	Additions	(Deductions)	Balance at End of Period
Allowance for Doubtful Accounts:				
Year ended December 31, 2014	$ 37,392	$ 40,714	$ (25,893)	$ 52,213
Year ended December 31, 2013	$ 26,257	$ 37,392	$ (23,474)	$ 37,392
Year ended December 31, 2012	$ 29,473	$ 9,659	$ (12,875)	$ 26,257
Inventory Reserve:				
Year ended December 31, 2014	$ 35,009	$ 19,701	$ (27,435)	$ 27,274
Year ended December 31, 2013	$ 27,579	$ 105,647	$ (98,217)	$ 35,009
Year ended December 31, 2012	$ 39,803	$ 37,009	$ (49,233)	$ 27,579
Deferred Tax Asset Valuation Allowance:				
Year ended December 31, 2014	$ 56,272,000	$ 13,035,000	$ —	$ 69,307,000
Year ended December 31, 2013	$ 38,266,000	$ 18,006,000	$ —	$ 56,272,000
Year ended December 31, 2012	$ 19,726,000	$ 18,540,000	$ —	$ 38,266,000

Allowances and reserves are deducted from the accounts to which they apply.

Exhibit 10.57

EXECUTION COPY

[* *] Portions of the this exhibit have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended.

EXCLUSIVE DISTRIBUTION AGREEMENT

This Exclusive Distribution Agreement (this "**Agreement**") is entered into as of October 2, 2014 (the "**Effective Date**"), by and between Baxter Healthcare Corporation, a Delaware corporation (the "**Distributor**"), and Rockwell Medical, Inc., a Michigan corporation (the "**Company**"). Capitalized terms used herein, to the extent not otherwise defined, have the meanings specified in **Exhibit A**.

RECITALS

Whereas, the Company develops, manufactures and sells hemodialysis concentrates (solutions and powders) and related ancillary products; and

Whereas, the Distributor develops, manufactures and sells dialysis and related healthcare products; and

Whereas, the Company and the Distributor would like for the Distributor to market, sell and distribute certain Company products on the terms and conditions set forth in this Agreement.

AGREEMENT

Therefore, in consideration of the mutual covenants set forth in this Agreement, and intending to be legally bound, the Parties hereby agree as follows:

Article 1
Distributor Rights and Commercialization

1.1 **Distributor Rights.**

(a) Subject to the terms and conditions of this Agreement, during the Term of this Agreement, the Company hereby (i) appoints the Distributor and each of its Affiliates as the exclusive distributor of the Products in the Territory; and (ii) grants the Distributor and each of its Affiliates an exclusive, royalty-free license under the Product Rights to Commercialize the Products in the Territory. The foregoing appointment and license grant are referred to collectively as the "**Distributor Rights.**"

(b) Within the scope of the Distributor Rights and subject to the terms and conditions of this Agreement, the Company shall sell Products to the Distributor and its Affiliates, who shall have the right to Commercialize the Products both directly to customers and indirectly through their network of independent distributors and other Marketing Partners. Solely to facilitate such indirect Commercialization, the Distributor and its Affiliates shall have the right to appoint sub-distributors and to grant

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non-exclusive, royalty-free sublicenses under the Distributor Rights. References herein to the "Distributor" shall be deemed to include its Affiliates and authorized Marketing Partners and sub-distributors for purposes of determining (i) the Distributor's satisfaction of its obligations hereunder (including the Minimum Order Threshold), (ii) the Distributor's achieving the First Extension Threshold, and (iii) the Persons who are entitled to exercise the rights of the Distributor to submit Firm Orders. Notwithstanding the foregoing, any proposed sub-distributors and Marketing Partners in the United States, other than the Pre-Approved Sub-Distributors and Marketing Partners, must be approved in advance by the Company, which approval shall not be unreasonably withheld, conditioned or delayed.

(c) Except as provided in this Agreement with respect to or on behalf of the Distributor and its Affiliates, for as long as the Distributor Rights are exclusive, the Company shall not, directly or indirectly, on its own behalf or through any Third Party, sell or otherwise Commercialize Products or Baxter Competitive Products in the Territory.

(d) The Distributor, its Affiliates, Marketing Partners and sub-distributors shall not have any Distributor Rights or Product Rights to Commercialize the Products outside the Territory or other than as specifically provided in this Agreement.

(e) Except as provided in this Agreement (including Sections 3.4 and 3.5), during the Term, the Distributor shall not manufacture or sell any Rockwell Competitive Products in the United States, in each case, other than the Excluded Products.

1.2 **Commercialization**. The Distributor and its Affiliates and their respective Marketing Partners shall, subject to Applicable Laws, have sole and absolute control and discretion over their respective Commercialization efforts and activities, including the pricing and other terms and conditions under which they market, promote and sell Products to customers.

1.3 **Original Customer Contracts**. As and when requested by the Distributor, the Company shall assign to the Distributor (in a manner consistent with the transition services referenced in Section 1.5 below) the Company's rights under the Original Customer Contracts to Commercialize the Products in the Territory during the Term. The Distributor shall assume the Company's obligations under each assigned Original Customer Contract, but only to the extent that such obligations are required to be performed after the effective date of the assignment. The assignment of all Original Customer Contracts shall occur no later than [* *] to the extent assignable without further Third Party consent. The Company shall use commercially reasonable efforts to obtain any consents required for the effective assignment of rights under the Original Customer Contracts to the Distributor. For so long as the Company is unable to obtain any such consent, the Company shall provide the Distributor with the economic and operational benefits to which the Company is entitled under the applicable Original Customer Contracts, and the Company shall pay to the Distributor the amount that the Distributor would be entitled to receive under any Original Customer Contract after payment to the Company of the Contract Price for the Products purchased thereunder after the Effective Date, less any applicable fees payable under **Exhibit C** in connection therewith.

1.4 **Promotional and Training Materials**. Upon the Distributor's request, the Company, at its sole cost and expense, shall supply the Distributor with all current promotional and training materials for the Products in the Company's possession and reasonably accessible to the Company as of the Effective Date. The Distributor shall have the right, at its own cost and expense, to develop and procure its own promotional and training materials for the Products. The Distributor shall have sole authority and discretion over the content of such materials; *provided*, *however*, that before implementing any new promotional or training materials for the Products, the Distributor shall provide copies to the Company, and the Company shall have the opportunity to review and comment on such materials for a period of [* *] Business Days after receipt. Any comments offered by the Company shall [* *]. For clarity, the Distributor's license to the Company's Licensed Trademarks shall extend to all such promotional and training materials.

1.5 **Transition Services**. The Company shall provide the transition services set forth in **Exhibit B**. Each Party shall be responsible for its own costs and expenses during the period in which such transition services are provided.

1.6 **Support Services**. The Company shall provide the support services set forth in **Exhibit C** (the "**Support Services**") beginning on the Effective Date. For purposes of this Agreement, the term "**Support Services Period**" shall mean the period of time during which the Company provides Support Services under this Agreement as set forth in **Exhibit C**. The Distributor shall compensate the Company for such services as set forth in **Exhibit C**.

Article 2
Manufacturing

2.1 **Quality Agreement.** No later than five Business Days after the Effective Date, the Parties shall enter into a Quality Agreement in form and substance substantially the same as the Quality Agreement attached hereto as **Exhibit D** (the "**Quality Agreement**") in order to establish reasonable detailed written procedures with respect to quality assurance and regulatory affairs matters relating to the Products. The Company shall Manufacture the Products in accordance with the Quality Agreement and the applicable Specifications, Regulatory Approvals and Regulatory Laws.

2.2 **Warranty.** The Company hereby warrants to the Distributor and its Affiliates, Marketing Partners and customers that all Products supplied by the Company hereunder will:

(a) Be manufactured in compliance with the Quality Agreement and all Applicable Laws, including Good Manufacturing Practices and the Quality System Regulations;

(b) Conform to the Product's Specifications and be free of defects (including design, engineering, material, fabrication, manufacture and label defects);

(c) Be free of liens, security interests or encumbrances of any nature imposed by or through the Company;

(d) Not be adulterated or misbranded within the meaning of Applicable Laws (including in the United States the Federal Food, Drug, and Cosmetic Act and the rules, regulations and guidance issued thereunder); and

(e) Not infringe the valid intellectual property rights of any Third Party.

Notwithstanding the foregoing, the product warranties made by the Company to any customer that is subject to an Original Customer Contract shall be limited to the warranties set forth in the applicable Original Customer Contract for so long as such Original Customer Contract is in effect, and the Company shall honor such warranties.

2.3 **Sample Testing; Audits.**

(a) At any time upon request by the Distributor, if the Distributor has received a written complaint from a customer or Governmental Authority indicating the potential need for a Field Action or customer action as defined by applicable Regulatory Law, the Company shall deliver samples of its Products (at no cost to the Distributor) in reasonable quantity and form to permit the Distributor or independent laboratories selected by the Distributor to perform quality testing

(b) The Distributor shall have the right, during the Company's usual business hours upon reasonable advance notice, to inspect and audit the Company's facilities and operations related to the Products (including Manufacturing and customer service operations) for the sole purpose of verifying the Company's compliance with its obligations hereunder, including the right to (i) inspect the Products, (ii) observe manufacturing, customer service and related operations, processes and methods with respect to the Products, (iii) review documentation, and (iv) conduct quality assurance, quality system and regulatory compliance audits with respect to the Products. The Distributor shall not perform more than one such inspection or audit in any [* *] period unless the Distributor reasonably determines that additional inspections or audits are warranted due to Product Complaints or Field Actions related to the Products. The Distributor shall bear its own expenses in connection with any inspection or audit. The Company shall cooperate, at its own expense, with Distributor's inspections and audits. The Company shall promptly remediate at its own cost any compliance failures that are mutually determined to require remediation or that are otherwise required under Regulatory Laws or requested by Regulatory Authorities.

2.4 **Identification Codes.** All Products shall be appropriately identified with the Company's unique identification code as required by Regulatory Laws.

2.5 **ISO 13485 Certification.** At the [* *] of the Distributor, the Company shall [* *] ISO 13485 certification if [* *].

Article 3
Commercial Supply

3.1 **Forecasts.** On or before each March 1, June 1, September 1 and December 1 during the Term, the Distributor shall provide the Company a Forecast of its expected unit

purchase quantities, broken down by Product and manufacturing facility, for the following [* *] Calendar Quarters. Each such Forecast shall be for information purposes only; *provided, however*, that the Distributor shall be obligated to submit Firm Orders in accordance with the unit purchase quantities of each Concentrate Product reflected in the [* *] of each such Forecast. The form for each Forecast shall be determined by mutual agreement of the Parties. Notwithstanding the foregoing, the initial Forecast shall be provided by the Distributor within 30 days from the Effective Date, and the initial Firm Order shall be submitted beginning with the second Forecast submitted by the Distributor.

3.2 **Customer Orders; Firm Orders.**

(a) The Parties acknowledge that during the Support Services Period, customers will order Products directly from the Company, the Company will ship or arrange to ship Products directly to customers in accordance with **Exhibit C**. The Company shall provide service levels to such [* *]. Orders placed by customers directly to the Company are referred to herein as (**"Customer Orders"**).

(b) Following the Support Services Period, or to the extent the Distributor otherwise desires during the Support Services Period to order and warehouse certain Products for later shipment to customers, the Distributor shall submit Firm Orders for the Products, each of which shall specify the following with respect to each ordered Product: Type of Product, unit quantity, Contract Price, delivery destination, manufacturing facility and requested delivery date. The form for Firm Orders shall be determined by mutual agreement of the Parties.

(c) The Company shall be obligated to confirm and accept, within [* *] after receipt, each Customer Order and Firm Order that states the correct price to be paid by the customer or Contract Price, as applicable, and requests shipment from a Company plant no earlier than Stipulated Shipping Date, to the extent it does not result in the purchase of quantities, when added to all other orders during the [* *], that would exceed in the aggregate the Company's commitment in Section 3.3. The Company shall use Commercially Reasonable Efforts to accept Firm Orders outside these parameters, including satisfying any expedited or off-schedule deliveries requested by any customer directly to the Company or indirectly by the Distributor in the time period requested by the customer.

3.3 **Manufacturing Capacity.** Beginning with the second Forecast provided by the Distributor, the Company shall maintain sufficient Manufacturing capacity for each Product at each manufacturing facility to enable the Company to supply the Distributor in any [* *] with a minimum of [* *]% of the forecasted purchase quantity of such Product for such manufacturing facility for such quarter based upon the most recently available Forecast. For avoidance of doubt, the Company shall make capital expenditures as necessary in order to maintain such Manufacturing capacity. The Company shall use Commercially Reasonable Efforts to supply quantities of Products in excess of the minimum. In the event of any Product shortage, the Company shall fulfill its obligations hereunder to the Distributor from its United States manufacturing facilities in preference and priority to its obligations to any other Person.

3.4 **Option to Assume Manufacturing**. If a Manufacturing Default occurs, the Distributor shall have the option, upon at least [* *] days' prior written notice, to assume Manufacturing, directly or through an Affiliate or Third Party (in either case, the "**Successor Manufacturer**"), of the Products at a site other than at a Company plant. If the Distributor exercises such option:

(a) The scope of the Distributor License automatically shall be expanded to include the right to make and have made the Products in the Territory until the time provided in Section 3.4(e).

(b) The Company shall cooperate in good faith to enable the Distributor's designated Successor Manufacturer to commence Manufacturing of the Products, including (1) providing any necessary license or sublicense under the Product Rights until the time provided in Section 3.4(e); (2) disclosing and teaching the Company's Proprietary Information, including Manufacturing procedures, know-how and trade secrets, provided that such Successor Manufacturer enters into a confidentiality agreement with the Company with restrictions on the disclosure and use of the Company's Confidential Information that are no less favorable to the Company than those set forth in the Confidentiality Agreement between the Distributor and the Company dated as of April 11, 2014; (3) making its employees and consultants available as reasonably required, during normal business hours upon at least [* *] Business Days written notice to the Company, to enable such Successor Manufacturer to replicate the process employed by or on behalf of the Company to Manufacture the Products and to ensure an orderly transition of the Company's Manufacturing technology; and (4) facilitating business relationships between the Successor Manufacturer and the Company's suppliers, vendors and service providers.

(c) The Company shall reimburse the Distributor for any out-of-pocket costs and expenses incurred by the Distributor in transitioning the Manufacturing of the Products to a Successor Manufacturer under this Section 3.4. To the extent that the purchase price for any Product paid by the Distributor to any Successor Manufacturer exceeds the Contract Price for such Product under this Agreement, the Company shall reimburse the Distributor for the difference. Amounts payable under this Section 3.4(c) shall be paid by the Company within [* *] days of its receipt of the Distributor's invoice.

(d) The Company shall continue to fulfill orders and supply the Products pursuant to this Agreement.

(e) The Distributor's rights under this Section 3.4 shall cease when the facts giving rise to the Manufacturing Default have been cured or no longer exist and no new Manufacturing Default has occurred for at least [* *] days thereafter.

For avoidance of doubt, the Distributor shall not be obligated to exercise its option to assume Manufacturing under this Section 3.4; and any failure to do so in one instance shall not constitute a waiver of its right to do so in a future instance. Any exercise of such option shall not be construed as an exclusive

remedy for the Company's Manufacturing Default.

3.5 **Cover.** If a Manufacturing Default occurs and the Distributor purchases replacement or substitute products from one or more Third Parties ("**Substitute Products**"), then the Company shall reimburse the Distributor for (a) the amount by which the purchase price for any Substitute Product purchased by the Distributor exceeds the Contract Price for the applicable Product under this Agreement (provided that the Distributor has used its Commercially Reasonable Efforts to obtain Substitute Product at a price comparable to the Contract Price), and (b) [* *]. Amounts payable under this Section 3.5 shall be paid by the Company within [* *] days of its receipt of the Distributor's invoice. The payment obligations under this Section 3.5 shall cease when the facts giving rise to the Manufacturing Default have been cured or no longer exist and no new Manufacturing Default has occurred for at least [* *] days thereafter. For avoidance of doubt, the Distributor shall not be obligated to exercise its option to purchase Substitute Products under this Section 3.5; and any failure to do so in one instance shall not constitute a waiver of its right to do so in a future instance. Any exercise of such option shall not be construed as an exclusive remedy for the Company's Manufacturing Default.

3.6 **Packaging; Shipping.**

(a) At the Distributor's request, within a reasonable time thereafter and giving consideration to the Company's use of existing inventory of labels and Products, the Company shall use commercially reasonable efforts to cause the packaging for the Products to indicate, conspicuously and in a manner reasonably acceptable to the Distributor, that the Distributor is the distributor of the Products. Distributor shall be responsible for all costs and expenses involved in modifying the Company's labels as provided in this Section (to the extent not included in Cost of Goods Sold).

(b) The Company shall inspect, package, label, store and ship all Products in a manner consistent with the Product warranties and, if applicable, the related Customer Orders and Firm Orders and in accordance with good commercial and industry practice. Without limiting the foregoing, the Company shall deliver the Products no later than the delivery date(s) specified in any Customer Order or Firm Order submitted in compliance with Section 3.2. Deliveries made by the Company as part of the Support Services shall be made pursuant to the terms in **Exhibit C**, and [* *] shall acquire insurance for shipment and shall bear the risk of loss during transport for such deliveries. Deliveries that are not included within the Support Services shall be FOB shipping point (the Company's manufacturing facilities) to the Distributor's facilities or directly to customers as designated by the Distributor, and the Distributor shall be responsible for freight, insurance and risk of loss from such shipping point, and all such deliveries shall be made by a carrier designated by the Distributor. For deliveries outside of the United States, the Company shall cooperate with the Distributor in clearing the Products for import/export and obtaining any import/export licenses with respect to the Products. For all deliveries, title to the Products shall transfer to the Distributor upon delivery to the carrier (whether a Third Party carrier or the Company's fleet) at the shipping point.

3.7 **Non-Conforming Product**. The Distributor, its Marketing Partners, Affiliates and/or customers (each, a "**Receiving Party**") may reject by written notice to the Company any Product that is reasonably discernible upon visual inspection not to conform to the Customer Order or Firm Order or the applicable warranties set forth in Section 2.2 (a "**Non-Conforming**

Product"), provided that such written rejection notice is delivered to the Company within [* *] Business Days after the Receiving Party receives such Product. The Distributor or any other Receiving Party may reject by written notice to the Company any Non-Conforming Product with a hidden non-conformity (i.e., a latent defect) within [* *] days after the discovery thereof. A non-conformity shall be deemed hidden if it could not reasonably have been discovered by a reasonable and customary visual inspection. Any notice of rejection shall describe the non-conformity with reasonable specificity. The Company shall ship replacement Product (free of charge) or refund (including freight, insurance, taxes and customs charges), at the Company's option, all rejected Non-Conforming Product, and shall reimburse the Distributor for the reasonable costs incurred by the Distributor in properly disposing of or returning to the Company (as instructed by the Company) such Non-Conforming Product, and for reasonable costs that the Distributor incurs in procuring substitute products for the Distributor's customers because the Non-Conforming Product is not available. Any Product that is not duly rejected in accordance herewith shall be deemed accepted, but such acceptance shall not be construed as a waiver of the Distributor's warranty and indemnification rights with respect to such Product. Notwithstanding the foregoing, with respect to any customer that is subject to an Original Customer Contract, if any term in such customer's Original Customer Contract is inconsistent with the terms in this Section 3.7, the conflicting term in such Original Customer Contract shall control with respect to such customer for so long as such Original Customer Contract is in effect.

3.8 **Minimum Requirements**.

(a) Subject to the terms of this Section 3.8, the exclusive Distributor Rights granted to the Distributor under Section 1.1 shall become non-exclusive at the option of the Company if the quantity of Concentrate Products, measured in gallons, ordered by the Distributor (or directly by its customers) in the United States during any Contract Year is less than the minimum order threshold for such Contract Year determined as follows (each, a "**Minimum Order Threshold**"):

Contract Years	Minimum Order Threshold
2	[* *]
3	[* *]
4	[* *]
5	[* *]
6	[* *]
7	[* *]
8	[* *]
9	[* *]
10	[* *]
11 and each Contract Year thereafter during the Term	[* *] of the Baseline Amount for Contract Year 11, and an incremental [* *]% increase for each Contract Year thereafter during the Term (resulting in a

Minimum Order Threshold of [* *]% of the Baseline Amount for Contract Year 20).

For purposes of this Section 3.8 and the definition of "Baseline Amount," Concentrate Products in powder form shall be measured in gallons by applying the conversion ratios set forth in **Exhibit E** hereto. The Company represents and warrants that such conversion ratios are consistent with (i) the mixing instructions provided by the Company to its customers as of the Effective Date, and (ii) any mixing information set forth in the Regulatory Approvals for such Concentrate Products.

To the extent that the gallons of Concentrate Products ordered for any Contract Year exceed the Minimum Order Threshold for such Contract Year, the excess shall be carried forward and applied against the Minimum Order Threshold for future Contract Years until the entire excess has been fully-credited. Solely for illustration purposes, if the Baseline Amount is 100,000 and the gallons of Concentrate Product ordered by the Distributor in Contract Year 2 and Contract Year 3 are [* *]and [* *], respectively, then a total of [* *] gallons may be applied against the Minimum Order Threshold for Contract Year 4 and future years until the [* *] gallons has been fully-credited.

(b) Notwithstanding any other provision hereof, if the Distributor's Commercialization of any Concentrate Product (or Concentrate Products) in any Contract Year is materially and adversely impacted by a Disruptive Event for a period of at least [* *] days during such Contract Year, then (i) the Distributor shall have no obligation to achieve the Minimum Order Threshold for such Contract Year, and (ii) the Minimum Order Threshold for the following Contract Year shall be the Minimum Order Threshold in effect during the Contract Year in which the Disruptive Event occurred and the schedule of Minimum Order Thresholds for future Contract Years shall be adjusted accordingly. The Distributor shall notify the Company in writing as soon as possible if it discovers facts or circumstances that are reasonably likely to materially and adversely impact its Commercialization of a Concentrate Product (or Concentrate Products) for purposes of this Section 3.8(b).

(c) If the Distributor fails to achieve the Minimum Order Threshold for any Contract Year and if the Company believes that the Distributor has not been excused from achieving the Minimum Order Threshold by reason of any Disruptive Event as set forth in Section 3.8(b), then the Company shall notify the Distributor in writing within [* *] days after the end of such Contract Year. Upon receipt of such notice, the Distributor shall have a period of [* *] days (the "**Shortfall Cure Period**") to submit one or more Firm Orders to make up for any shortfall and, upon so doing, the gallons of Concentrate Product reflected in such Firm Orders shall count (without duplication) toward the Distributor's satisfaction of the Minimum Order Threshold for such Contract Year.

(d) The Company's sole remedy for the Distributor's failure to achieve the Minimum Order Threshold under Section 3.8(a) is to render non-exclusive the Distributor Rights. In order to exercise its right to render the Distributor Rights non-exclusive, the Company must notify the Distributor in writing thereof within [* *] days after the expiration of the Shortfall Cure Period. If the Company fails to so notify the Distributor within such [* *] -day period, the Distributor Rights shall remain exclusive. If the Company so notifies the Distributor within such [* *] -day period, then the Distributor

Rights shall be non-exclusive effective as of the date the Distributor receives such notice from the Company; *provided, however*, that if the Distributor contends that the applicable Minimum Order Threshold has been satisfied or that such Minimum Order Threshold does not apply by reason of a Disruptive Event, then the Distributor Rights shall remain exclusive until the dispute is resolved in accordance with Section 11.15.

3.9 **West Coast Facility**. The Parties shall evaluate strategies and resource requirements for Commercializing the Products in the Pacific Time zone, including the establishment of a facility in that area for Manufacturing the Concentrate Products (a "**West Coast Facility**"). If the Company determines to establish a West Coast Facility, then the Company shall consult with the Distributor about all material matters relating to the West Coast Facility, including site selection, building specifications and drawings, selecting architects and engineers, equipment and other pertinent matters. The Company shall consider in good faith any reasonable suggestions that the Distributor may have with respect to such matters and shall otherwise in good faith attempt to address any concerns with respect to such matters raised by the Distributor. The Company shall use commercially reasonable efforts to cause the West Coast Facility to be designed to operate at least as efficiently and cost-effectively as [* *]. Until the First Commercial Release from the West Coast Facility, (i) the Company shall keep the Distributor apprised of material developments with the West Coast Facility, and (ii) the Distributor shall be entitled to visit and inspect the West Coast Facility from time to time during normal business hours and upon reasonable advance notice to the Company.

3.10 **Joint Steering Committee.**

(a) Promptly after the Effective Date, the Parties shall establish a joint steering committee (the "**Committee**"). The Committee shall be comprised of three representatives of each Party, each of whom shall have expertise and operational responsibilities with respect to the Products and sufficient seniority within the appointing Party's organization to facilitate productive interaction and decision-making within the Committee. A Party may appoint and change any of its representatives from time to time in its sole discretion, effective upon notice to the other Party, provided that the Key Person shall serve on the Committee as a representative of the Company for a minimum of two years after the Effective Date.

(b) The Committee shall be a forum for review, oversight and management of matters relating to the Manufacture and Commercialization of the Products, including:

(i) Transition and support services contemplated in this Agreement;

(ii) Estimated COGS, status of Cost of Goods Sold at any point relative to Estimated COGS and key variance drivers, and opportunities for reducing Cost of Goods Sold;

(iii) Strategies for the West Coast market;

(iv) Marketing and promotional matters, including branding and labeling;

(v) Progress toward achieving the Minimum Order Threshold and First Extension Threshold;

(vi) Intellectual property and regulatory matters concerning the Products;

(vii) Key performance indicators;

(viii) Capital expenditures; and

(ix) Research and development activities for Product improvements.

(c) The Committee shall meet no less frequently than quarterly unless otherwise agreed by the Parties. The Parties shall establish a meeting schedule by mutual agreement and each Party shall cause its representatives to use best efforts to attend each scheduled meeting. Meetings may be held remotely if so agreed. Subject to reasonable advance notice to the other Party and appropriate confidentiality undertakings, a Party may invite other members of its organization to attend a particular meeting. Each Party shall be responsible for the expenses incurred by its own representatives in participating in the Committee.

3.11 **Key Person.** For a period of no less than two years from the Effective Date, the Company shall cause the Key Person to maintain active involvement in the Company's operations related to the Products and to devote sufficient time and attention to such operations as is reasonably necessary to oversee the Company's fulfillment of its obligations under this Agreement.

Article 4
Compensation

4.1 **Upfront Payment.** In consideration for the rights granted to the Distributor hereunder, the Distributor shall make an initial payment to the Company in the amount of $20,000,000 in immediately available funds by wire transfer within two Business Days from the Effective Date (the "**Upfront Payment**").

4.2 **Contract Price - 2014**. The Contract Price for Products ordered by the Distributor (or directly by its customers) during 2014 shall be as set forth in the Initial Price Schedule.

4.3 **Contract Price — Balance of the Term**.

(a) Within twenty Business Days of the Effective Date, and on or before [* *] of each calendar year thereafter, the Company shall deliver to the Distributor a written notice (each, an "**Estimated COGS Notice**") with the Company's good faith estimate of the Cost of Goods Sold for each Product for the following calendar year ("**Estimated COGS**") and the resulting Contract Price for each Product. The Estimated COGS Notice shall include a detailed itemization of all components of the Estimated COGS for each Product and such other information as the Committee may determine. **Exhibit F** sets

forth the methodology used to determine the Contract Price for each Product in effect for 2014 pursuant to Section 4.2 above. The Company shall use the methodology set forth in **Exhibit F** for determining Estimated COGS and actual Cost of Goods Sold throughout the Term unless another methodology is agreed upon by mutual written agreement of the Parties.

(b) At the Distributor's request, prior to any new Contract Price going into effect for any calendar year, the Committee shall discuss and evaluate opportunities for reducing Costs of Good Sold for such calendar year, as well as adjustments to the Company's Estimated COGS. The Company may adjust the Estimated COGS set forth in any Estimated COGS Notice with written notice to the Distributor at any time prior to December 15 of the calendar year during which such Estimated COGS Notice was delivered. Any such adjustments shall be incorporated into the Contract Price calculation for such calendar year pursuant to Section 4.3(c) below. The Company shall use Commercially Reasonable Efforts to reduce (or minimize increases in) Cost of Goods Sold for the Products. In the event that the Committee does not convene during any calendar quarter for any reason, at the request of the Distributor, the Company shall provide, not more than once per Calendar Quarter, an update on actual Cost of Goods Sold for the Products relative to Estimated COGS.

(c) Subject to the adjustments set forth below, the Contract Price for each Product (determined by specific Product code) to be ordered during 2015 and each calendar year thereafter shall be determined based upon the Target Margin Percentage for such Product set forth in the Price Schedule in accordance with the following formula:

$$\frac{[* *]}{[* *]} = [* *]$$

(d) Within 60 days following each calendar year, the Company shall deliver to the Distributor a written notice ("**True-Up Notice**") setting forth (i) the actual Cost of Goods Sold for each Product ordered by the Distributor (or directly by its customers) during such calendar year, (ii) the aggregate Contract Price paid or to be paid for each Product ordered during such calendar year, and (iii) the aggregate Contract Price that the Distributor would have paid for each Product ordered during such calendar year had the Contract Price been determined using the actual Cost of Goods Sold (versus Estimated COGS). Upon receipt of the True-Up Notice, the Distributor shall have the right to audit the Company's records for purposes of verifying the information set forth in the True-Up Notice. Such audit may be conducted by the Distributor's personnel and/or its agents. Such audit shall be conducted during normal business hours and upon reasonable advance notice to the Company. The Distributor shall bear its own expenses in connection with any such audit. The Company shall reasonably cooperate, at its own expense, with any such audit. Within 30 days of its receipt of the True-Up Notice, the Distributor shall notify the Company in writing of any objections to the information set forth therein (the "**Objection Notice**") in which case the Parties shall attempt to resolve any such objections within 60 days after the Company's receipt of the

Objection Notice. If the Parties are unable to resolve the disputed matters within such 60-day period, such matters shall be resolved pursuant to Section 11.15.

(e) For the Distributor's planning purposes, the Company shall deliver to the Distributor a good faith estimate of the information to be provided in each True Up Notice no later than December 15 of the calendar year to which the True Up Notice will apply.

(f) If the aggregate Contract Price paid or to be paid by the Distributor (or directly by its customers) to the Company for all Products ordered during any calendar year was *greater* than the aggregate Contract Price that the Distributor would have paid for all of such Products ordered during such calendar year had the Contract Price been determined using the actual Cost of Goods Sold (versus Estimated COGS), then the Distributor shall be entitled to credit the difference against future Product purchases (or receive payment for the difference to the extent that the credit exceeds the amount of future Product purchases). If the aggregate Contract Price paid by the Distributor (or directly by its customers) to the Company for all Products ordered during any calendar year was *less* than the aggregate Contract Price that the Distributor would have paid for all of such Products ordered during such calendar year had the Contract Price been determined using the actual Cost of Goods Sold (versus Estimated COGS), then the Distributor shall pay to the Company the difference in immediately available funds within [* *] days from the Distributor's receipt of the True-Up Notice; provided, however, that if the Distributor delivered a timely Objection Notice with respect to such True-Up Notice, such payment shall be due within [* *] days from the date on which all disputed matters referenced in the Objection Notice have been resolved in accordance with Section 4.2(d) above. For avoidance of doubt, only orders that have been fulfilled and invoiced shall be taken into account for purposes of this Section 4.3(f).

(g) The Company shall update the Price Schedule to reflect any increases or decreases in Contract Prices to be implemented pursuant to this Section 4.3.

(h) The Parties may mutually agree in writing at any time during the Term that additional Products not then listed in the Price Schedule may be Commercialized by the Distributor within the Territory pursuant to this Agreement. The intent of the Parties is that the obligations and financial terms regarding any such Products will be substantially similar to those applicable to the Products then listed. The Parties may add to or modify the Price Schedule, including adding new Products with related information, at any time with mutual written consent.

4.4 **Invoice; Payment.** The Company shall invoice the Distributor for the applicable Contract Price, plus freight and insurance charges and any applicable federal, state, county or municipal sales or use tax, excise tax or similar governmental charges assessed on the sale of Products hereunder (for clarity, excluding any tax assessed against income), on the date of delivery to the customer. Notwithstanding the foregoing, the Distributor shall reimburse the Company for [* *] % of the Medical Device Excise Tax applicable to the Products sold to the Distributor or directly to its customers. The Company shall submit to the Distributor a reasonably detailed invoice, on a monthly basis, for the amount of Medical Device Excise Tax paid by the Company with respect to the Products sold to the Distributor or directly to its customers during the prior month and the amount of which the Distributor is responsible for reimbursement hereunder. Undisputed amounts shall be due and payable within [* *] days after

receipt of the invoice. The Company may assess a late fee of [* *]% in the event payment is made after [* *] days.

4.5 **West Coast Facility Fee.** The following shall apply if the Company has determined to establish a West Coast Facility and the Company has complied with Section 3.9:

(a) The Company shall notify the Distributor in writing when construction of the West Coast Facility building improvements has commenced after all permits necessary to begin construction have been obtained (the **"Construction Start Date"**). The Distributor shall pay to the Company an amount equal to $5,000,000 (the **"Construction Payment"**) by wire transfer of immediately available funds within 10 Business Days of the Distributor's receipt of such notice. Upon receipt of the Construction Payment, the Company shall use commercially reasonable efforts to establish the West Coast Facility. Proceeds from the Construction Payment shall be used to the extent necessary to pay bona fide expenditures relating to construction, equipment, inventory, validation, security deposits, leasing costs, initial operating expenses and other expenses reasonably related to the preparation of the West Coast Facility.

(b) The Distributor shall make a payment to the Company within 30 days from the First Commercial Release from the West Coast Facility as follows:

Date of First Commercial Release	**Payment Amount**
Within 12 months from the Construction Start Date	$ 5,000,000
Within [* *] months from the Construction Start Date	[* *]
Within [* *] months from the Construction Start Date	[* *]
After [* *] months from the Construction Start Date	[* *]

Notwithstanding the foregoing, if the First Commercial Release is delayed due to a Force Majeure, then the time periods referenced in the table above will be extended by the length of the delay (measured in days) caused by the Force Majeure.

Payments under this Section 4.5 are collectively referred to as the **"West Coast Facility Fee"**.

4.6 **Refund of Upfront Payment and West Coast Facility Fee.**

(a) If a Refund Trigger Event occurs, the Company shall refund to the Distributor a portion of the Upfront Payment and West Coast Facility Fee paid to the Company within 30 days of a Refund Trigger Event as follows:

Period During Which the Refund Trigger	**Percentage of the Aggregate Upfront**

Event Occurs	Payment and West Coast Facility Fee to be Refunded
Effective Date — December 31, 2016	50%
January 1, 2017 — December 31, 2018	33%
January 1, 2019 — December 31, 2021	25%

If a Refund Trigger Event occurs prior to the payment in full by the Distributor of the West Coast Facility Fee, then the amount of any portion of the West Coast Facility Fee becoming due and payable after the Refund Trigger Event shall be reduced in accordance with the schedule above.

(b) If the Distributor terminates this Agreement pursuant to Section 10.2(g) on or before December 31, 2019, the Company shall refund to the Distributor the amount set forth below within 30 days of the termination date.

Period During Which the Termination Occurs	Payment to be Refunded
Effective Date — December 31, 2018	$ 10,000,000
January 1, 2019 — December 31, 2019	$ 6,600,000

(c) Notwithstanding any provision in this Agreement to the contrary, Distributor shall not be entitled to more than one refund payment under this Section 4.6.

Article 5
Regulatory Matters

5.1 **Approvals.** The Company represents and warrants that it has applied for and received all necessary Regulatory Approvals for the Products in the portions of the Territory where the Products are being sold on the Effective Date and that such Regulatory Approvals are in effect as of the Effective Date. The Company shall maintain all such Regulatory Approvals at its own cost and expense. If the Distributor notifies the Company of its intent to sell Products in a jurisdiction in which the Company is not selling Products on the Effective Date and in which Regulatory Approval is required prior to such sales, the Company agrees to use its Commercially Reasonable Efforts, at the Distributor's sole cost and expense, to obtain such Regulatory Approval and the Distributor agrees to cooperate with the Company in its efforts to obtain such Regulatory Approval.

5.2 **Labeling.** The Company shall be responsible for the content of all Product labeling and Package Inserts and for accurate translations into all required languages throughout the Territory.

5.3 **Proceedings.** If either Party receives notice of an actual or threatened inspection, investigation, inquiry, import or export ban, product seizure, enforcement proceeding or similar action by a Regulatory Authority with respect to a Product or a Party's activities in connection with a Product, it will notify the other Party in writing within two Business Days after its receipt of notice of the action and will promptly deliver to the other Party copies of any relevant documents received from the Regulatory Authority. The Parties shall cooperate in response to the action, including providing information and documentation as requested by the Regulatory

Authority. If the action primarily concerns the Distributor's activities or of any Marketing Partner or sub-distributor, then the Distributor shall have primary responsibility to respond to the Regulatory Authority; otherwise, the Company shall have primary responsibility to respond. In either case, upon request of the responding Party, the other Party shall cooperate and provide consulting advice and assistance with the response.

5.4 **Reporting.** Each Party shall maintain a system of collecting and recording Product Complaints and MDR reportable events relating to the Products in accordance with its standard procedures and policies in effect from time to time. Each Party shall promptly notify the other of any material information such Party learns concerning the accuracy, performance, safety or efficacy of the Products, regardless of whether formal reporting to any Regulatory Authority is required. The Parties shall cooperate in the investigation of MDR reportable events and Product Complaints. The Company shall be responsible for all post-market surveillance and for submitting to applicable Regulatory Authorities all required reports and other materials, including annual reports, distribution reports, product performance reports, medical device reports and similar safety reports. The Quality Agreement shall set forth further provisions regarding response to and reporting of MDR reportable events.

5.5 **Field Actions.** If any Regulatory Authority issues or requests that a Field Action be conducted with respect to any Product, or if either Party notifies the other that, in its opinion, an event has occurred or circumstance arisen by reason of which such a Field Action may be necessary, then the Parties shall share all relevant facts and information *within two Bu*siness Days. Thereafter, the Parties shall proceed in accordance with the Quality Agreement.

Article 6
Intellectual Property

6.1 **Product Rights.** To the extent reasonably necessary for the Manufacturing, use and Commercialization of the Products in a manner consistent with the Manufacturing, use and Commercialization of the Products as of the Effective Date, the Company shall (a) be responsible for prosecuting and maintaining all Patents, Trademarks and other intellectual property registrations arising from or associated with the Product Rights as of the Effective Date in any jurisdiction in which they are then in effect and to bear all costs and expenses associated therewith, (b) assert or defend any term extension, interference, opposition, cancellation, reissue or re-examination proceeding relating to any intellectual property registrations associated with the Product Rights and bear all costs and expenses associated therewith, (c) bring actions for infringement of Product Rights against a Third Party and bear all costs and expenses associated therewith, (d) defend any action for invalidity/nullity brought by a Third Party against Product Rights and bear all costs and expenses associated therewith, and (e) defend against any third party claim brought for infringement of third party intellectual property rights against Products and bear all costs and expenses associated therewith. The Company shall keep the Distributor informed of material developments in any such proceeding.

6.2 **Trademark Licenses.** Each Party hereby grants to the other a nonexclusive, royalty-free license under the Licensed Trademarks of the grantor Party solely for the purpose of exercising the grantee's rights and performing the grantee's obligations under this Agreement. The licensee shall not have the right to grant sublicenses and its use of the Licensed Trademarks

shall inure solely to the benefit of the licensor, except the Distributor may grant sublicenses to the Licensed Trademarks reasonably necessary to exercise any sublicense to the Distributor Rights granted under Section 1.1 herein. Each Party, to the extent it is the licensee of the other Party's Licensed Trademarks, shall:

(a) comply with all reasonable instructions of the licensor as to the form and manner in which the Licensed Trademarks are used, including any instructions as to quality, style and graphic integrity;

(b) not make any addition to, deletion from or other modification to the Licensed Trademarks;

(c) prior to the production of packaging, labeling or other materials bearing any of the Licensed Trademarks, provide the licensor a reasonable opportunity to review and approve the presentation of the Licensed Trademarks;

(d) not adopt, use or register as its own any Trademarks, designs or other indicia that are confusingly similar to, or that dilute, the Licensed Trademarks; and

(e) not use the Licensed Trademarks other than pursuant to this Agreement.

6.3 **Rights in Bankruptcy**.

(a) The licenses granted in this Agreement shall be deemed to be, for purposes of Section 365(n) of the United States Bankruptcy Code and all applicable foreign equivalents (collectively, the "**Bankruptcy Code**"), a license of rights to "intellectual property" as defined in the Bankruptcy Code. Upon the occurrence of any Insolvency Event with respect to the Company, each licensee under this Agreement shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code. In connection therewith, the Parties agree and acknowledge that (i) all payments by the Distributor hereunder do not constitute royalties within the meaning of Section 365(n) of the Bankruptcy Code or relate to licenses of intellectual property hereunder; and (ii) "embodiments" of intellectual property within the meaning of Section 365(n) of the Bankruptcy Code include laboratory notebooks, research studies and data, and Regulatory Approvals. The Company shall, during the Term, create and maintain current copies or, if not amenable to copying, detailed descriptions or other appropriate embodiments, to the extent feasible, of all such intellectual property.

(b) If (i) a case under the Bankruptcy Code is commenced by or against the Company, (ii) this Agreement is rejected as provided in the Bankruptcy Code, and (iii) the Distributor elects to retain its rights hereunder as provided in Section 365(n) of the Bankruptcy Code, then the Company (in any capacity, including debtor-in-possession) and its successors and assigns (including any trustee) shall provide to the Distributor all such intellectual property (including all embodiments thereof) held by the Company and such successors and assigns, or otherwise available to them, promptly upon the Distributor's written request solely for the purpose of performing the Company's obligations hereunder. Whenever the Company or any of its successors or assigns provides to the Distributor any of the intellectual property licensed hereunder (or

any embodiment thereof) pursuant to this Section 6.3(b), the Distributor shall have the right to perform the Company's obligations hereunder with respect to such intellectual property, but neither such provision nor such performance by the Distributor shall release the Company from liability resulting from rejection of this Agreement or the failure to perform such obligations. The rights to intellectual property under this Section 6.3(b) shall be exclusive unless the Distributor Rights have been rendered non-exclusive pursuant to Section 3.8.

(c) All rights, powers and remedies of the Distributor provided herein are in addition to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at law or in equity (including the Bankruptcy Code) in the event of the commencement of a case under the Bankruptcy Code with respect to the Company. The Parties agree that they intend the following rights to extend to the maximum extent permitted by law, and to be enforceable under Bankruptcy Code Section 365(n):

(i) the right of access to any intellectual property (including all embodiments thereof) of the Company, or the right of the Company to intellectual property of any Third Party with whom the Company contracts to perform an obligation of the Company under this Agreement, and, in the case of the Third Party, which is necessary for the manufacture, use, sale, import or export of the Product; and

(ii) the right to contract directly with any Third Party to complete the contracted work.

Article 7
Indemnification

7.1 **Scope.** Each Party shall indemnify and hold harmless the other Party (and its Affiliates, employees and agents) from any liability, damage, loss, action, cause of action, tax, cost or expense (whether or not arising out of a third party legal claim or action) (including reasonable attorneys', consultants' and experts' fees and expenses and all amounts paid in investigation, defense and settlement of any of the foregoing) (collectively, "**Losses**") arising out of, in connection with or relating to any breach of contract, legal violation or gross negligence in connection with this Agreement by the indemnifying Party or any of its Affiliates, employees or agents (including any breach of contract, legal violation or negligence by the Company in performing the services required under this Agreement). In addition, the Company shall indemnify and hold harmless the Distributor from all Losses arising out of, in connection with or relating to any third party legal claim or action (a) alleging personal injury, death, property damage or other Loss arising from any actual or alleged defect in the design, engineering, fabrication, Manufacture, Package Insert or label (including label warnings) of any Product or from the failure of any Product to conform to the applicable Specifications (a "**Product Liability Claim**"), (b) alleging intellectual property infringement or

misappropriation arising from the Manufacture or Commercialization of any Product or (c) arising under or in connection with any Original Customer Contract to the extent arising from acts, omissions, events or other conditions that occurred or existed at any time prior to the assignment of the Company's rights and obligations under such Original Customer Contract to the Distributor pursuant to this Agreement.

If the Parties have indemnification obligations to one another in connection with a single third party legal claim or action, they shall contribute to the aggregate damages and costs in proportion to their relative responsibilities therefor based upon all relevant equitable considerations.

7.2 **Notice.** The indemnified Party shall promptly notify the indemnifying Party in writing and in reasonable detail of each indemnity claim, but any delay or deficiency of such notice shall not excuse the indemnifying Party's indemnification obligations except to the extent that its legal position is materially prejudiced due to the delay or deficiency.

7.3 **Defense.** The indemnifying Party shall have the right to assume and control the defense and settlement of any third party legal claim or action if the predominant claims therein are covered by its indemnity. If the indemnifying party assumes the defense, it shall employ counsel reasonably acceptable to the indemnified Party (which approval shall not be unreasonably withheld, conditioned or delayed) and shall defend the claim or action with diligence. If the indemnifying Party assumes the defense and the Parties have a conflict of interest with respect to such legal claim or action, the indemnified Party shall have the right to separate counsel (but no more than one law firm) reasonably acceptable to the indemnified Party (which approval shall not be unreasonably withheld, conditioned or delayed) at the indemnifying Party's cost. The Parties acknowledge that the law firms representing the Parties in connection with the negotiation of this Agreement shall, in any event, be deemed acceptable. In all events, the Party not controlling the defense shall cooperate with the controlling Party and shall be permitted to participate in the defense at its own expense.

7.4 **Settlement.** Neither Party shall settle a third party legal claim or action covered by indemnification under Section 7.1 without the other Party's prior written consent, which shall not be unreasonably withheld, conditioned or delayed, except that the indemnifying Party shall have the right to do so if (a) it will pay in full all monetary elements of the settlement, (b) the settlement does not include non-monetary elements, findings or admissions that would be detrimental to the other Party's ongoing business, and (c) the settlement includes a full release in favor of the other Party from all Losses arising out of, in connection with or relating to such legal claim or action.

7.5 **Insurance.** The Company shall maintain, from the Effective Date through the first anniversary of the expiration date of the Term, a policy of insurance for Product Liability Claims with a per occurrence limit of at least $[* *] million and an annual aggregate limit of at least $[* *] million. Such policy shall provide for at least 30 days' advance written notice to the Distributor of cancellation or material change in coverage. The Company shall provide to the Distributor evidence of such coverage promptly upon the Distributor's request.

Article 8
Representations and Warranties

8.1 **Mutual Representations.** Each Party hereby represents and warrants to the other Party that:

(a) It is a corporation duly organized, validly existing and in good standing under the laws of its jurisdiction of incorporation and has all requisite corporate power

and authority to conduct its business and engage in the transactions provided for in this Agreement.

(b) This Agreement has been duly authorized by all requisite corporate action of such Party and constitutes the legally binding obligation of such Party.

(c) Its execution and performance of this Agreement will not violate any Applicable Laws, Orders, corporate organizational documents, contracts or agreements by which it is bound, except as set forth in the "Company Disclosure Schedule" delivered in connection with the Investment Agreement between the Parties.

(d) It is not obligated to obtain any governmental or third party approvals or consents to enter into and perform this Agreement except as expressly contemplated herein.

8.2 **Company Representations**. The Company hereby represents and warrants to the Distributor that:

(a) It has the legal and valid right to grant the Distributor Rights.

(b) All Patents and Trademarks included in the Product Rights that have been registered or are subject to a pending registration in any country or jurisdiction in the Territory are listed in Schedule 8.2(b). To the knowledge of the Company, it owns or holds all Patent, Trademark and other intellectual property rights necessary to Manufacture, use and Commercialize the Products without infringing, violating or misappropriating the intellectual property rights of any Third Party. The Company has not received any written notice, claim or assertion from any Person (i) challenging the ownership, validity or enforceability of any of the Product Rights, (ii) alleging that the license, use or practice of the Product Rights infringes, violates or misappropriates the intellectual property rights of any Person, or (iii) seeking to enjoin or restrain such license, use or practice. The Company has no knowledge that any Person intends to give any such notice or make any such claim or assertion, or that any Person has a valid basis to do so.

(c) Schedule 8.2(c) sets forth a true, accurate and complete summary of all granted and pending Regulatory Approvals, classified by country/jurisdiction, for all current Products. All such Regulatory Approvals are held by the Company except as otherwise indicated in Schedule 8.2(c). In the case of any such Regulatory Approval not held by the Company, the holder thereof is contractually obligated to assign such Regulatory Approval to the Company at any time upon request of the Company.

(d) The Company has not received any notice of, and to the Company's knowledge there are not, any unresolved actions, citations, decisions, Orders, product recalls, medical device reports, information requests, untitled letters, warning letters, Section 305 notices, or any similar notices or communications, written or oral, from the FDA or any corollary entity in any other jurisdiction applicable to any Product.

(e) The Company has complied in all material respects with all Regulatory Laws with respect to (i) the design, development, investigation, Manufacture, labeling, testing, storing, inspection, marketing or promotion of any of the Products, and/or (ii) the Company's operation of its Manufacturing facilities. Without limiting the foregoing, no Product is or has been (x) adulterated or misbranded within the meaning of any Regulatory Law or (y) developed, researched, investigated, manufactured, distributed, marketed, advertised, promoted or sold in a manner that is materially inconsistent with any Regulatory Law, its approved or cleared labeling, its applicable filings, or any other requirements of applicable Regulatory Authorities.

(f) No Product has been the subject of a Field Action. The Company is not considering any Field Action with respect to any Product. To the knowledge of the Company, no Field Action with respect to a Product (i) is required to be implemented by the Company in order to comply with any Regulatory Law, or (ii) has been requested or ordered by any Regulatory Authority, health care professional or consumer group.

(g) Except as set forth in Schedule 8.2(g), the Company has made available to the Distributor true and complete copies of all of the Original Customer Contracts, each as amended and in full force and effect. Except as set forth in Schedule 8.2(g), the Original Customer Contracts constitute all of the contracts and agreements in effect as of the Effective Date between the Company and any of its customers with respect to the Products in the Territory. Each Original Customer Contract is valid, binding and enforceable in accordance with its terms. There are no existing defaults or events of default, or any events which, with or without notice or lapse of time or both, would constitute a default under any Original Customer Contract by the Company or, to the knowledge of the Company, by any other party thereto. Upon assignment by the Company to the Distributor of its rights under the Original Customer Contracts, Distributor will have all of the Company's rights thereunder during the Term to the same extent as though the Distributor was the original party thereto.

(h) The Cost of Goods Sold used to determine the Contract Price for each Product in effect for 2014 as set forth in **Exhibit J** has been determined in accordance with GAAP as in effect as of the Effective Date, if applicable, and to the extent not inconsistent with GAAP as in effect as of the Effective Date, the Company's routine accounting practices.

8.3 **Distributor Representations.** The Distributor hereby represents and warrants to the Company that:

(a) Neither the Distributor nor any Affiliate has received any notice of, and to the Distributor's knowledge there are not, any unresolved actions, citations, decisions, Orders, product recalls, medical device reports, information requests, untitled letters, warning letters, Section 305 notices, or any similar notices or communications, written or oral, from the FDA or any corollary entity in any other jurisdiction that could materially affect the Distributor's ability to perform its obligations under this Agreement.

(b) The Distributor is not aware of any reason under Regulatory Laws why it cannot execute, deliver and perform this Agreement and the transactions contemplated hereby.

Article 9
Confidentiality

9.1 **Scope.** In the course of their activities pursuant to this Agreement, the Parties anticipate that they may disclose Confidential Information to one another and that either Party may, from time to time, be a disclosing Party or a recipient of Confidential Information. The Parties wish to protect such Confidential Information in accordance with this Article 9. The provisions of this Article 9 shall apply to disclosures furnished to or received by a Party and its agents and representatives (which may include agents and representatives of its Affiliates) at any time, including prior to the Effective Date. Each Party shall advise its agents and representatives of the requirements of this Article 9 and shall be responsible to ensure their compliance with such provisions. The provisions of this Article 9 shall supersede and replace any prior agreements between the Parties relating to Confidential Information covered hereby. In addition to any other remedies available in law or equity, the disclosing Party shall be entitled to temporary and permanent injunctive relief in the event of a breach by the recipient under this Article 9.

9.2 **Confidential Information.** For purposes hereof, **"Confidential Information"** with respect to a disclosing Party means all Proprietary Information, in any form or media, concerning the disclosing Party or its Affiliates that the disclosing Party or its Affiliates furnish to the recipient, whether furnished before or after the date hereof, and all notes, analyses, compilations, studies and other materials, whether prepared by the recipient or others, that contain or reflect such Proprietary Information; *provided, however*, that Confidential Information does not include information that (a) is or hereafter becomes generally available to the public other than as a result of a disclosure by the recipient, (b) was already known to the recipient prior to receipt from the disclosing Party as evidenced by prior written documents in its possession not subject to an existing confidentiality obligation to the disclosing Party, (c) is disclosed to the recipient Party on a non-confidential basis by a Person who is not in default of any confidentiality obligation to the other Party, or (d) is independently developed by or on behalf of the recipient without reliance on information received from or on behalf of the other Party. The content of this Agreement shall be deemed to be Confidential Information of each Party, except to the extent such content becomes generally available to the public as a result of one or more disclosures required under Applicable Laws and made in accordance with Sections 9.3 or 9.5 below.

9.3 **Obligations.** The recipient of Confidential Information shall (a) use such Confidential Information solely and exclusively in connection with the exercise of its rights and the discharge of its obligations under this Agreement and (b) not disclose such Confidential Information without the prior written consent of the disclosing Party to any Person other than those of its agents and representatives who need to know such Confidential Information for such permitted use and who are bound by obligations of confidentiality with respect thereto. Notwithstanding the foregoing, the recipient of Confidential Information may disclose it to the extent necessary to comply with Applicable Laws or with an Order issued by a court or

regulatory body with competent jurisdiction; provided that, in connection with such disclosure, the recipient shall (i) provide reasonable advance notice of such disclosure to the disclosing Party; (ii) limit the disclosure to the information that is legally required to be disclosed, and (iii) use commercially reasonable efforts to obtain confidential treatment or an appropriate protective order, to the extent available, with respect to such Confidential Information. The obligations under this Section 9.3 shall remain in effect from the Effective Date through the fifth anniversary of the termination or expiration of this Agreement.

9.4 **Return and Destruction.** Upon the termination or expiration of this Agreement, the recipient of Confidential Information shall promptly redeliver to the disclosing Party all Confidential Information provided to the recipient in tangible form, and the recipient shall not retain any copies, extracts or other reproductions, in whole or in part, of such Confidential Information. All notes or other work product prepared by the recipient based upon or incorporating Confidential Information of the disclosing Party shall be destroyed, and such destruction shall be certified in writing to the disclosing Party by an authorized representative of the recipient who supervised such destruction. Notwithstanding the foregoing, the recipient shall be permitted to retain (but not use) (a) one file copy of all Confidential Information on a confidential basis to evidence the scope of and to enforce the Party's obligation of confidentiality under this Article 9; and (b) all back-up electronic media maintained in the ordinary course of business for archival purposes.

9.5 **Publicity.** Neither Party shall issue any press release or otherwise publicly announce the existence of this Agreement without the prior written approval of the other Party, except to the extent that such press release or other public announcement is required under Applicable Laws. In the event of a required press release or other public announcement, the releasing Party shall provide the other Party with a copy of the proposed text prior to such announcement. The Parties agree that if either Party is required to file this Agreement with any Governmental Authority, the disclosing Party shall redact the competitively sensitive terms of this Agreement to the extent consistent with applicable interpretations and guidance of the staff of the Securities and Exchange Commission.

Article 10
Term and Termination

10.1 **Term.**

(a) **Initial Term.** The term of this Agreement (the "**Term**") shall begin on the Effective Date and, unless terminated by mutual agreement of the Parties or otherwise in accordance with this Agreement, shall continue for an initial term expiring on the tenth anniversary of the Effective Date (the "**Initial Term Expiration Date**").

(b) **Extensions**.

(i) The Distributor shall have the option to extend the Term for a period of five years following the Initial Term Expiration Date (the "**First Extension**") provided that (x) the aggregate Contract Price paid for the Concentrate Products purchased by the Distributor or directly by its customers is

at least $[* *]during any period of four consecutive Calendar Quarters ending on or before [* *] (the "**First Extension Threshold**"); and (y) the Distributor shall pay to the Company an extension fee of $7,500,000 (the "**First Extension Fee**"). In the event that the Distributor has satisfied the criteria in clause (x) and desires to extend the Term, then the Distributor shall (A) notify the Company in writing at least [* *] days prior to the Initial Term Expiration Date and reference the Distributor's option for the First Extension under this Section, and (B) pay the First Extension Fee to the Company in immediately available funds within five Business Days of delivering such notice.

(ii) If the Term is extended by the First Extension, then the Term shall be automatically extended again for a period of five years following the expiration of the First Extension (the "**Second Extension**") unless the Distributor elects not to extend the Term for the Second Extension and delivers written notice thereof to the Company at least 90 days prior to the expiration of the First Extension. For avoidance of doubt, no extension fee shall be payable in connection with the Second Extension.

10.2 **Termination.**

(a) **Dissolution or Insolvency.** Either Party may terminate this Agreement by delivering written notice of its decision to do so if the other Party is dissolved under applicable corporate law or becomes subject to an Insolvency Event.

(b) **General Default.** If either Party (the "**Initiator**") believes the other Party (the "**Responder**") is in material default of any of its representations or material obligations under this Agreement, the Initiator may give written notice of such alleged default (the "**Default Notice**") to the Responder. If the Responder disputes such alleged default, it shall notify the Initiator of such dispute within ten Business Days after receipt of the Default Notice, in which case such dispute shall be resolved in accordance with Section 11.15. If the Responder does not dispute such alleged default or if upon resolution of a dispute in accordance with Section 11.15, it is determined that such default exists, then the Responder shall have, in the case of non-monetary defaults, [* *] days or, in the case of monetary defaults, [* *] days, after receipt of the Default Notice or determination of the default, as applicable, in which to remedy such default. If such default is not remedied in the time period set forth above, the Initiator shall have the right to terminate this Agreement immediately upon delivery to the Responder of written notice of termination. The Initiator's right to terminate this Agreement shall not be construed as an exclusive remedy.

(c) **Contract Price Increase**. The Distributor shall have the right to terminate this Agreement immediately upon written notice to the Company in the event that (i)(A) the aggregate weighted average Contract Prices for all Products increases from one calendar year to the next by more than [* *]%, or (B) the aggregate weighted average Contract Prices for all Products increases during any [* *] calendar year period by more than [* *]% in the aggregate, and (ii) the Distributor delivers such written notice to the Company within [* *] days from the date on which the applicable true-up payment is due

under Section 4.3(f) as a result of the increase in the applicable calendar year with respect clause (A) above and for the third calendar year with respect to clause (B) above.

(d) **Change of Control.** The Distributor shall have the right to terminate this Agreement upon 270 days' prior written notice to the Company in the event that the Company is subject to a Change of Control.

(e) **Distributor's Option.** The Distributor shall have the right to terminate this Agreement at any time upon 270 days' prior written notice to the Company.

(f) **Force Majeure.** The Parties shall have the right to terminate this Agreement as provided in Section 11.16.

(g) **IP Infringement.** The Distributor shall have the right to terminate this Agreement immediately upon written notice to the Company in the event that the Distributor is enjoined by a court of competent jurisdiction from Commercializing any Product in the United States due to a claim of intellectual property infringement or misappropriation relating to such Product. This termination right is in addition to all other rights and remedies to the Distributor provided in this Agreement.

10.3 **Surviving Rights and Obligations.** The following provisions shall survive any expiration or termination of this Agreement:

- Sections 2.2, 5.3, 5.4 (until the Distributor is no longer permitted to Commercialize Products) and 5.5;
- Articles 7, 8, 9, 10 and 11; and
- any provisions required for the interpretation or enforcement of any of the foregoing.

Expiration or termination of this Agreement shall not relieve any Party of any obligations that are expressly indicated to survive expiration or termination and shall be without prejudice to any rights that shall have accrued to the benefit of any Party prior to such expiration or termination. For avoidance of doubt, the Distributor's payment obligations under Section 4.5 shall not survive the expiration or termination of this Agreement, except to the extent that any payment obligations thereunder are due and owing prior to such expiration or termination.

10.4 **Fulfillment of Customer Contracts.** If, as of the expiration or termination of this Agreement for any reason other than pursuant to Section 10.2(b), as a result of a material default by the Distributor, Section 10.2(e) or Section 10.2(f), the Distributor is subject to one or more valid and binding contracts to supply Products to customers, then notwithstanding the expiration of the Term, the Company shall continue, upon the election of the Distributor, for a period of up to twelve months after the expiration or termination date, to sell Products to the Distributor on the terms and conditions of this Agreement to the extent required by the Distributor to fulfill its obligations under such customer contracts.

10.5 **Remaining Inventory.** Without limiting Section 10.4 above, upon the expiration or termination of this Agreement for any reason other than pursuant to Section 10.2(b) as a result of a material default by the Distributor, (a) at the Distributor's written request, the Company shall continue to manufacture and deliver all Products that are the subject of Firm Orders submitted by the Distributor prior to the expiration or termination of this Agreement, and (b) the Distributor shall be permitted for a period not to exceed 12 months to sell to depletion any remaining inventory of the Products, including any Products delivered pursuant to clause (a) above; *provided*, *however*, that the average end user pricing charged by the Distributor for any Product during such 12-month period shall not be less than the average end user pricing charged by the Distributor for such Product during the six month period immediately prior to the expiration or termination of this Agreement.

10.6 **Noncompetition.** In the event that the Distributor terminates this Agreement pursuant to Section 10.2(c), for a period of two years from the termination date, the Distributor shall not manufacture any Rockwell Competitive Products in the United States, other than the Excluded Products. In the event that the Distributor terminates this Agreement pursuant to Section 10.2(e), for a period of two years from the termination date, the Distributor shall not manufacture or sell any Rockwell Competitive Products in the United States, in each case, other than the Excluded Products.

Article 11
Miscellaneous

11.1 **Compliance; Conflicts.** Each Party and its Affiliates and their respective employees and agents shall comply in all material respects with all Applicable Laws that pertain to its activities under this Agreement and, except as otherwise provided herein, shall bear the entire cost and expense of such compliance. The Parties shall not, directly or indirectly, take any action (including the grant of any right or the undertaking of any obligation) that is in conflict with any provision of this Agreement.

11.2 **Interpretive Conventions.** Whenever the words "include," "includes" or "including" are used in this Agreement, they shall be understood to be followed by the words "without limitation." Pronouns, including "he," "she" and "it," when used in reference to any person, shall be deemed applicable to entities or individuals, male or female, as appropriate in any given case. Standard variations on defined terms (such as the plural form of a term defined in the singular form, and the past tense of a term defined in the present tense) shall be deemed to have meanings that correlate to the meanings of the defined terms. Article, Section and other headings contained in this Agreement are for reference purposes only and are not intended to describe, interpret, define or limit the scope, extent or intent of any provision of this Agreement. When a reference is made in this Agreement to a Recital, an Article, a Section, a Schedule, an Attachment or an Exhibit, such reference is to a Recital, Article or Section of, or a Schedule, Attachment or Exhibit to, this Agreement, unless otherwise indicated. All references to "dollars" or "$" shall be deemed to be references to the lawful currency of the United States.

11.3 **Assignment.** A Party shall not have the right to assign any of its rights or obligations under this Agreement without the prior written consent of the other Party, except that (a) either Party shall have the right to assign this Agreement to the acquiror in connection with a

Change of Control of such Party, and (b) either Party shall have the right to assign any of its rights and/or obligations hereunder to an Affiliate organized under the laws of any State in the United States, provided that the assigning Party remains liable for the performance of its obligations hereunder. Any assignment not in accordance with this Section shall be void.

11.4 **Entire Agreement.** This Agreement, together with the Quality Agreement and the Investment Agreement, constitute the entire agreement between the Parties concerning the subject matter hereof and thereof and supersede all previous negotiations, agreements and commitments with respect thereto. In the event a term in this Agreement conflicts with a term in the Quality Agreement or the Investment Agreement, the conflicting term in this Agreement shall govern and control.

11.5 **Amendments.** This Agreement shall not be amended or modified in any manner except by a written instrument signed by duly authorized officers or representatives of each of the Parties.

11.6 **Governing Law.** Any claim or controversy relating in any way to this Agreement shall be governed by and interpreted exclusively in accordance with the laws of the State of Delaware, without regard to the conflicts of law principles thereof.

11.7 **Partial Illegality.** If any provision of this Agreement or the application thereof to any Party or circumstances shall be declared void, illegal or unenforceable, the remainder of this Agreement shall be valid and enforceable to the extent permitted by Applicable Laws. In such event, the Parties shall use their best efforts to replace the invalid or unenforceable provision by a provision that, to the extent permitted by the Applicable Laws, achieves the purposes intended under the invalid or unenforceable provision. Any deviation by any Party from the terms and provisions of this Agreement (including with respect to the Distributor Rights) in order to comply with Applicable Laws shall not be considered a breach of this Agreement.

11.8 **Waiver of Compliance.** No provision of this Agreement shall be waived by any act, omission or knowledge of a Party or its agents or employees, except by an instrument in writing expressly waiving such provision and signed by a duly authorized officer of the waiving Party, which waiver shall be effective only with respect to the specific obligation and instance described therein.

11.9 **Notices.** All notices and other communications in connection with this Agreement shall be in writing and shall be sent to the respective Parties at the following addresses, or to such other addresses as may be designated by the Parties in writing from time to time in accordance with this Section, by registered or certified mail, postage prepaid, or by express courier service, service fee prepaid:

If to the Company:

Rockwell Medical, Inc.
30142 Wixom Road
Wixom, MI 48393
Attention: Robert L. Chioini
Email: rchioini@rockwellmed.com

with a copy (which will not constitute notice) to:

Dykema Gossett PLLC
39577 Woodward Ave., Suite 300
Bloomfield Hills, MI 48304
Attention: Mark A. Metz
Email: mmetz@dykema.com

If to the Distributor:

Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, Illinois 60015
Attention: General Counsel
Telecopy: 224.948.2000

with a copy (which will not constitute notice) to:

Faegre Baker Daniels LLP
600 East 96th St., Suite 600
Indianapolis, Indiana 46240
Attention: Trevor J. Belden
Email: Trevor.Belden@FaegreBD.com

All notices shall be deemed given and received (i) if delivered by hand or by electronic mail, immediately, (ii) if sent by United States first class mail, five Business Days after posting, or (iii) if delivered by express courier service for next day delivery, the next Business Day in the jurisdiction of the recipient.

11.10 **Counterparts; Electronic or Facsimile Transmission.** This Agreement may be executed in counterparts, each of which shall be deemed to be an original and all of which together shall be deemed to be one and the same instrument. This Agreement may be delivered by one or both Parties by facsimile or electronic transmission with the same effect as if delivered personally.

11.11 **Further Assurances.** From time to time, as and when requested by any Party, the other Party shall execute and deliver, or cause to be executed and delivered, all such documents and instruments and shall take, or cause to be taken, all such further actions as such other Party may reasonably deem necessary or desirable to carry out the intentions of the Parties embodied in this Agreement.

11.12 **Jointly Prepared.** This Agreement has been prepared jointly and shall not be strictly construed against either Party.

11.13 **Relationship of Parties.** Each Party to this Agreement is an independent contractor. Employees and agents of one Party are not employees or agents of the other Party,

shall not hold themselves out as such, and shall not have any authority or power to bind the other Party to any contract or other obligation.

11.14 **Third Party Beneficiaries.** Nothing in this Agreement, whether express or implied, is intended to confer any rights or remedies under or by reason of this Agreement on any Persons other than the Parties hereto and their respective successors, assigns and Affiliates.

11.15 **Dispute Resolution.**

(a) The Parties shall negotiate in good faith and use reasonable efforts to settle any dispute, controversy or claim arising from or related to this Agreement or the breach thereof. If the Parties are unable to settle the matter through negotiation within 30 days, then at the request of either Party, the Parties shall endeavor to resolve the dispute, controversy or claim by confidential mediation pursuant to the Mediation Procedure of the International Institute for Conflict Prevention and Resolution, Inc. ("**CPR**") using a mutually agreeable mediator with prior experience in the medical products business. If the matter remains unresolved for 45 days after appointment of such mediator and a Party wishes to pursue it further, then such dispute, controversy or claim, except for any Excluded Claim, shall be finally resolved by binding arbitration in accordance with the CPR Rules for Non-Administered Arbitration, and judgment on the arbitration award may be entered in any court having jurisdiction thereof.

(b) The arbitration shall be conducted by a panel of three persons experienced in the medical products business. Within 30 days after initiation of arbitration, each Party shall select one person to act as arbitrator and the two Party-selected arbitrators shall select a third arbitrator within 30 days of their appointment. If the arbitrators selected by the Parties are unable or fail to agree upon the third arbitrator, the third arbitrator shall be appointed by the CPR. The Parties shall not be obligated to select arbitrators from the CPR panel of arbitrators. The place of arbitration shall be Chicago, Illinois, and all proceedings and communications shall be in English.

(c) Either Party may apply to the arbitrators for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. Either Party also may, without waiving any remedy under this Agreement, seek from any court having jurisdiction any injunctive or provisional relief necessary to protect the rights or property of that Party pending the arbitration award. The arbitrators shall have no authority to award punitive or any other type of damages not measured by a Party's compensatory damages. Each Party shall bear its own costs and expenses and attorneys' fees and an equal share of the arbitrators' fees and any administrative fees of arbitration.

(d) Except to the extent necessary to confirm an award or as may be required by law, neither a Party nor an arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of both Parties. In no event shall an arbitration be initiated after the date when commencement of a legal or equitable proceeding based on the dispute, controversy or claim would be barred by the applicable Delaware statute of limitations.

(e) The Parties agree that, in the event of a good faith dispute over the nature or quality of performance under this Agreement, neither Party may terminate this Agreement until final resolution of the dispute through arbitration or other judicial determination. The Parties further agree that any payments made pursuant to this Agreement pending resolution of the dispute shall be refunded if an arbitrator or court determines that such payments are not due.

(f) As used in this Section, the term "**Excluded Claim**" shall mean a dispute, controversy or claim that concerns (i) the validity or infringement of intellectual property rights; or (ii) any disclosure in violation of Article 9, or any misuse or misappropriation of Confidential Information of the disclosing Party.

11.16 **Force Majeure.** If the performance of any obligation under this Agreement is prevented, restricted or interfered with by reason of any Force Majeure event, then the Party so affected shall be excused, upon giving prior written notice to the other Party, from such performance to the extent of such prevention, restriction or interference, provided that the Party so affected shall use reasonable commercial efforts to avoid or remove such causes of nonperformance and shall continue performance to the extent reasonably possible and, in any event, at such time as the Force Majeure conditions come to an end. If the Force Majeure conditions prevent performance completely and such prevention continues for more than 180 days, then the Parties shall attempt to negotiate a mutually acceptable compromise within the spirit and intent of this Agreement. If the Parties are unable to reach a mutually acceptable compromise within 90 days and if performance is still completely prevented at the end of that time, then the either Party shall have the option, by delivery of written notice of termination to the other Party, to terminate this Agreement with immediate effect.

11.17 **Debt Payment; Restriction on Liens**. Within 180 days from the Effective Date, the Company shall (a) repay in full all indebtedness of the Company owed under the Hercules Loan Agreement (including all accrued interest, costs and expenses, and other amounts due thereunder); and (b) obtain the complete release of all liens granted under the Hercules Loan Agreement. Effective as of the release of such liens, the Company shall not enter into any subsequent contract or other arrangement granting a security interest to any Person (other than to the Distributor or any of its Affiliates) in any of the Company's assets that are used primarily in the Manufacture or Commercialization of the Products without the prior written consent of the Distributor in its sole discretion.

[SIGNATURES ON FOLLOWING PAGE;
REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

The Distributor and the Company have executed this Agreement as of the Effective Date to evidence their agreement to the terms and provisions set forth herein.

Baxter Healthcare Corporation		**Rockwell Medical, Inc.**	
By:	/s/Robert J. Hombach	By:	/s/ Robert L. Chioini
Name:	Robert J. Hombach	Name:	Robert L. Chioini
Title:	CVP, Chief Financial Officer	Title:	CEO

Signature Page to Exclusive Distribution Agreement

EXHIBIT A
DEFINITIONS

"**Affiliate**" means a parent, subsidiary or sister company of a Party, and for this purpose, (a) "parent" means any corporation or business entity that owns, directly or indirectly, a majority of the Party's voting stock or comparable equity securities; (b) "subsidiary" means any corporation or business entity of which the Party owns, directly or indirectly, a majority of the voting stock or comparable equity securities; and (c) "sister company" means any corporation or business entity of which a parent owns, directly or indirectly, a majority of the voting stock or comparable equity securities.

"**Agreement**" has the meaning set forth in the opening paragraph.

"**Ancillary Products**" means (a) the products listed under the heading "Ancillary Products" on the Initial Price Schedule; and (b) all improvements, upgrades, enhancements, modifications, substitutions and next-generation versions thereof or thereto. For the avoidance of doubt, "Ancillary Products" shall not include Triferic, Calcitriol or any other drug product.

"**Applicable Laws**" means all applicable laws, statutes, rules, regulations, orders, judgments, injunctions and/or ordinances of any Governmental Authority.

"**Bankruptcy Code**" has the meaning set forth in Section 6.3(a).

"Baseline Amount" means the number of gallons of Concentrate Products ordered by the Distributor, its Affiliates and Marketing Partners, or directly by its customers, in the United States during Contract Year 1.

"**Baxter Competitive Product**" means any product used by dialysis clinics, but excluding the Company's Calcitriol and Triferic products.

"**Business Day**" means any day other than a Saturday, a Sunday or a day on which banks in the City of Chicago are authorized or obligated by law or executive order to remain closed.

"**Calendar Quarter**" means a period of three consecutive months beginning on January 1, April 1, July 1 or October 1; *provided*, *however*, that the first Calendar Quarter shall begin on the Effective Date and end on the day before the start of the next Calendar Quarter, and the last Calendar Quarter shall end on the last day of the Term.

"**Change of Control**" means with respect to a Party: (a) the sale of all or a majority of such Party's assets or business relating to this Agreement; (b) a merger, reorganization or consolidation involving such Party in which the voting securities of such Party outstanding immediately prior thereto cease to represent at least 50% of the combined voting power of the surviving entity immediately after such merger, reorganization or consolidation; or (c) a Person or group of Persons acting in concert acquire more than 50% of the voting equity securities of such Party.

"**Commercialize**" means, with respect to a product, any and all activities directed to the offering for sale and sale of the product, including activities related to promoting, marketing, distributing, importing, selling and providing support for the product.

"**Commercially Reasonable Efforts**" means that effort customarily exerted by a Party with respect to its own products of similar strategic importance and commercial potential, taking into account all relevant factors that impact the Party's decisions as to resource allocation for its products, such as intellectual property position, regulatory risk, safety and efficacy, product reliability and performance, the competitive environment, reimbursement status, product life cycle and product profitability.

"**Committee**" has the meaning set forth in Section 3.10 (a).

"**Company**" has the meaning set forth in the opening paragraph.

"**Competitor**" means (i) [* *]; (ii) [* *]; (iii) [* *]; (iv) [* *]; (v) [* *]; (vi) any direct parent entity that, directly or indirectly, owns 100% of the outstanding equity of a Person specified in clauses (i) through (v), and any subsidiary of such direct parent entity; and (vii) any successor to a Person specified in clauses (i) through (vi).

"**Concentrate Products**" means (a) the Company's CitraPure products, acid products and bicarbonate products, in each case as identified on the Initial Price Schedule; (b) all current and future formulations, concentrations and packaging configurations (e.g., powder or liquid) of the Company's CitraPure products, acid products and bicarbonate products; and (c) all improvements, upgrades, enhancements, modifications, substitutions and next-generation versions thereof or thereto; *provided*, *however*, that the Concentrate Products shall not include any formulations containing the Company's bio-pharmaceutical iron drug branded "Triferic."

"**Confidential Information**" has the meaning set forth in Section 9.2.

"**Construction Start Date**" has the meaning set forth in Section 4.5(a).

"**Construction Payment**" has the meaning set forth in Section 4.5(a).

"**Contract Price**" means the purchase price at which the Company sells Products to the Distributor pursuant to this Agreement.

"**Contract Year**" means any year of the Term ending on an anniversary of the Effective Date, and Contract Year 1 means the first Contract Year, Contract Year 2 means the second Contract Year, and so on.

"**Cost of Goods Sold**" means the Company's actually incurred cost to manufacture one unit of a particular Product in accordance with the terms of this Agreement (e.g., in accordance with the Quality Agreement and Specifications), and including direct material, direct labor, material variances, volume variances, material purchase price variances, indirect labor, utilities, depreciation, laboratory testing, Quality Assurance, facilities costs, warehousing costs, warehousing operations costs, manufacturing costs, and other operations costs including other capitalized inventory costs. For avoidance of doubt, Cost of Goods Sold shall exclude the

following: (i) costs related to the transport of finished Product after it is shipped from the Company's facility to a customer or to Distributor or its Affiliates, Marketing Partners or sub-distributors, (ii) separately billed Support Services, and (iii) general corporate expenses of the Company. Such costs shall be determined in accordance with GAAP, and to the extent not inconsistent with GAAP, the Company's routine accounting practices in accordance with any other authoritative accounting principles applicable at such time.

"**CPR**" has the meaning set forth in Section 11.15(a).

"Customer Orders" has the meaning set forth in Section 3.2(a).

"**Default Notice**" has the meaning set forth in Section 10.2(b).

"**Disruptive Event**" means, with respect to a Product, (a) any claim, action or litigation (including product liability and intellectual property claims) relating to such Product; (b) any occurrence or development that calls into question the safety or efficacy of such Product or that reasonably could result in a material liability to the Distributor; (c) any adverse regulatory action, ruling or development; (d) any breach or violation of this Agreement or the Quality Agreement by the Company, including any inability to fulfill Customer Orders or Firm Orders submitted in compliance with Section 3.2 and in line with its Forecasts; or (e) any Force Majeure event.

"**Distributor**" has the meaning set forth in the opening paragraph.

"**Distributor Rights**" has the meaning set forth in Section 1.1(a).

"**Effective Date**" has the meaning set forth in the Preamble.

"**Estimated COGS**" has the meaning set forth in Section 4.3(a).

"**Estimated COGS Notice**" has the meaning set forth in Section 4.3(a).

"**Excluded Claim**" has the meaning set forth in Section 11.15(f).

"**Excluded Products**" means (i) BiCart®, SoftPac™, BiCart Select®, SelectBag® One, SelectBag® Citrate, VIVIA Haemodialysis System, Diasol, Hospasol; (ii) any concentrate product not used for hemodialysis applications; and (iii) any other product that the Distributor commercializes (including any products in any of the Distributor's product catalogues) or has in development, in each case, as of the Effective Date.

"**FDA**" means the United States Food and Drug Administration (or any successor agency having the administrative authority to grant Regulatory Approval in the United States).

"**Field Action**" means any action by a Party that meets the criteria of "recall," "correction," or "removal" or similar field or customer action as defined by applicable Regulatory Law.

"**Firm Order**" means a definitive order submitted by the Distributor in accordance with this Agreement that, upon acceptance, gives rise to binding obligations of purchase and sale.

"**First Commercial Release**" means the release for commercial sale of finished Concentrate Products in both liquid and powder form (including CitraPure) Manufactured at the West Coast Facility.

"**First Extension**" has the meaning set forth in Section 10.1(b)(i).

"**First Extension Fee**" has the meaning set forth in Section 10.1(b)(i).

"**First Extension Threshold**" has the meaning set forth in Section 10.1(b)(i).

"**Force Majeure**" means any war, revolution, civil commotion, act of terrorism, blockade, embargo, strike, scarcity of raw materials or necessary packaging supplies, flood, earthquake, change in Applicable Law or other event that is beyond the reasonable control of the Party affected.

"**Forecast**" means a non-binding estimate of future product purchases provided to facilitate planning and resource allocation. A Forecast is not an offer to purchase.

"**GAAP**" means United States generally accepted accounting principles as modified from time to time.

"**Good Manufacturing Practices (GMPs)**" means the then-current standards for conducting manufacturing activities for medical devices as are required by any applicable Regulatory Authority, including the Quality System Regulations in the United States.

"**Governmental Authority**" means any court, agency, authority, department, regulatory body or other instrumentality of any government or country or of any national, federal, state, provincial, regional, country, city or other political subdivision of any such government or any supranational organization of which any such country is a member.

"**Hercules Loan Agreement**" means the Loan and Security Agreement between the Company, Rockwell Transportation, Inc. and Hercules Technology III, L.P, dated as of June 14, 2013, as amended.

"**Initial Price Schedule**" means the Price Schedule attached to this Agreement as of the Effective Date.

"**Initial Term Expiration Date**" has the meaning set forth in Section 10.1(a).

"**Initiator**" has the meaning set forth in Section 10.2(b).

"**Insolvency Event**" means that the Party has (a) commenced a voluntary proceeding under any insolvency law, or (b) had an involuntary proceeding commenced against it under any insolvency law that has continued undismissed or unstayed for 60 consecutive days, (c) had a receiver, trustee or similar official appointed for it or for any substantial part of its property, or (d) made an assignment for the benefit of creditors, or (e) had an order for relief entered with respect to it by a court of competent jurisdiction under any insolvency law. For purposes hereof,

the term "insolvency law" means any applicable bankruptcy, insolvency or other similar law now or hereafter in effect.

"**Investment Agreement**" means the Investment Agreement between the Company and Distributor, dated as of the Effective Date.

"**Key Person**" means Robert L. Chioini or, if Mr. Chioini is no longer employed by the Company, the chief executive officer of the Company.

"**Licensed Trademarks**" means, with respect to each Party, those Trademarks set forth below its name on **Exhibit G**.

"**Losses**" has the meaning set forth in Section 7.1.

"**Manufacture**" or "**Manufacturing**" means all operations necessary or appropriate to make, test, release, package, store, label and ship a Product in accordance with industry standards, GMPs, QSRs, Applicable Laws, and the Product's Specifications.

"**Manufacturing Default**" means (a) a material breach of the Company's obligations under Sections 3.2, 3.3 or 3.6 that is not cured within [* *] days following written notice from Distributor; (b) within [* *] months after the cure or waiver of a material breach referred to in clause (a), the Company commits another material breach of its obligations under Sections 3.2, 3.3 and 3.6 (in which case the Manufacturing Default shall exist immediately upon the occurrence of the subsequent breach); (c) the Company is subject to an Insolvency Event and has materially breached its obligations under Sections 3.2, 3.3 or 3.6; or (d) a Regulatory Authority takes any action that reasonably would be expected to materially disrupt the Company's ability to fulfill its obligations under Sections 3.2, 3.3 and 3.6 for a period of more than [* *] days.

"**Marketing Partner**" means a Third Party that markets, distributes, promotes and/or sells a Party's products under a contractual arrangement with the Party.

"**MDR**" means Medical Device Reporting under applicable FDA regulations.

"**Medical Device Excise Tax"** means the tax imposed on the sale of taxable medical devices pursuant to Section 1405 of the Health Care and Education Reconciliation Act of 2010.

"**Minimum Order Threshold**" has the meaning set forth in Section 3.8(a).

"**Non-Conforming Product**" has the meaning set forth in Section 3.6.

"**Objection Notice**" has the meaning set forth in Section 4.3(d).

"**Order**" means any award, decision, injunction (whether temporary, preliminary or permanent), judgment, stipulation, order, ruling, subpoena, writ, decree, consent decree or verdict entered, issued, made or rendered by any court, administrative agency, arbitrator or other Governmental Authority.

"**Ordering Guidelines**" means the Ordering Guidelines set forth in **Exhibit H**, and as they may be modified from time to time with the mutual consent of the Parties.

"**Original Customer Contracts**" means the written contracts between the Company and its current customers for the Products as of the Effective Date.

"**Package Insert**" means information supplied by the manufacturer of a product that includes all the information needed to use it safely and in compliance with Applicable Laws. Specifications for the Package Insert content vary with regulatory jurisdiction, but typically include operating instructions, warnings and/or precautions, indications, contraindications, information relative to sterilization, instructions in the event of damage to sterile packaging, cleaning, disinfection information and the like.

"**Party**" means the Distributor and/or the Company.

"**Patents**" means all inventions, discoveries, ideas or technology that are patented under Applicable Law relating to the Products, and all related (i) patents and patent applications (including provisional applications and applications for a certificate of invention); (ii) reissues, substitutions, confirmations, registrations, validations, re-examinations, additions, continuations, continued prosecution applications, continuations-in-part, and divisions of, to or for any patent or patent application; and (iii) term extensions, supplementary protection certificates and other governmental actions that extend exclusive rights to an invention or technology beyond the original patent expiration date.

"**Person**" means a natural person, a corporation, a partnership, a trust, a joint venture, a limited liability company, any Governmental Authority, or any other entity or organization.

"Pre-Approved Sub-Distributors and Marketing Partners" means the Persons set forth on **Exhibit I**.

"**Price Schedule**" means a schedule of Products and associated Target Margin Percentages and Contract Prices, which schedule shall be supplemented, amended and updated from time to time in accordance with Sections 4.3(g) and (h). The initial Price Schedule is attached hereto as **Exhibit J**.

"**Product Complaint**" means any written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness or performance of a product or device after it is released for distribution.

"**Product Liability Claim**" has the meaning set forth in Section 7.1.

"**Product Rights**" means all Patents, Trademarks, copyrights, trade secrets, know-how and other intellectual property rights that are subject as of the Effective Date, or become subject during the Term, to the Company's control and that are necessary or useful for the Manufacture, use or Commercialization of any Product. For this purpose, the Company shall be considered to control an intellectual property right if the Company or any of its Affiliates owns or has a license to it and also has the right to license or sublicense it to the Distributor.

"**Products**" means the Concentrate Products and the Ancillary Products.

"**Project Development Agreement**" has the meaning set forth in Section 3.9.

"**Proprietary Information**" means a Party's trade secrets, know-how, business plans, manufacturing processes, clinical strategies, product specifications, scientific data, market analyses, formulae, designs, training manuals and other non-public information (whether business, financial, commercial, scientific, clinical, regulatory or otherwise) that the Party treats as proprietary and uses commercially reasonable efforts to protect.

"**Quality Agreement**" has the meaning set forth in Section 2.1.

"**Quality System Regulations (QSRs)**" means, with respect to the United States, the Quality System Regulations promulgated by the FDA and set forth in 21 C.F.R. § 820, and which describe the minimum requirements for the methods, facilities and controls used in the manufacturing, processing, packaging or holding of a medical device.

"**Receiving Party**" has the meaning set forth in Section 3.7.

"**Refund Trigger Event**" means any of the following: (a) the Company is the subject of a Change of Control and the acquiror is a Competitor; (b) the Distributor terminates this Agreement pursuant to Sections 10.2(a), (b) or (c); (c) either party terminates this Agreement pursuant to Section 10.2(f); (d) any claim, action or litigation (including product liability and intellectual property claims) relating to a Product is settled or adjudicated by a court of competent jurisdiction and, as a result, the Distributor's Commercialization of such Product is materially and adversely affected; and (e) any regulatory action or ruling relating to a Product that materially and adversely affects the Distributor's Commercialization of such Product.

"**Regulatory Approval**" means all approvals from the relevant Regulatory Authority necessary to make, use and sell a Product in that country or jurisdiction.

"**Regulatory Authority**" means, with respect to any country or jurisdiction, any Governmental Authority involved in granting regulatory approval for the manufacture, marketing, sale, reimbursement and/or pricing of a Product, or in administering Regulatory Laws in that country or jurisdiction,

including the FDA in the United States.

"**Regulatory Laws**" means all Applicable Laws governing the import, export, testing, investigation, manufacture, marketing, promotion, distribution or sale of a Product, or establishing recordkeeping or reporting obligations for product complaints or adverse events, or relating to field actions or similar regulatory matters.

"**Responder**" has the meaning set forth in Section 10.2(b).

"Rockwell Competitive Product" means (i) the Concentrate Products listed on the Initial Price Schedule as of the Effective Date, and (ii) any Concentrate Products which at the time of determination: (a) are manufactured by the Company and (b) have the same intended use as the Concentrate Products listed on the Initial Price Schedule as of the Effective Date.

"**Second Extension**" has the meaning set forth in Section 10.1(b)(ii).

"**Shortfall Cure Period**" has the meaning set forth in Section 3.8(c).

"**Specifications**" means, with respect to any Product, the chemical, mechanical, physical and other properties, and performance and functionality characteristics, of the Product as described in the Company's Regulatory Approval documents and promotional materials relating to the Product.

"**Stipulated Shipping Date**" means (i) for Customer Orders, the shipping date provided in the Ordering Guidelines and (ii) for Firm Orders, the date that is [* *] days after a Firm Order is submitted by the Distributor, as applicable.

"**Substitute Products**" has the meaning set forth in Section 3.5.

"**Support Services**" has the meaning set forth in Section 1.6.

"**Support Services Period**" has the meaning set forth in Section 1.6.

"**Target Margin Percentage**" means the Target Margin Percentage for each Product as set forth in the Price Schedule.

"**Term**" has the meaning set forth in Section 10.1(a).

"**Territory**" means the entire world, other than the territories set forth in **Exhibit K**.

"**Third Party**" means Persons other than the Parties or Affiliates thereof.

"**Trademarks**" means all trademarks, service marks, trade dress, logos, labels, domain names, websites and trade names, together with all translations, adaptations, derivations and combinations thereof (including all goodwill associated therewith), and all applications, registrations and renewals in connection therewith.

"**True-Up Notice**" has the meaning set forth in Section 4.3(d).

"**United States**" means the United States of America and its territories and possessions, including the Commonwealth of Puerto Rico.

"**Upfront Payment**" has the meaning set forth in Section 4.1.

"**West Coast Facility**" has the meaning set forth in Section 3.9.

"**West Coast Facility Fee**" has the meaning set forth in Section 4.5.

Exhibit B
Transition Services

Workstream	Description	Timing for Completion
Sales & Marketing	Rockwell shall support Customer communication of the Distributor Agreement in coordination with Baxter as mutually agreed upon with Baxter.	
Sales & Marketing	Rockwell shall support the determination and communication of product availability and logistics along with the processing of prioritized backorders in a mutually agreed upon manner with Baxter.	Effective Date + 30 days
Sales & Marketing	Rockwell shall provide its trade show participation plan for its Concentrate Products in trade shows, conferences, and conventions and participation in those events must be mutually agreed upon with Baxter. Rockwell will continue to participate at trade shows informing prospective customers that Baxter is the exclusive sales, marketing and distribution agent of all Concentrate Products.	Plan to be shared within Effective Date + 5 days with mutual agreement on participation going forward within Effective Date + 30 days
Sales & Marketing	Rockwell shall transfer existing marketing and promotional collateral used externally with customers and trade partners for purposes of sales, trade shows, conferences and conventions as of the Effective Date for reference by Baxter.	Effective Date + 1 days

Sales & Marketing	Rockwell shall transfer existing product training material for use by sales force with customers or for customers as of the Effective Date for use by Baxter.	Effective Date + 10 days
Quality	The two parties shall establish a process to manage Recalls and Field Corrective Actions in an automated manner such that all necessary customer information is mutually available as defined in the Definitive Agreement. Prior to formalizing the process, Rockwell shall use all commercially reasonable efforts to provide Baxter with all necessary information as requested in the event of a Recall or Field Corrective Action.	Effective Date + 60 days
Sales & Marketing	Rockwell shall provide all necessary information related to Ancillary Products including, but not limited to mixer design details, part numbers and warranty periods.	Effective Date + 15 days
Sales & Marketing	As requested by either Party, each Party shall provide additional and commercially reasonable effort to support additional requests for preparedness through the Transition Services period.	Effective Date + 180 days
Account Maintenance	Rockwell shall provide a full download of its customer master file of domestic customers as of the Effective Date. Rockwell will provide a transfer of its price file for its domestic customers. Rockwell will provide a download of year to date sales transaction detail by customer by invoice.	Effective Date + 10 days
Account Maintenance	The two parties shall be mutually responsible for maintaining customer account information relating to customers prior to and following the Effective Date in all relevant systems. The exact format of how that will be established shall be determined as soon as practical after the customer master file is transferred.	Effective Date + 180 days
Sales Transaction Processing and Order Fulfillment	Rockwell will continue to accept customer orders, deliver and invoice customers until Baxter is ready to cutover to billing to Baxter with a target date no later than [* *]. The Parties will make their best efforts to be prepared to cutover invoicing as of that date. Rockwell will continue to operate business in the same manner as it currently operates retaining title to inventory, invoicing customers and collecting cash related to those invoices from customers. Such activity will continue until Baxter is prepared to assume invoicing responsibility.	Effective Date until cutover but targeted to be on but not later than [* *]
Economic Settlement of Fourth Quarter Activity	Rockwell will provide Baxter with a financial summary of total sales performance on a monthly basis during the first three months of the Agreement. Rockwell will reconcile for Baxter the fourth quarter sales transaction activity as part of the year-end True-Up. Rockwell will provide Baxter with a summary of the actual Rockwell invoices sent to domestic customers for products sold to those customers at the customer prices along with associated costs of goods sold including delivery (transportation) services and that gross profit will be compared to the profit Baxter would have earned on those sales using the Contract Prices in the agreement for 2014 and the actual costs of those sales as incurred by the Company. Such profit difference will be paid by Rockwell to Baxter unless the costs incurred by Rockwell exceeded the revenue generated by those sales from Rockwell to Baxter at the Contract Prices. Rockwell will provide detailed sales performance by customer for each of the first three months of the agreement. That file will be shared with Baxter by the 10th business day of the subsequent month.	True-Up Period per Agreement
Sales Transaction Conversion	Rockwell will coordinate with Baxter on the configuration of EDI interchange of billing information whereby Rockwell will invoice Baxter for product shipments to customers during the Support Services period and Baxter will utilize such EDI interchange to bill customers directly. Each party will incur its own costs for such information technology preparation and the parties will test and verify to each other's satisfaction that the processes and systems work	Readiness for cutover to Baxter by [* *]

	as planned prior to cutover of customer invoicing.	
Customer Service	Rockwell will continue to operate customer service activities as described in Exhibit C during the period and Rockwell will include the cost of such services in the 2014 True-Up period.	Effective Date
Distribution and Transportation	Rockwell will continue to deliver products during the transition period as described in Exhibit C. The cost of such services during the period up to December 31, 2014 will be included in the 2014 True-Up reconciliation.	Effective Date
Finance	During the Transition Period, Rockwell will manage the collection of Rockwell Accounts Receivable. Subsequent to the cutover of invoicing to Baxter, to the extend Rockwell communicates uncollected accounts receivable to Baxter, Baxter will make reasonable business efforts to ensure that Rockwell accounts receivable are collected, to the extent it is doing business with the account.	Effective Date
Finance	Rockwell will provide transaction level sales detail on a monthly basis to Baxter until Baxter assumes invoice processing. Baxter may have access to other available Rockwell reporting.	Effective Date
Finance	Invoicing Report: construct report with invoicing activity as of the Effective Date for all revenue of Concentrate Product, Ancillary Product and service fees.(1) Mutually agree on timing and format of report on a go-forward basis until all invoicing has been properly transitioned over to Baxter.	Effective Date + 10 days
Finance	Establish process for tracking accounts receivable reporting as of the Effective Date until all accounts receivable management has been properly transitioned over the Baxter. Rockwell to	Effective Date + 10 days

	be responsible for collecting and remitting A/R information until invoicing has been fully transitioned to Baxter.	
Finance	Establish formal cost of goods sold calculation and tracking process by manufacturing plant for use in estimating annual costs of goods sold by manufacturing plant following the first formal Forecast scheduled to be provided to Rockwell by Baxter on the Effective Date + 30 days. This report should include validated processes for transfer of payments for Support Services, Freight, Transfer Price payments and annual True Ups.	Effective Date + 30 days
Finance	Establish process for wire payments from Baxter to Rockwell.	Effective Date + 5 days
Regulatory	Rockwell to provide label copies, and MSDS sheets for all Concentrate Products and Ancillary Products.	Effective Date + 10 days
Quality	Rockwell and Baxter shall work to establish all necessary requirements as outlined through the Quality Services Agreement in a manner that will be sustainable over time.	Effective Date + 180 days
Joint Steering Committee	Schedule date, location and attendees for the first two Joint Steering Committee meetings.	Effective Date + 30 days
Joint Steering Committee	Rockwell to provide physical copies of contracts and/or buying arrangements with 3rd party providers of freight, logistics, and fleet vehicles with intent to consolidate purchasing as cost-effectively as possible.	Effective Date + 30 days
Joint Steering Committee	Rockwell and Baxter to provide physical copies of contracts and/or buying arrangements with Raw Material suppliers of significance with intent to consolidate purchasing as cost-effectively as possible; provided, however, that such disclosure does not violate the confidentiality agreement in any supplier contract	Effective Date + 30 days
Joint Steering Committee	Quarterly Performance Report: Mutually agree upon a quarterly reporting packet to be reviewed by Joint Steering Committee to measure all key performance indicators including, but not limited to sales activity in gallons, service levels, gross freight costs, freight costs net of fuel, Support Services fee estimates, manufacturing key performance indicators, costs of goods sold performance, Firm Orders and Forecasts.	In place by first Joint Steering Committee Meeting

(1) Service Fees: fees invoiced to customers for including but not limited to all expedited and off-schedule orders

Exhibit C

Support Services

The Company will provide the services as described below under the following terms and conditions for the benefit of the Distributor's efforts to Commercialize the Products.

Support Service

Support Services to be provided include customer service ("Customer Service") and transportation/distribution service ("Transportation Services"), each as more fully described below.

Customer Service

Customer Service includes all services necessary to support customers with the ordering of Products through the fulfillment of Product orders, including fielding and resolving all inquiring and disputes related thereto. More specifically (and without limiting the foregoing), Customer Services include support related to order processing, order management, order fulfillment information technology, order fulfillment problem resolution, customer service inquiries related to orders and product use (including with respect to [* *]), sales force support for new customer set up, general inquiries around customer order status and technical service support deployment for Dri-Sate® Dry Acid Concentrate Mix System units (whether such units were installed prior to, on or after the Effective Date).

Transportation Service

Transportation Service includes all services necessary to ensure that Products ordered by customers or the Distributor are delivered from the applicable Company manufacturing facility to the applicable customer in accordance with the applicable delivery instructions. More specifically (and without limiting the foregoing), Transportation Services include support related to distribution and delivery services including customer routing, shipments to customers and delivery of products within customer locations, as well as to fleet operations, hiring and instructing truck drivers, cross dock operations, transshipment costs to cross docking operations, facilitating local delivery, courier services, retaining, managing and paying third party freight carriers, supplying and paying for fuel, paying fleet management costs, obtaining insurance consistent with past practice of the Company, filing and managing insurance claims and disputes, regulatory compliance in connection with Product transportation and overall transportation services management.

Dri-Sate® Dry Acid Concentrate Mix Systems [* *]

At the Distributor's [* *], the Company will (i) [* *] with respect to assisting customers with the Dri-Sate® Dry Acid Concentrate Mix Systems units for such units installed on or after the Effective Date and (ii) [* *] with such respect to the Dri-Sate® Dry Acid Concentrate Mix Systems [* *]. In addition, the Company will [* *] with respect to Dri-Sate® Dry Acid Concentrate Mix Systems units for such units installed prior to the Effective Date [* *].

Dedicated Resources

The Company commits to utilize the resources necessary to adequately fulfill customer orders and deliveries and to otherwise perform the Support Services, the Transportation Services and the [* *] (the "Services"). These resources will remain in place and dedicated to the Distributor's efforts to Commercialize Concentrate Products unless (i) significant changes occur around sales activity justifying a change, either increase or decrease, over the duration of the Services period and (ii) Distributor consents to such changes. Such changes will be communicated to the Distributor for approval no less than 10 days prior to taking effect.

Term of Services

The Services shall be provided by the Company for an initial term continuing through December 31, 2017; provided, however, that such term shall automatically be extended for successive one-year periods unless the Distributor, not later than the September 1 prior to the then-anticipated end of the term, provides written notice to the Company of the intent not to extend such term for an additional one-year period. Notwithstanding the foregoing, the Distributor shall be entitled to: (i) terminate all or a portion of any of the Services on [* *] days' advance written notice to the Company at any time on or after December 31, 2017 and (ii) at any time, provide any services comparable to the Services (in lieu of using the Company to provide them) in connection with Commercializing Concentrate Products to any customer that has not ordered Concentrate Products from the Company at any time within six months prior to the Effective Date (in which case, if requested by the Distributor, the Company will ship Product orders to the Distributor's warehouses). In connection with the termination or expiration of the Services, the Company agrees to support the Distributor with the transition of the Services to the Distributor in the manner reasonably requested by the Distributor (at no cost other than as provided in "Fees" below).

Following a termination of all of the Services, with respect to any transportation equipment leased by the Company with a lease ("Ongoing Equipment Lease") in effect on the Effective Date and expiring on or before [* *], the Distributor and the Company shall assign any Ongoing Equipment Lease used primarily in connection with the Transportation Services to the Distributor if such leases are assignable without consent. If assignment of any such leases is not permitted under any applicable lease agreement for such equipment, both parties shall use commercially reasonable efforts to obtain any consents required for the effective assignment of such leases, but if any such consent is not obtained, the Company will use the applicable equipment as directed by the Distributor and the Distributor will reimburse the Company for the costs actually incurred under such lease until the lease term expires. The Company will indemnify and hold harmless the Distributor for any Losses arising from any Ongoing Equipment Lease to the extent arising from acts, omissions, events or other conditions that occurred or existed at any time prior to the assignment of the Company's rights and obligations under such lease. The Distributor will indemnify and hold harmless the Company for any Losses arising from any Ongoing Equipment Lease to the extent arising from acts, omissions, events or other conditions that occurred or existed at any time after the assignment of the Company's rights and obligations under such lease, including failure to pay the lease obligation. The Company will use commercially reasonable efforts to reduce the costs of any Ongoing Equipment Lease obligation as requested by the Distributor.

Fees

The Customer Service costs will be limited to the costs of personnel and operating expenses to provide the Customer Services, in each case, as determined using the same methodology as used by the Company in its 10-Q filing with the SEC for the calendar quarter ended June 30, 2014. Distributor will pay a management fee of [* *]% of the Customer Service costs.

The Transportation Services costs will be limited to the costs of personnel and operating expenses to provide the Transportation Services, in each case, as determined using the same methodology as used by the Company in its 10-Q filing with the SEC for the calendar quarter ended June 30, 2014, as well any reasonable out-of-pocket expenses paid in connection therewith. Distributor will pay a management fee of [* *]% of the Transition Service costs.

The [* *] Services costs will be limited to the costs of personnel and operating expenses to provide the [* *] Services, in each case, as determined using the same methodology as used by the Company in its 10-Q filing with the SEC for the calendar quarter ended June 30, 2014.

Invoices and Payment Terms

Starting with the period covering the first calendar quarter of 2015, the Company will invoice Baxter for the Services estimated to be incurred during such quarter, plus the management fee payable on such amounts for Customer Services and Transportation Services. For the avoidance of doubt, the costs of the Services provided prior to January 1, 2015 will be governed by the terms of Exhibit B.

The Distributor will pay the Company in accordance with the Distributor payment terms set forth in Section 4.4 of the Agreement; provided that the Company may not submit to Distributor the invoice for any quarter until the first calendar day of such quarter (e.g., the first invoice may not be submitted until January 1, 2015).

Within one month after each calendar quarter, the Company shall deliver to the Distributor a "True-Up" notice (a "True-Up Notice") that details the actual costs of the Services for such quarter, including Rockwell Transportation Inc. financial statements including a summary of expenses by statement line. The Distributor will have the right to audit and dispute the True-Up Notice in accordance with the procedures set forth in Section 4.3(d) of the Agreement. Upon final resolution of amounts in the True-Up Notice, the party which owes the other party any true-up payments shall pay such amounts within [* *] days from such final resolution.

In addition to its rights with respect to True-Up Notices, the Distributor may perform an onsite audit of expenses at the Company at its own expense which the Company will facilitate and cooperate with and such audit will be on a frequency no greater than once a quarter.

Joint Steering Committee Review

The Company will provide to the Joint Steering Committee an annual budgeted amount for the Services at least 30 days prior to the commencement of each fiscal year and a summary of actual costs of the Services each quarter within 30 days after such quarter, in each case, together with a detailed line item budget in support of such budget and actual costs. The Joint Steering

Committee will be responsible to review such budgets and Fee estimates with respect to Services on an annual basis and to review the costs of the Company's provision of such Services on a quarterly basis.

If (i) the Joint Steering Committee or (ii) the Distributor (after conducting an audit), concludes that the cost per shipment (excluding fuel costs) of any Products during any quarter has increased by more than [* *]% of such costs as of the Effective Date, then the Company will remediate such costs to equal the cost per shipment (excluding fuel costs) of such Products as of the Effective Date to the extent such costs can be remediated.

Exhibit D
Quality Agreement

See attached.

Finished Goods Supplier — Device — Category B — Quality Agreement

QUALITY AGREEMENT

This Quality Agreement is made between

BAXTER Healthcare
(Hereinafter called Baxter)

And

Rockwell Medical
(Hereinafter called SUPPLIER)

This Quality Agreement ("Agreement") defines responsibilities between SUPPLIER and Baxter, so as to ensure compliance with regulations of the applicable Regulatory Authorities. Capitalized terms not otherwise defined herein shall be defined as set forth in the Exclusive Distribution Agreement between Baxter and SUPPLIER, dated as of October 2, 2014 (the "Distribution Agreement").

Important note:

This Agreement SHALL be approved and maintained by a Quality function only.

Scope

This Agreement covers the Products Manufactured by SUPPLIER. The Products will remain registered/CE marked as SUPPLIER Products.

This Agreement applies to all Products procured by Baxter from SUPPLIER categorized as Finished Goods Category B. Finished Goods Category B Product is defined by Baxter as design ownership by the SUPPLIER and Baxter maintains the level of regulatory responsibility defined in this Agreement.

In the event any term in this Agreement conflicts with a term in the Distribution Agreement, the conflicting term in the Distribution Agreement shall govern and control.

Product Classification

The Products included in this Agreement are classified as Class B per applicable Regulatory Laws where the Products are sold.

Confidentiality of Data

Both parties will treat as Confidential Information all data supplied by the other in relation to the Manufacture of the Product and will not use or disclose such Confidential Information except as permitted by the Distribution Agreement.

Product Changes

SUPPLIER shall notify Baxter in advance and in writing of any proposed change in the SUPPLIER's quality control system.

These changes include the following aspects of the products and their components:

- Form: a change that affects the shape, size, color, weight, physical configuration, appearance, material formulation, label copy, packaging construction or packaging configuration, finished product specification (release and shelf-life).

- Function: a change that affects the directions for use of the product or the operation, performance, performance claims or intended use of the product.

Any change notifications to Baxter shall be directed to the following address: SNC@baxter.com using the form in Appendix I (CQF0061).

SUPPLIER shall have a documented and effective system in place with its suppliers that will evaluate all changes made by its suppliers according to a formal change control system.

SUPPLIER will remain responsible for making decisions regarding whether proposed changes to the Products require a Marketing Application (new 510(k) or PMA Supplement)/Change notification to adjust the current EC certificate and for obtaining approval thereof prior to implementation of the change when required.

Labeling

SUPPLIER will be responsible for labeling the Products as provided in the Distribution Agreement.

Quality Control

a. All Products shall meet GMP specifications and shall be subject to quality control inspection by SUPPLIER in accordance with SUPPLIER'S quality control standards and systems. Baxter reserves the right to audit/inspect the SUPPLIER, no more than once in any calendar year, as required to verify integrity and adherence to the Baxter Service Requirements, provided that the Distributor shall have the right to audit/inspect more frequently than once in any calendar year if Baxter reasonably determines that additional audits/inspections are warranted due to Product Complaints or Field Actions related to the Product (as such terms

are defined in the Distribution Agreement). SUPPLIER will permit Baxter or Baxter authorized third party representatives to visit the SUPPLIER's facility at reasonable, mutually agreed times with a representative of SUPPLIER present in order to assure satisfaction of the requirements of the Baxter Service Requirements, including this Quality Agreement. Additionally, the SUPPLIER shall permit Baxter to review the SUPPLIER's processes, quality control procedures, and records to verify conformance to the Baxter Service Requirements, including this Quality Agreement. SUPPLIER must provide Baxter Healthcare action plan(s) to audit observation(s) 30 days from Audit report issuance. Failure to provide action plans to compliance gaps may result in risk plan associated with SUPPLIER.Baxter may inspect or audit the products for integrity and adherence to the specifications agreed with the manufacturer or marketing authorization. If any of the products of a continuous production run or shipment (a « Lot ») fails to meet Supplier's warranties or to conform to the specifications, Baxter shall notify SUPPLIER in writing within [* *] days of non-conformance identification. If the Baxter investigation determines that the problem is a distribution issue, SUPPLIER will respond, in writing, within [* *] days after receipt of notice of such issue/complaint. This response shall include root cause analysis, corrective action taken (if any), preventive action taken (if any) and disposition of the product. Baxter will make a preliminary evaluation of each complaint it receives and will conduct all follow-up and communication which it deems appropriate. Thereafter Baxter may return such « Lot » and, at Baxter's option and at Supplier's expense, Baxter shall receive credit, refund or replacement of such products from Supplier at Supplier's expense.

b. SUPPLIER is obligated to continuously monitor the relevant Product specifications, provide controls for the Products and comply with applicable GMP requirements. SUPPLIER will preserve batch history, and quality records pertaining directly to the Products according to their GMP protocol (currently 4 years).

Regulatory Responsibilities*SUPPLIER* shall be responsible for maintaining the necessary documentation related to production of the Product to support compliance with applicable Regulatory Laws.

SUPPLIER shall be responsible for maintaining the necessary documentation related to supply of the product to support compliance with applicable regulations and agrees to provide any documentation in case of request from an Authority (e.g. Ministry of Health, FDA or Therapeutic Goods Authority/Med safe).

SUPPLIER agrees to notify Baxter immediately of actions or situations that may change their compliance status with any regulatory requirements (for example significant complaints, regulatory or notified body inspection findings).

SUPPLIER shall notify Baxter if issues arise that may adversely impact continued certification of the Quality System or change Rockwell Medical's state of compliance to applicable regulations. If the authority revokes the certificate/licensure, Baxter is to be notified immediately.

Complaints

For purposes of this Agreement, a "Complaint" shall be defined as, "any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a Product after it is released for distribution. A Complaint includes any indication of the failure of a Product to meet customer expectations for quality or to meet performance specifications. A Complaint may involve the possible failure of the Product itself, its packaging, or its labeling (i.e., product label, package insert, or any instructions for use).

SUPPLIER shall be responsible for investigating and responding to all Complaints, including without limitation conducting investigation activities, corrective action (if any), and preventive

action taken (if any) to address the Complaints. Both SUPPLIER and Baxter will provide appropriate Complaint handling and reporting contacts or addresses as applicable, and provide notification of any changes within [* *] days.

If SUPPLIER becomes aware of a potential product complaint related to an adverse event with respect to a product distributed to Baxter customers, then SUPPLIER will send notification of the event to:

global_pharmacovigilance_deerfield@baxter.com
and
corporate_product_complaints_round_lake@baxter.com.

Should Baxter receive a customer complaint related to SUPPLIER'S quality of Product, unrelated to BAXTER'S performance as a distributor, Baxter will notify the SUPPLIER'S QA Director as soon as possible but no later than [ ] after receiving the customer complaint. SUPPLIER will be responsible for evaluating any complaint and responding to Baxter as soon as practicable, and in writing within [* *] business days after receipt of a sample, and will notify Baxter promptly if additional time is required to determine root cause and/or corrective action. The SUPPLIER's written response shall include root cause analysis, corrective action taken (if any), preventive action taken (if any) and disposition of the product. Baxter may make a preliminary evaluation of each complaint it receives and will conduct follow-up and communication which it deems appropriate.

A SCAR (Supplier Corrective Action Report) may be issued by Baxter based on the investigation result. SUPPLIER will respond to the Baxter SCAR in writing within thirty 30 business days after receipt of notice of such issue/complaint. This response shall include root cause analysis, corrective action taken (if any), preventive action taken (if any) and disposition of the product. Baxter will make a preliminary evaluation of each complaint it receives and will conduct all follow-up and communication which it deems appropriate.

Medical Device Reports/Device Adverse Events

SUPPLIER shall be solely responsible for determining reportability of the Complaints related to the Product and for submitting to the Medical Device Reports ("MDR"), as defined in applicable FDA regulations, 21 CFR Part 803, Medical Device reporting as well as global reports as needed. SUPPLIER is solely responsible for determining the need to submit a MDR and for submitting such MDRs.

Product Hold or Recall

SUPPLIER is solely responsible for the final decision relating to a Product hold or recall and for implementing any Product hold or recall. Both SUPPLIER and Baxter will be responsible for notifying customers.

In the event that *SUPPLIER* withholds Products from distribution or recalls any of the Products due to deficiencies related to design, Manufacturing, or packaging, then *SUPPLIER* shall bear all costs and expenses of such holds or recall, including, without limitation, expenses or obligations to third parties, the cost of notifying customers and costs associated with the shipment of recalled Products from customer to *SUPPLIER*.

Traceability

SUPPLIER is responsible for managing traceability of Products provided to Baxter.

Product Release

SUPPLIER is responsible for releasing the Product after making sure the Product complies with specifications agreed with Baxter.

Validity

This Agreement commences on the Effective Date hereof and remains in effect during the Term. Each party is responsible to keep the content of this Agreement up to date and to inform the other party of any change impacting this Agreement.

Signatures

Baxter Quality VP		Supplier	
(print name & title)		(print name & title)	
Date		Date	
Signature		Signature	

Exhibit E
Gallon Conversion Formulas

Product Code or Product	Gallons per Unit
CitraPure Dry Acid	**25**
CitraPure Liquid Acid Case	**4**
CitraPure Citric Acid Drum	**55**
Dri-Sate Dry Acid	**25**
RenalPure Liquid Acid Case	**4**

RenalPure Liquid Acid Drum	**55**
RenalPure Bicarb (2-25gal Bags)	**50**
RenalPure Bicarb (4-15gal Bags)	**60**
RenalPure Bicarb (20-2.1gal Bags)	**42**
Sterilyte Liquid Bicarbonate Case	**4**

If the amount or concentration of Concentrate Product in any given "Unit" is altered after the Effective Date by packaging or configuration changes, or clinical data is discovered that impacts the above conversion formulas, the Parties will adjust the conversion formulas accordingly by mutual agreement.

Exhibit F
Estimated COGS Methodology

Estimated COGS and actual Costs of Goods Sold for any Concentrate Products shall be calculated for any period as follows:

(i) First, by determining the [* *] attributable to such Product for such period as determined using [* *] (the "Material Costs");

(ii) Second, by determining the aggregate following costs for all of the manufacturing facilities that manufacture Concentrate Products for such period: [* *] in each case, as determined using [* *] (the "[* *]");

(iii) third, by allocating [* *] to the Concentrate Products based on an activity based costing methodology as determined using [* *] (for each Concentrate Product, its "[* *]");

(iv) fourth, by adding the [* *] and [* *] for such Concentrate Products (such sum for such product, the "[* *]"); and

(v) fifth, by dividing the [* *] for such Concentrate Product by [* *].

Such procedure will be followed for Estimated Cost of Goods Sold using expected future costs for [* *] and [* *] along with expected future volumes for Products by facility.

Estimated COGS and actual Costs of Goods Sold shall be determined based upon [* *].

For the avoidance of doubt, the calculation of Estimated COGS and actual Costs of Goods Sold for any Concentrate Products shall exclude: (i) any and all costs related to or incurred in connection with [* *], (ii) any and all costs (including [* *]) related to or incurred in connection with [* *], (iii) the impact of financial variations related to business performance in [* *] and (iv) the costs of any [* *]; provided, that if any of the foregoing costs are incurred in connection with the manufacture of Concentrate Products sold in [* *], then the Company will allocate such costs based on the same methodology used to determine Estimated COGS and Actual Cost of Goods Sold.

For purposes of clarification, the Company will prepare Estimated COGS for its other concentrate products not sold to Distributor and will [* *].

Estimated COGS and actual Costs of Goods Sold for any Ancillary Products shall be calculated for any period by determining the [* *] for such product [* *] solely for such products for such period by [* *].

Exhibit G
Licensed Trademarks

Rockwell Medical, Inc.

CitraPure

RenalPure

Dri-Sate

SteriLyte

Exhibit H
Order Guidelines

See attached.

ORDERING GUIDELINES

Dear Valued Customer:

We greatly appreciate your business, and we will continue to work hard to provide you with prompt, friendly and efficient customer service.

Please keep the following **ORDERING GUIDELINES** in mind when placing your order:

- Product orders are due [* *] (via email, EDI or fax @ 248-960-9015) before your scheduled [* *]. Orders received after [* *] will incur a [* *] fee.
- Changes to existing orders after [* *] will incur a [* *] fee and possibly freight charges for delivery.
- Orders received after [* *] will incur the cost of freight for delivery.
- Orders that need to be expedited will incur the cost of freight for delivery.
- Minimum order delivery requirement for concentrate is [* *] of product otherwise the freight cost to deliver the entire order will be charged (we are happy to assist you in calculating your minimum order weight).
- Custom formulas require a minimum volume commitment of [* *] gallons plus [* *].
- Returned product will incur a [* *] restocking fee, plus [* *].
- A [* *] charge for lost drums and an [* *] charge for lost pallets will be applied.

We truly value you as our customer and we remain committed to providing you with exceptional customer and delivery service.

Please feel free to contact us anytime if you need further assistance; 800-449-3353.

Sincerely,
Rockwell Medical, Inc.

30142 Wixom Road · Wixom, MI 48393 · (248) 960-9009 · Fax (248) 960-9015 · (800) 449-3353

Exhibit I
Pre-Approved Sub-Distributors and Marketing Partners

[* *]

Exhibit J
Price Schedule

Target Margins — Concentrate Products

[* *]	Target Gross Margin
2014	[* *]%
2015	[* *]%
2016	[* *]%
2017	[* *]%
2018	[* *]%
2019	[* *]%
2020	[* *]%
2021	[* *]%
2022	[* *]%
2023	[* *]%
2024	[* *]%
2025	[* *]%
2026	[* *]%
2027	[* *]%
2028	[* *]%
2029	[* *]%

Other Domestic ([* *])	Transfer Gross Margin
2014	[* *]%
2015	[* *]%
2016	[* *]%
2017	[* *]%
2018	[* *]%
2019	[* *]%
2020	[* *]%
2021	[* *]%
2022	[* *]%
2023	[* *]%
2024	[* *]%
2025	[* *]%
2026	[* *]%
2027	[* *]%
2028	[* *]%
2029	[* *]%

Initial Price Schedule — Concentrate Products

[* *] Contract Price

Rockwell Medical Product Line / Product Code / Product or Item		2014
CitraPure Dry Acid	$	[* *]
CitraPure Liquid Acid Case	$	[* *]
CitraPure Citric Acid Drum	$	[* *]
Dri-Sate Dry Acid	$	[* *]
RenalPure Liquid Acid Case	$	[* *]
RenalPure Liquid Acid Drum	$	[* *]
RenalPure Bicarbonate (2-25gal Bags)	$	[* *]
RenalPure Bicarbonate (4-15gal Bags)	$	[* *]
RenalPure Bicarbonate (20-2.1gal Bags)	$	[* *]
Sterilyte Liquid Bicarbonate Case	$	[* *]

Other [* *] ([* *]) Contract Price

Rockwell Medical Product Line / Product Code / Product or Item		2014
CitraPure Dry Acid	$	[* *]
CitraPure Liquid Acid Case	$	[* *]
CitraPure Citric Acid Drum	$	[* *]
Dri-Sate Dry Acid	$	[* *]
RenalPure Liquid Acid Case	$	[* *]
RenalPure Liquid Acid Drum	$	[* *]
RenalPure Bicarbonate (2-25gal Bags)	$	[* *]
RenalPure Bicarbonate (4-15gal Bags)	$	[* *]
RenalPure Bicarbonate (20-2.1gal Bags)	$	[* *]
Sterilyte Liquid Bicarbonate Case	$	[* *]

Target Margins — Ancillary Products

Applies to Rockwell Medical Product Lines: Blood Tubing, Needles & Other, Salt (25lb bag), Salt (50lb bag), Sanitizer (Acetic Acid) and Mixers	Target Gross Margin
2014	[* *]%
2015	[* *]%
2016	[* *]%
2017	[* *]%
2018	[* *]%
2019	[* *]%
2020	[* *]%
2021	[* *]%
2022	[* *]%
2023	[* *]%
2024	[* *]%
2025	[* *]%
2026	[* *]%
2027	[* *]%
2028	[* *]%
2029	[* *]%

Initial Price Schedule — Ancillary Products

Rockwell Medical Product Line / Product Code / Product or Item	2014
Blood Tubing	**$** [* *]
Needles & Other	**$** [* *]
Salt (25lb bag)	**$** [* *]
Salt (50lb bag)	**$** [* *]
Sanitizer (Acetic Acid)	**$** [* *]
Mixer	**$** [* *]

Exhibit K
Excluded Territories

[* *] [* *]

Notwithstanding anything in the Agreement or this Exhibit K to the contrary, during the Term, Distributor shall have the right to supply Concentrate Products to all hemodialysis clinics owned by the Distributor in all of the territories listed above, provided that the Company is not already the primary supplier to those clinics as of the Effective Date.

Exhibit 10.58

Execution Copy

INVESTMENT AGREEMENT

This Investment Agreement (this "**Agreement**"), dated as of October 2, 2014, is made and entered into by and between Rockwell Medical, Inc., a Michigan corporation (the "**Company**"), and Baxter Healthcare Corporation, a Delaware corporation (the "**Purchaser**"). The Company and the Purchaser are referred to from time to time in this Agreement individually as a "**party**" and, collectively, as the "**parties**."

WHEREAS, the Company and the Purchaser are entering into a Distribution Agreement as of the date hereof (the "**Distribution Agreement**");

WHEREAS, the Purchaser desires to purchase, and the Company desires to issue and sell, shares of the Company's common stock, no par value per share (the "**Common Stock**"), at a price per share equal to the Purchase Price (as defined below) and a total purchase price of $15 million on the terms and conditions set forth in this Agreement;

NOW THEREFORE, in consideration of the representations, warranties and covenants herein contained, and other good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, the Company and the Purchaser agree as follows:

1. **Sale of Shares**. Subject to the terms and conditions of this Agreement, at the Closing (as defined in Section 2.1) the Purchaser shall purchase, and the Company shall sell and issue to the Purchaser, 1,316,944 shares of Common Stock (the "**Shares**"), for an aggregate purchase price equal to $15,000,000 (the **"Aggregate Purchase Price").**

2. **The Closing**.

2.1 **Closing**. The closing (the "**Closing**") of the sale and purchase of the Shares under this Agreement will take place remotely via wire transfer and an electronic exchange of documents and signatures on the third NASDAQ Trading Day following the date hereof, or at such other time, date and place as are mutually agreeable to the Company and the Purchaser. The date of the Closing is hereinafter referred to as the "**Closing Date**." References to "**NASDAQ Trading Days**" are to any day for which sales of Common Stock were reported by the NASDAQ Stock Market.

2.2 **Delivery of Shares; Payment of Aggregate Purchase Price**. At the Closing, (a) the Company shall deliver or cause to be delivered the opinion referenced in Section 5.3, (b) the Purchaser shall deliver the Aggregate Purchase Price to the Company by wire transfer of immediately available funds to the account number furnished to the Purchaser by the Company at least one business day prior to the Closing Date, and (c) following receipt of the Aggregate Purchase Price, the Company shall, at its option, either (1) deliver to the Purchaser irrevocable instructions addressed to the Company's transfer agent instructing it to issue a certificate registered in the name of the Purchaser representing the Shares, or (2) cause the

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Shares to be issued for the Purchaser's account pursuant to the procedures of the DWAC delivery system.

3. **Representations of the Company**. Except (a) as disclosed in the Company SEC Documents (as defined in Section 3.8) filed prior to the date of this Agreement, to the extent that the applicable disclosure in the Company SEC Documents is such that its relevance to a representation or warranty contained in this Article 3 is reasonably apparent on the face of such disclosure, or (b) subject to Section 8.6(b), as disclosed in the corresponding section of the disclosure letter delivered by the Company to the Purchaser simultaneously with the execution of this Agreement (the "**Company Disclosure Letter**"), the Company hereby makes the following representations and warranties to the Purchaser as of the date hereof and the Closing Date:

3.1 **Subsidiaries**. The Company's only subsidiary is Rockwell Transportation, Inc. (the "**Subsidiary**"). The Company owns, directly or indirectly, all of the capital stock or other equity interests of the Subsidiary free and clear of any Liens, and all of the issued and outstanding shares of capital stock of the Subsidiary are validly issued and are fully paid, non-assessable and free of preemptive and similar rights to subscribe for or purchase securities.

3.2 **Incorporation**. Each of the Company and the Subsidiary is a corporation duly organized, validly existing and in good standing under the laws of the State of Michigan, and is in good standing as a foreign corporation in each jurisdiction in which the nature of the business conducted or the character of the property owned by it makes such qualification necessary, except where the failure to be so qualified or in good standing, as the case may be, would not reasonably be expected to result in a material adverse effect on (a) the assets, business, properties, financial condition, prospects or results of operations of the Company and the Subsidiary taken as a whole, (b) the legality, validity or enforceability of this Agreement, or (c) the Company's ability to perform in any material respect on a timely basis its obligations under this Agreement (any of (a), (b) or (c), a "**Material Adverse Effect**"). Neither the Company nor the Subsidiary is in violation or default under any of the provisions of its respective articles of incorporation or bylaws.

3.3 **Authorization; Enforcement**. The Company has the requisite corporate power and authority and has taken all necessary corporate action to execute and deliver this Agreement and to carry out and perform its obligations hereunder, and no further consent or authorization of the Company, its board of directors or its shareholders is required. This Agreement has been duly executed by the Company and, when delivered in accordance with the terms hereof, will constitute the valid and binding obligation of the Company, enforceable in accordance with its terms, except as limited by (a) general equitable principles (regardless of whether enforceability is considered in a proceeding in equity or at law) and applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting enforcement of creditors' rights generally, (b) laws relating to the availability of specific performance, injunctive relief or other equitable remedies and (c) insofar as indemnification and contribution provisions may be limited by applicable law. To the Company's knowledge, no proceeding has been instituted in any jurisdiction revoking, limiting or curtailing or seeking to revoke, limit or curtail such power and authority or qualification.

3.4 **No Conflicts**. The execution, delivery and performance of this Agreement and the Distribution Agreement by the Company and the consummation by the Company of the transactions contemplated hereby and thereby do not and will not (a) violate any provision of the Company's Restated Articles of Incorporation or Bylaws, each as amended to date, (b) constitute a default (or an event which with notice or lapse of time or both would become a default) under, result in the creation of any lien upon any of the property or assets of the Company or the Subsidiary, or give to others any rights of termination, amendment, acceleration or cancellation (with or without notice, lapse of time or both) of, any agreement, credit facility, debt or other instrument to which the Company or the Subsidiary is a party or by which the Company's or the Subsidiary's property or assets are bound, or (c) result in a violation of any federal, state, local or foreign statute, rule, regulation, order, judgment or decree (including federal and state securities laws and regulations) applicable to the Company or the Subsidiary or by which any property or asset of the Company or the Subsidiary is bound or affected, except in the case of clauses (b) and (c) for such as would not, individually or in the aggregate, have or reasonably be expected to have a Material Adverse Effect.

3.5 **Governmental Approvals** The Company is not required to obtain any consent, waiver, authorization or order of, give any notice to, or make any filing or registration with, any court or governmental agency in order for it to execute or deliver this Agreement or the Distribution Agreement or perform any of its obligations under this Agreement or the Distribution Agreement (other than the filing of Form D, a Form 8-K and a Form 10-Q with the SEC (as hereinafter defined), any notices, filings, consents and approvals which may be required to be made by the Company under applicable state securities laws, rules or regulations, and the filing of notice of issuance of the Shares with the NASDAQ Stock Market, prior to or subsequent to the Closing, and in the case of the Distribution Agreement, approvals and notices in connection with the construction of a new facility and to federal regulators (a) necessary to conduct the Company's business in the ordinary course, or (b) that would be required in the operation of the Company's business in the absence of the Distribution Agreement).

3.6 **Valid Issuance of Shares**. The Shares are duly authorized and, when issued, sold and delivered in accordance with the terms of this Agreement upon receipt of the consideration expressed in this Agreement, the Shares will be validly issued, fully paid, non-assessable and free and clear of all liens imposed by the Company other than restrictions imposed or created under this Agreement or by applicable federal securities law. The Company has reserved from its duly authorized capital stock the number of Shares to be issued under this Agreement.

3.7 **Capitalization**. The authorized capital stock of the Company is as set forth in the Company SEC Documents. The Company has not issued any capital stock since its most recently filed periodic report under the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"), other than pursuant to the exercise of employee stock options under the Company's equity compensation plans and pursuant to the exercise of warrants to purchase Common Stock outstanding as of the date of the most recently filed periodic report under the Exchange Act. No individual or entity (a "**Person**") has any right of first refusal, preemptive right, right of participation, or any similar right to participate in the transactions contemplated by this Agreement. Except as described in the Company SEC Documents, there are no outstanding options, warrants, scrip rights to subscribe to, calls or commitments of any character whatsoever

relating to, or securities, rights or obligations convertible into or exercisable or exchangeable for, or giving any Person any right to subscribe for or acquire, any shares of Common Stock, or contracts, commitments, understandings or arrangements by which the Company or the Subsidiary is or may become bound to issue additional shares of Common Stock or rights to acquire Common Stock. The issuance and sale of the Shares will not obligate the Company to issue shares of Common Stock or other securities to any Person (other than the Purchaser) and will not result in a right of any holder of Company securities to adjust the exercise, conversion, exchange or reset price under any of such securities. All of the outstanding shares of capital stock of the Company are duly authorized, validly issued, fully paid and nonassessable, have been issued in compliance with all federal and state securities laws, and none of such outstanding shares was issued in violation of any preemptive rights or similar rights to subscribe for or purchase securities. No further approval or authorization of any shareholder, the Board of Directors or others is required for the issuance and sale of the Shares. There are no shareholders agreements, voting agreements or other similar agreements with respect to the Company's capital stock to which the Company is a party or, to the knowledge of the Company, between or among any of the Company's shareholders.

3.8 **Financial Statements and SEC Filings**. Since January 1, 2013, the Company has filed all required reports, schedules, forms, financial statements and other documents (including exhibits and all other information incorporated therein) with the Securities and Exchange Commission (the "**Company SEC Documents**"). As of their respective dates or, if amended, as of the date of the last such amendment, the Company SEC Documents complied as to form in all material respects with the applicable requirements of the Securities Act of 1933, as amended (the "**Securities Act**") or the Exchange Act, as the case may be, and the rules and regulations of the Securities and Exchange Commission ("**SEC**") promulgated thereunder applicable to such Company SEC Documents. At the time they were filed with the SEC, the Company SEC Documents did not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The Company is not an issuer subject to Rule 144(i) under the Securities Act. The consolidated financial statements of the Company included in the Company SEC Documents, as amended, complied as to form in all material respects with applicable accounting requirements and the published rules and regulations of the SEC with respect thereto in effect at their respective filing dates. Such financial statements have been prepared in accordance with United States generally accepted accounting principles ("**GAAP**") applied on a consistent basis during the periods involved (except (a) as may be otherwise indicated in such financial statements or the notes thereto, or (b) in the case of unaudited interim statements, as permitted by the SEC on Form 10-Q), and fairly present in all material respects the financial position of the Company and its consolidated Subsidiary as of and for the dates thereof and the results of operations and cash flows for the periods then ended, subject, in the case of unaudited statements, to normal year-end audit adjustments.

3.9 **Material Changes; Undisclosed Events, Liabilities or Developments**. Since the date of the latest audited financial statements included within the Company SEC Documents, except as specifically disclosed in a subsequent SEC Report filed prior to the date hereof, (i) there has been no event, occurrence or development that has had or that would reasonably be expected to result in a Material Adverse Effect, (ii) the Company has not incurred

any material liabilities (contingent or otherwise) other than (A) trade payables and accrued expenses incurred in the ordinary course of business consistent with past practice and (B) liabilities not required to be reflected in the Company's financial statements pursuant to GAAP or disclosed in filings made with the SEC, (iii) the Company has not altered its method of accounting, (iv) the Company has not declared or made any dividend or distribution of cash or other property to its shareholders or purchased, redeemed or made any agreements to purchase or redeem any shares of its capital stock and (v) the Company has not issued any equity securities to any officer, director or affiliate (as such term is defined in Rule 405 under the Securities Act, an "**Affiliate**"), except pursuant to existing Company equity compensation plans. The Company does not have pending before the SEC any request for confidential treatment of

information. Except for the issuance of the Shares contemplated by this Agreement, no event, liability, fact, circumstance, occurrence or development has occurred or exists or is reasonably expected to occur or exist with respect to the Company or its Subsidiary or their respective businesses, prospects, properties, operations, assets or financial condition that is required to be disclosed by the Company under applicable securities laws at the time this representation is made or deemed made that has not been publicly disclosed at least one NASDAQ Trading Day prior to the date that this representation is made.

3.10 **Litigation**. There is no action, suit, inquiry, notice of violation, proceeding or investigation pending or, to the knowledge of the Company, threatened against or affecting the Company, its Subsidiary or any of their respective properties before or by any court, arbitrator, governmental or administrative agency or regulatory authority (federal, state, county, local or foreign) which (i) adversely affects or challenges the legality, validity or enforceability of this Agreement or the Distribution Agreement or (ii) would, if there were an unfavorable decision, reasonably be expected to result in a Material Adverse Effect. To the knowledge of the Company, there is no pending or contemplated investigation by the SEC involving the Company. The SEC has not issued any currently pending stop order or other order suspending the effectiveness of any registration statement filed by the Company or any Subsidiary under the Exchange Act or the Securities Act.

3.11 **Labor Relations**. No labor dispute exists or, to the knowledge of the Company, is imminent with respect to any of the employees of the Company, which would reasonably be expected to result in a Material Adverse Effect. Except as disclosed in the Company SEC Documents, none of the Company's or the Subsidiary's employees is a member of a union that relates to such employee's relationship with the Company or such Subsidiary, and neither the Company nor the Subsidiary is a party to a collective bargaining agreement, and the Company and the Subsidiary believe that their relationships with their employees are good. To the knowledge of the Company, no executive officer of the Company or the Subsidiary, is, or is now expected to be, in violation of any material term of any employment contract, confidentiality, disclosure or proprietary information agreement or non-competition agreement, or any other contract or agreement or any restrictive covenant in favor of any third party, and the continued employment of each such executive officer does not subject the Company or the Subsidiary to any liability with respect to any of the foregoing matters.

3.12 **Compliance**. Neither the Company nor the Subsidiary: (i) is in default under or in violation of (and no event has occurred that has not been waived that, with notice or lapse of time or both, would result in a default by the Company or its Subsidiary under), nor has

the Company or the Subsidiary received notice of a claim that it is in default under or that it is in violation of, any indenture, loan or credit agreement or any other agreement or instrument to which it is a party or by which it or any of its properties is bound (whether or not such default or violation has been waived), (ii) is in violation of any judgment, decree or order of any court, arbitrator or other governmental authority or (iii) is or has been in violation of any statute, rule, ordinance or regulation of any governmental authority, including all foreign, federal, state and local laws relating to taxes, environmental protection, occupational health and safety, product quality and safety, employment and labor matters, the Currency and Foreign Transactions Reporting Act of 1970, as amended, and the Foreign Corrupt Practices Act, except in each case as would not reasonably be expected to result in a Material Adverse Effect.

3.13 **Regulatory Permits**. The Company and the Subsidiary possess all certificates, authorizations and permits issued by the appropriate federal, state, local or foreign regulatory authorities necessary to conduct their respective businesses as described in the Company SEC Documents, except where the failure to possess such permits would not reasonably be expected to result in a Material Adverse Effect ("**Material Permits**"), and neither the Company nor the Subsidiary has received any notice of proceedings relating to the revocation or modification of any Material Permit.

3.14 **Title to Assets**. The Company and the Subsidiary have good and marketable title to all real and personal property owned by them that is material to the business of the Company and the Subsidiary, in each case free and clear of all liens, charges, pledges, security interests and encumbrances (collectively, "**Liens**"), except for (i) Liens as do not materially affect the value of such property and do not materially interfere with the use made and proposed to be made of such property by the Company and the Subsidiary and (ii) Liens for the payment of federal, state or other taxes, for which appropriate reserves have been made in accordance with GAAP and the payment of which is neither delinquent nor subject to penalties. To the Company's knowledge, any real property and facilities held under lease by the Company and the Subsidiary are held by them under valid, subsisting and enforceable leases with which the Company and the Subsidiary are in compliance.

3.15 **Intellectual Property**. The Company and the Subsidiary have, or have rights to use, all patents, patent applications, trademarks, trademark applications, service marks, trade names, trade secrets, inventions, copyrights, licenses and other intellectual property rights and similar rights that are materially necessary to the conduct of their respective businesses as described in the Company SEC Documents (collectively, the "**Intellectual Property Rights**"). Neither the Company nor the Subsidiary has received a written notice, nor has the Company or the Subsidiary received, to the knowledge of the Company, a non-written notice, that any of, the Intellectual Property Rights has expired, terminated or been abandoned, or is expected to expire or terminate or be abandoned, since January 1, 2013. Neither the Company nor any Subsidiary has received, since January 1, 2013, a written notice of a claim or otherwise has any knowledge that the Intellectual Property Rights violate or infringe upon the rights of any Person. All such Intellectual Property Rights are enforceable and, to the Company's knowledge, there is no existing infringement by another Person of any of the Intellectual Property Rights. The Company and the Subsidiary have taken reasonable security measures to protect the secrecy, confidentiality and value of all of their Intellectual Property Rights, except where failure to do so

would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

3.16 **Insurance**. The Company and the Subsidiary are insured against such losses and risks and in such amounts as are prudent and customary in the businesses in which the Company and the Subsidiary are engaged. Neither the Company nor the Subsidiary has any reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business without a significant increase in cost.

3.17 **Transactions With Affiliates**. Except as set forth in the Company SEC Documents, none of the officers or directors of the Company or the Subsidiary is presently a party to any transaction with the Company or any Subsidiary (other than for services as officers and directors) required to be disclosed pursuant to Item 404(a) of SEC Regulation S-K.

3.18 **Internal Accounting Controls; Disclosure Controls**. The Company maintains a system of internal accounting controls for the Company and the Subsidiary sufficient to provide reasonable assurance that: (i) transactions are executed in accordance with management's general or specific authorizations, (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain asset accountability, (iii) access to assets is permitted only in accordance with management's general or specific authorization, and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. The Company has established disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the Company and the Subsidiary and designed such disclosure controls and procedures to ensure that all material information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. The Company's certifying officers have evaluated the effectiveness of the disclosure controls and procedures of the Company as of the end of the period covered by the most recently filed periodic report under the Exchange Act (such date, the "**Evaluation Date**"). The Company presented in its most recently filed periodic report under the Exchange Act the conclusions of the certifying officers about the effectiveness of the disclosure controls and procedures based on their evaluations as of the Evaluation Date. Since the Evaluation Date, there have been no changes in the internal control over financial reporting (as such term is defined in the Exchange Act) of the Company that have materially affected, or are reasonably likely to materially affect, the internal control over financial reporting of the Company.

3.19 **Private Placement**. Assuming the accuracy of the Purchaser's representations and warranties set forth in Section 4, no registration under the Securities Act is required for the offer and sale of the Shares by the Company as contemplated hereby. The issuance and sale of the Shares hereunder do not contravene the applicable Marketplace rules of the NASDAQ Stock Market.

3.20 **Investment Company**. The Company is not, and is not an Affiliate of, and immediately after receipt of payment for the Shares, will not be or be an Affiliate of, an

"investment company" within the meaning of the Investment Company Act of 1940, as amended.

3.21 **Registration Rights**. No Person has any right to cause the Company or any Subsidiary to effect the registration under the Securities Act of any securities of the Company or any Subsidiary as a result of the issuance of the Shares.

3.22 **Listing and Maintenance Requirements**. The Common Stock is registered pursuant to Section 12(b) of the Exchange Act, and the Company has taken no action designed to, or which to its knowledge is likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act nor has the Company received any notification that the SEC is contemplating terminating such registration. The Company has not, in the 12 months preceding the date hereof, received notice from the NASDAQ Stock Market to the effect that the Company is not in compliance with the applicable maintenance requirements. To the Company's knowledge, the Company is in compliance with all such listing and maintenance requirements.

3.23 **Application of Takeover Protections**. The Company and its Board of Directors have taken all necessary action, if any, in order to render inapplicable any control share acquisition, business combination, poison pill (including any distribution under a rights agreement) or other similar anti-takeover provision under the Company's Restated Articles of Incorporation or the laws of its state of incorporation that is or would become applicable to the Purchaser as a result of the Company's issuance and the Purchaser's ownership of the Shares.

3.24 **Tax Status**. Except for matters that would not, individually or in the aggregate, have or reasonably be expected to result in a Material Adverse Effect, the Company and its Subsidiary each (i) has made or filed all United States federal, state and local income and all foreign income and franchise tax returns, reports and declarations required by any jurisdiction to which it is subject to be made on or before the date hereof, or has a valid extension, and (ii) has paid all taxes and other governmental assessments and charges that are material in amount, shown or determined to be due on such returns, reports and declarations, except for taxes for which adequate accruals or reserves have been established.

3.25 **Accountants**. To the knowledge and belief of the Company, the accounting firm that audited the Company's financial statements included in the Company SEC Documents is a registered public accounting firm as required by the Exchange Act.

3.26 **Acknowledgment Regarding Purchaser's Purchase of Securities**. The Company acknowledges and agrees that the Purchaser is acting solely in the capacity of an arm's length purchaser with respect to this Agreement and the transactions contemplated thereby. The Company further acknowledges that the Purchaser is not acting as a financial advisor or fiduciary of the Company (or in any similar capacity) with respect to this Agreement and the transactions contemplated thereby and any advice given by any Purchaser or any of their respective representatives or agents in connection with this Agreement and the transactions contemplated thereby is merely incidental to the Purchaser's purchase of the Securities. The Company further represents to the Purchaser that the Company's decision to enter into this Agreement has been

based solely on the independent evaluation of the transactions contemplated hereby by the Company and its representatives.

3.27 **Regulation M Compliance**. The Company has not, and to its knowledge no one acting on its behalf has, (i) taken, directly or indirectly, any action designed to cause or to result in the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of any of the Shares, (ii) sold, bid for, purchased, or, paid any compensation for soliciting purchases of, any of the Shares, or (iii) paid or agreed to pay to any Person any compensation for soliciting another to purchase any other securities of the Company, in each case, in violation of Regulation M under the Exchange Act.

3.28 **Equity-Based Compensation Plans**. Each stock option granted by the Company under the Company's equity-based compensation plans was granted (i) in accordance with the terms of the plan pursuant to which the option purported to be granted and (ii) with an exercise price at least equal to the fair market value of the Common Stock on the date of grant as determined pursuant to such plan. No stock option granted under the Company's stock option plan has been backdated.

3.29 **Office of Foreign Assets Control**. Neither the Company nor the Subsidiary nor, to the Company's knowledge, any director, officer, agent, employee or affiliate of the Company or the Subsidiary is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department.

3.30 **Customers and Suppliers**. Since December 31, 2013, none of the 20 largest customers of the Company and the Subsidiary by revenue during 2013 (on a consolidated basis) has cancelled, terminated or materially and adversely modified, in each case in writing, or, to the knowledge of the Company, threatened in writing to cancel, terminate or materially and adversely modify (including by materially decreasing the rate or amount of services or products obtained from the Company or the Subsidiary) its relationship with the Company or the Subsidiary. Since December 31, 2013, none of the top 20 vendors or suppliers of the Company and the Subsidiary on the basis of amounts paid during 2013 by the Company and the Subsidiary (on a consolidated basis) for goods or services rendered has cancelled, terminated or materially and adversely modified, in each case in writing, or, to the knowledge of the Company, threatened in writing to cancel, terminate or materially and adversely modify its relationship with the Company or the Subsidiary.

3.31 **Disclosure.** To the Company's knowledge, the press releases disseminated by the Company during the twelve months immediately preceding the date of this Agreement taken as a whole do not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading.

3.32 **U.S. Real Property Holding Corporation**. The Company is not has not been within the past five years a U.S. real property holding corporation within the meaning of Section 897 of the Internal Revenue Code of 1986, as amended, and the Company shall so certify upon Purchaser's reasonable request.

3.33 **Brokers and Finders.** No Person will have, as a result of the transactions contemplated by this Agreement, any valid right, interest or claim against or upon the Purchaser for any commission, fee or other compensation pursuant to any agreement, arrangement or understanding entered into by or on behalf of the Company.

4. **Representations of the Purchaser**. The Purchaser represents and warrants to the Company as of the date hereof and the Closing Date as follows:

4.1 **Incorporation**. The Purchaser is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware and is in good standing as a foreign corporation in each jurisdiction in which the nature of the business conducted or the character of the property owned by it makes such qualification necessary, except where the failure to be so qualified or in good standing, as the case may be, would not result in a material adverse effect on (a) the assets, business, properties, financial condition or results of operations of the Company and the Subsidiary taken as a whole, (b) the legality, validity or enforceability of this Agreement, or (c) the Company's ability to perform in any material respect on a timely basis its obligations under this Agreement (any of (a), (b) or (c), a "**Purchaser Material Adverse Effect**"). The Purchaser is not in violation or default under any of the provisions of its charter or bylaws.

4.2 **Authorization; Enforcement**. The Purchaser has the requisite corporate power and authority and has taken all necessary corporate action to execute and deliver this Agreement and to carry out and perform its obligations hereunder, and no further consent or authorization of the Purchaser, its board of directors or its shareholders is required. This Agreement has been duly executed by the Purchaser and, when delivered in accordance with the terms hereof, will constitute the valid and binding obligation of the Purchaser, enforceable in accordance with its terms, except as limited by (a) general equitable principles (regardless of whether enforceability is considered in a proceeding in equity or at law) and applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting enforcement of creditors' rights generally, (b) laws relating to the availability of specific performance, injunctive relief or other equitable remedies and (c) insofar as indemnification and contribution provisions may be limited by applicable law. No proceeding has been instituted in any jurisdiction revoking, limiting or curtailing or seeking to revoke, limit or curtail such power and authority or qualification.

4.3 **No Conflicts**. The execution, delivery and performance of this Agreement and the Distribution Agreement by the Purchaser and the consummation by the Purchaser of the transactions contemplated hereby and thereby do not and will not (a) violate any provision of the Purchaser's Certificate of Incorporation or Bylaws, each as amended to date, (b) constitute a default (or an event which with notice or lapse of time or both would become a default) under, result in the creation of any lien upon any of the property or assets of the Purchaser or its subsidiaries, or give to others any rights of termination, amendment, acceleration or cancellation (with or without notice, lapse of time or both) of, any agreement, credit facility, debt or other instrument to which the Purchaser or its subsidiaries is a party or by which the Purchaser's or any of its subsidiaries' property or assets are bound, or (c) result in a violation of any federal, state, local or foreign statute, rule, regulation, order, judgment or decree (including federal and state securities laws and regulations) applicable to the Purchaser or its subsidiaries or by which

any property or asset of the Purchaser or its subsidiaries is bound or affected, except in the case of clauses (b) and (c) for such as would not, individually or in the aggregate, have or reasonably be expected to have a Purchaser Material Adverse Effect.

4.4 **Governmental Approvals** The Purchaser is not required to obtain any consent, waiver, authorization or order of, give any notice to, or make any filing or registration with, any court or governmental agency in order for it to execute or deliver this Agreement or the Distribution Agreement or perform any of its obligations under this Agreement or the Distribution Agreement.

4.5 **Litigation**. There is no action, suit, inquiry, notice of violation, proceeding or investigation pending or, to the knowledge of the Purchaser, threatened against or affecting the Purchaser before or by any court, arbitrator, governmental or administrative agency or regulatory authority (federal, state, county, local or foreign) which adversely affects or challenges the legality, validity or enforceability of this Agreement or the Distribution Agreement.

4.6 **Ownership of the Company**. Immediately following the Closing, the Purchaser, together with its Affiliates and the members of any "group" (within the meaning of Rule 13d-5(b) under the Exchange Act) in which the Purchaser or its Affiliates is a member, will not directly or indirectly

"beneficially own" (as defined in Rule 13d-3 under the Exchange Act), or have the right to acquire (including by virtue of beneficially owning securities exercisable for Common Stock) any voting securities of the Company other than the Shares.

4.7 **Purchase Entirely for Own Account**. The Purchaser is acquiring the Shares for investment for its own account, not as a nominee or agent, and not with a view to the resale or distribution of any part thereof, and it has no present intention to sell, grant any participation in, or otherwise distribute any of the Shares. The Purchaser has no current agreement, arrangement, undertaking, obligation or commitment providing for the disposition of the Shares and has not been organized, reorganized or recapitalized specifically for the purpose of acquiring the Shares.

4.8 **Access to Information**. The Purchaser has received all the information that it has requested and that it considers necessary or appropriate for deciding whether to enter into this Agreement and to acquire the Shares. The Purchaser has had an opportunity to ask questions and receive answers from the Company regarding the terms and conditions of the offering of the Shares and the merits and risks of investing in the Shares.

4.9 **Investment Experience**. The Purchaser acknowledges that it is able to fend for itself, can bear the economic risk of its investment and has such knowledge and experience in financial and business matters that it is capable of evaluating the merits and risks of the investment in the Shares. Purchaser acknowledges that it has not received any legal or tax advice from the Company or any of its representatives with respect the transactions contemplated hereby. The Purchaser has consulted such legal, tax and investment advisors as it has deemed necessary or appropriate in connection with its purchase of the Shares.

4.10 **No General Solicitation**. The Purchaser is not buying the Shares as a result of any advertisement, article, notice, or other form of general solicitation or general advertising (within the meaning of Regulation D under the Securities Act) regarding the Shares.

4.11 **Status of the Purchaser**. The Purchaser is a corporation with total assets in excess of $5 million and an "accredited investor" as such term is defined in Rule 501(a)(3) under the Securities Act. The Purchaser is not engaged in the business of a broker-dealer, is not a registered broker dealer under the Exchange Act and is not a member of the Financial Industry Regulatory Authority, Inc. The Purchaser's principal executive office and place of business is set forth in Section 8.5 of this Agreement.

4.12 **Shares Not Registered**. The Purchaser understands that the Shares have not been registered under the Securities Act, by reason of their issuance by the Company in a transaction exempt from the registration requirements of the Securities Act, and that the Shares must continue to be held by the Purchaser unless a subsequent disposition thereof is registered under the Securities Act or is exempt from such registration.

4.13 **No Transactions in Common Stock**. The Purchaser has not directly or indirectly, nor has any Person acting on behalf of or pursuant to any understanding with the Purchaser, at any time since the 30th day immediately prior to the date of this Agreement, engaged in any transactions in the securities of the Company (including any short sales as defined in Rule 200 promulgated under Regulation SHO under the Exchange Act and all types of direct and indirect stock pledges, forward sale contracts, options, puts, calls, swaps and similar arrangements (collectively, "**Short Sales"**)) or made any bids with any broker or dealer to purchase Common Stock.

4.14 **Brokers and Finders.** No Person will have, as a result of the transactions contemplated by this Agreement, any valid right, interest or claim against or upon the Company for any commission, fee or other compensation pursuant to any agreement, arrangement or understanding entered into by or on behalf of the Purchaser.

5. **Conditions to the Obligations of the Purchaser**. The obligation of the Purchaser to consummate the Closing and purchase the Shares is subject to the fulfillment, or the waiver by the Purchaser, of each of the following conditions on or before the Closing:

5.1 **Accuracy of Representations and Warranties**. Each representation and warranty of the Company contained in Section 3 shall be true and correct in all material respects on and as of the Closing Date with the same effect as though such representation and warranty had been made on and as of that date (except to the extent such representations and warranties are expressly made as of a specific date, in which case such representations and warranties shall be so true and correct as of such specific date only).

5.2 **No Governmental Proceedings**. No proceeding challenging this Agreement or the transactions contemplated hereby, or seeking to prohibit, alter, prevent or materially delay the Closing, shall have been instituted before any governmental entity and shall be pending.

5.3 **Opinion**. The Purchaser shall have received the opinion of Dykema Gossett PLLC, dated as of the Closing Date, that subject to the assumptions, limitations and qualifications stated therein, that (a) upon delivery of the Common Stock upon payment in accordance with this Agreement, the Shares will be validly issued, fully paid and nonassessable, (b) the Company has duly authorized, executed and delivered this Agreement, and this Agreement constitutes its valid and binding obligations enforceable against it in accordance with their terms, (c) the execution and delivery by the Company of this Agreement and the performance by the Company of its obligations under this Agreement, including its issuance and sale of the Shares, do not and will not (i) violate the law of Michigan or United States federal law, (ii) result in a breach of, or constitute a default under, any of the agreements or instruments filed as an exhibit to the Company SEC Documents since January 1, 2014, or (iii) violate the Company's articles of incorporation or bylaws and (d) the issuance and sale of the Shares are not subject to any preemptive rights under Michigan law or the Company's articles of incorporation or bylaws.

6. **Conditions to the Obligations of the Company**. The obligations of the Company to consummate the Closing and to issue and sell the Shares are subject to fulfillment of the following conditions on or before the Closing:

6.1 **Accuracy of Representations and Warranties**. The representations and warranties of the Purchaser contained in Section 4 shall be true and correct in all material respects on and as of the Closing Date with the same effect as though such representations and warranties had been made on and as of that date (except to the extent such representations and warranties are expressly made as of a specific date, in which case such representations and warranties shall be so true and correct as of such specific date only).

6.2 **No Governmental Proceedings**. No proceeding challenging this Agreement or the transactions contemplated hereby, or seeking to prohibit, alter, prevent or materially delay the Closing, shall have been instituted before any governmental entity and shall be pending.

6.3 **Receipt of Wire Transfer**. The Company shall have received from the Purchaser the wire transfer contemplated in Section 2.2.

7. **Limitations on Transfer and Trading**.

7.1 **Restricted Shares**.

(a) "**Restricted Shares**" means (i) the Shares and (ii) any other shares of capital stock of the Company issued in respect of such Shares (as a result of stock splits, stock dividends, reclassifications, recapitalizations or similar events); provided, however, that shares of Common Stock which are Restricted Shares shall cease to be Restricted Shares upon any sale pursuant to an effective registration statement under the Securities Act or pursuant to Rule 144 or another exemption available under the Securities Act. In no event may the Restricted Shares be sold or transferred unless either (A) they first shall have been registered under the Securities Act or (B) the Company shall have been furnished with an opinion of legal counsel, reasonably

satisfactory to the Company, to the effect that such sale or transfer is exempt from the registration requirements of the Securities Act.

(b) Notwithstanding any other provision herein to the contrary, (1) the Purchaser shall not sell, transfer, assign, donate, pledge or otherwise dispose of the Restricted Shares until the date which is one year after the date hereof, and (2) the Purchaser shall not at any time, directly or indirectly, sell, transfer or otherwise dispose of any Restricted Shares when Purchaser is in possession of material non-public information about the Company.

(c) Any certificate representing Restricted Shares shall bear a legend substantially in the following form:

> The shares represented by this certificate have not been registered under the Securities Act of 1933, as amended, and may not be offered, sold or otherwise transferred, pledged or hypothecated unless and until such shares are registered under such Securities Act or an opinion of counsel satisfactory to the Company is obtained to the effect that such registration is not required. Such shares are also subject to a restriction on transfer contained in an Investment Agreement, dated as of October 2, 2014. A copy of the Investment Agreement is available at the Company's principal executive offices.

(d) The Purchaser acknowledges and agrees that the Company, in its discretion, may also cause stop transfer orders to be placed with its transfer agent with respect to the Restricted Shares in order to facilitate the transfer restrictions referred to in this Section 7.1. The Company shall remove the legend from the certificates representing any Restricted Shares at the request of the holder thereof at such time as they are sold pursuant to an effective registration statement under the Securities Act or an exemption from the registration requirements of the Securities Act.

(e) The Purchaser shall not engage, directly or indirectly, in any Short Sales with respect to the Common Stock of the Company for a period of three years from the date of this Agreement.

7.2 **Standstill Agreement**.

(a) Except as specifically permitted or required by this Agreement, the Purchaser will not, directly or indirectly, without the prior approval of the Board of Directors of the Company (the "**Company Board**"),

(i) acquire any shares of Common Stock by any means whatsoever such that the number of shares of Common Stock beneficially owned (as defined in SEC Regulation 13D-G) by the Purchaser at any time exceeds 4.9% of the number of shares of Common Stock outstanding as reflected in the Company's then most recent periodic filing with the SEC under the Exchange Act;

(ii) engage, or become a participant, in any "solicitation" of "proxies" (as such terms are defined in Regulation 14A under the Exchange Act) or consents to vote any shares of Common Stock;

(iii) grant a proxy or otherwise transfer the right to vote any shares of Common Stock, other than to the Company's designee(s) pursuant to a proxy solicitation conducted by or on behalf of the Company Board;

(iv) act or seek to control the management, the Company Board or policies of the Company by seeking to call a shareholders meeting, proposing or nominating any Person for election to the Company's Board, submitting a proposal for action at a shareholders meeting or by consent of the shareholders in lieu of a meeting, publicly proposing a merger, statutory share exchange or other business combination or extraordinary corporate transaction, or otherwise; provided, that this clause (iv) shall not be construed to prohibit the Purchaser from proposing a merger, statutory share exchange or other business combination or extraordinary corporate transaction (including a transaction involving all or a portion of the assets of the Company's concentrates business) to the Company Board or management, provided that such proposal is not publicly disclosed by Purchaser without the Company's consent;

(v) publicly disclose any intention, plan or arrangement inconsistent with the foregoing; or

(vi) advise, assist or encourage any other Persons in connection with any of the foregoing or to do any of the foregoing.

(b) The obligations of the Purchaser under Section 7.2(a) shall terminate in the event (i) any bona fide third party tender or exchange offer is publicly announced and commenced by any Person other than the Purchaser or an Affiliate of the Purchaser for at least 50% of the outstanding shares of Common Stock that is conditioned upon the offeror receiving tenders for at least 50% of the outstanding shares of Common Stock, or (ii) the Company enters into any agreement to merge or enter into a statutory share exchange with any Person other than the Purchaser or an Affiliate of the

Purchaser following the closing of which the Common Stock would cease to be registered under the Exchange Act. All of the provisions of Section 7.2(a) shall be reinstated and shall apply in full force according to their terms in the event that: (A) if the provisions of Section 7.2(a) shall have terminated as the result of clause (i), and such tender or exchange offer (as originally made or as amended or modified) shall have terminated without acquisition by the Offeror of at least 50% of the outstanding shares of Common Stock; or (B) if the provisions of Section 7.2(a) shall have terminated as a result of clause (ii), such merger or share exchange agreement shall have been terminated prior to its closing. Upon reinstatement of the provisions of Section 7.2(a), the provisions of this Section 7.2(b) shall continue to govern in the event that any of the events described in this Section 7.2(b) shall subsequently occur.

(c) Except as otherwise provided in Section 7.2(b), the covenants in this Section 7.2 shall remain in effect until the earlier of (i) the expiration or termination of the Distribution Agreement, or (ii) one year following the receipt of notice from Purchaser that neither it nor any of its Affiliates own, beneficially or of record, the Shares.

7.3 **Indemnification**.

(a) The Company shall indemnify, defend and hold harmless the Purchaser and its officers, directors, employees and agents from and against and in respect of, and shall compensate and reimburse the foregoing persons for, all losses, deficiencies, damages, expenses, liabilities, claims, assessments and judgments (regardless of whether or not such losses, deficiencies, damages, expenses, liabilities, claims, assessments and judgments involve or relate to a third party claim, and shall include consequential damages, diminution in value and reasonable costs and attorneys' fees and other expenses arising out of any claim, or the defense or investigation thereof, made with respect to any of the foregoing) (collectively, the "**Indemnifiable Expenses**") incurred or suffered by the Purchaser and its officers, directors, employees or agents arising out of, based upon or resulting from any breach by the Company of any of the Company's representations or warranties set forth in Section 3 of this Agreement.

(b) The Purchaser shall indemnify and hold harmless the Company and its officers, directors, employees and agents from and against and in respect of any Indemnifiable Expenses incurred or suffered by the Company or its officers, directors, employees and agents arising out of, based upon or resulting from any breach by the Purchaser of the Purchaser's representations or warranties set forth in Section 4 of this Agreement.

(c) Notwithstanding any other provision in this Agreement to the contrary, neither party shall in any event be liable on account of any indemnification obligation set forth in this Section 7.3 for any punitive damages, and such damages shall not constitute Indemnifiable Expenses, except to the extent such damages are awarded to a third party in connection with a third party claim made against any person or entity entitled to indemnification under this Section 7.3.

(d) The representations and warranties contained in Sections 3 and 4 of this Agreement shall survive the Closing for 24 months, except for the representations and warranties in Sections 3.1, 3.2, 3.3, 3.5, 3.6, 3.7, 3.19, 3.23, 3.26, 4.1, 4.2, 4.7, 4.8, 4.9, 4.10 and 4.11, which shall survive until the relevant statute of limitations has run.

(e) Indemnification pursuant to this Section 7.2 shall not preclude any party from exercising any other remedies they may have under this Agreement, applicable law or otherwise. If the Shares have been issued, in no event shall either party's liability under this Agreement, applicable law or otherwise exceed the Aggregate Purchase Price.

8. **Miscellaneous**.

8.1 **Successors and Assigns**. No party may assign this Agreement or any rights or obligations hereunder without prior written consent from the other party. Subject to the foregoing, this Agreement shall be binding upon and inure to the benefit of the Company and the Purchaser and their respective successors and permitted assigns.

8.2 **Severability**. The invalidity or unenforceability of any provision of this Agreement shall not affect the validity or enforceability of any other provision of this Agreement.

8.3 **Specific Performance**. In addition to any and all other remedies that may be available at law in the event of any breach of this Agreement, each party shall be entitled to specific performance of the agreements and obligations of the other party hereunder and to such other injunctive or other equitable relief as may be granted by a court of competent jurisdiction.

8.4 **Governing Law**. This Agreement shall be governed by and construed in accordance with the internal laws of the State of Michigan (without reference to the conflicts of law provisions thereof).

8.5 **Notices**. All notices, requests, consents and other communications under this Agreement shall be in writing and shall be deemed delivered (a) two business days after being sent by registered or certified mail, return receipt requested, postage prepaid or (b) one business day after being sent via a reputable nationwide overnight courier service guaranteeing next business day delivery, in each case to the intended recipient as set forth below:

If to the Company:

Rockwell Medical, Inc.
30142 Wixom Road
Wixom, MI 48393
Attention: Thomas Klema
Email: tklema@rockwellmed.com

with a copy (which will not constitute notice) to:

Dykema Gossett PLLC
39577 Woodward Ave., Suite 300
Bloomfield Hills, MI 48304
Attention: Mark A. Metz
Email: mmetz@dykema.com

If to the Purchaser:

Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, Illinois 60015
Attention: General Counsel
Telecopy: 224.948.2000

with a copy (which will not constitute notice) to:

Faegre Baker Daniels LLP
2200 Wells Fargo Center
90 South Seventh Street
Minneapolis, Minnesota 55402-3901
Attention: Jonathan Zimmerman
Email: Jon.Zimmerman@FaegreBD.com

or in each case at such other address or addresses as may have been furnished in writing to the other party. Either party may give any notice, request, consent or other communication under this Agreement using any other means (including personal delivery, messenger service, telecopy, first class mail or electronic mail), but no such notice, request, consent or other communication shall be deemed to have been duly given unless and until it is actually received by the other party. Either party may change the address to which notices, requests, consents or other communications hereunder are to be delivered by giving the other party notice in the manner set forth in this Section 8.5.

8.6 **Interpretation**.

(a) The parties have participated jointly in the negotiation and drafting of this Agreement. In the event an ambiguity or question of intent or interpretation arises, this Agreement shall be construed as if drafted jointly by the parties, and no presumption or burden of proof shall arise favoring or disfavoring any party by virtue of the authorship of any provisions of this Agreement.

(b) Disclosure of any fact, circumstance or information in any Section of the Company Disclosure Letter shall be deemed to be disclosure of such fact, circumstance or information with respect to any other Section of the Company Disclosure Letter if it is reasonably apparent that such disclosure relates to any such other Section. The inclusion of any item in the Company Disclosure Letter shall not be deemed to be an admission or evidence of materiality of such item, nor shall it establish any standard of materiality for any purpose whatsoever.

(c) The words “hereof,” “herein,” “hereby,” “hereunder” and “herewith” and words of similar import shall refer to this Agreement as a whole and not to any particular provision of this Agreement. References to articles and sections are to the articles and, sections of this Agreement, unless otherwise specified and shall not affect in any way the meaning or interpretation of this Agreement. Whenever the words “include,” “includes” or “including” are used in this Agreement, they shall be deemed to be followed by the phrase “without limitation.” When used in reference to the Company, the term “material” shall be measured against the Company and the Subsidiary, taken as a whole. References to “business day” shall mean any Monday, Tuesday, Wednesday, Thursday or Friday other than a federal holiday on which United States federal government offices are closed. References to the Company’s knowledge shall mean the actual knowledge of the Company’s officers as defined in SEC Rule 16a-1(f) under the Exchange Act.

8.7 **Complete Agreement**. This Agreement constitutes the entire agreement and understanding of the parties with respect to the subject matter hereof and supersedes all prior agreements and understandings relating to such subject matter.

8.8 **Amendments and Waivers**. Except as otherwise expressly set forth in this Agreement, any term of this Agreement may be amended or terminated and the observance of any term of this Agreement may be waived (either generally or in a particular instance and either retroactively or prospectively), but only with the written consent of the Company and the Purchaser.

8.9 **Counterparts; Facsimile Signatures**. This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original, and all of which shall constitute one and the same document. The delivery of a signature page of this Agreement by one party to the other party via facsimile transmission shall constitute the execution and delivery of this Agreement by the transmitting party.

8.10 **Legal Fees and Expenses**. Each of the parties to this Agreement will bear its own legal fees and other expenses with respect to the transaction contemplated by this Agreement.

Executed as of the date first written above.

ROCKWELL MEDICAL, INC.

By: /s/ Robert L. Chioini
Name: Robert L. Chioini
Its: Chief Executive Officer

BAXTER HEALTHCARE CORPORATION

By: /s/ Robert J. Hombach
Name: Robert J. Hombach
Its: CVP, Chief Financial Officer

Investment Agreement
Company Disclosure Schedule

Section 3.4

Loan and Security Agreement, dated as of June 14, 2013, among Rockwell Medical, Inc., Rockwell Transportation, Inc. and Hercules Technology III, L.P. (*note, however, that the Company has received written confirmation from Hercules Technology III, L.P. that the transactions may proceed without violation of the Loan and Security Agreement and that no waiver is necessary*)

First Amended and Restated Products Purchase Agreement dated May 8, 2013, by and between Rockwell Medical, Inc. and DaVita Healthcare Partners, Inc.

University of Mississippi Pricing Agreement (consent to assignment required)

University of Iowa Memorandum of Agreement, dated June 5. 2013, as amended May 2, 2014 (consent to assignment required)

Section 3.9

The Company is currently contemplating a $60 - $80 million underwritten public offering that would likely occur early in the fourth quarter of 2014.

The Company has been informed that the FDA has scheduled an “advisory committee” meeting for November 6 in connection with its approval process for Triferic.

Exhibit 10.59

AMENDMENT TO OCTOBER 1, 2014 STOCK OPTION AGREEMENT

This Amendment, effective as of October 1, 2014, between Rockwell Medical, Inc. (the "Company") and Robert L. Chioini (the "Optionee").

WHEREAS, the October 1, 2014 resolutions of the Compensation Committee authorizing the October 1, 2014 Tranche B grant of 250,000 options (the "Tranche B Options") to Optionee provide that the related option agreement shall state that such options are not intended to be exempt from Section 162(m) of the Internal Revenue Code of 1986;

WHEREAS, this Amendment is being executed in accordance with the authorizing resolutions for the Tranche B Options in order to modify the grant agreement, dated as of October 1, 2014 (the "Tranche B Grant Agreement");

NOW THEREFORE, the Tranche B Grant Agreement is amended as follows:

1. Section 1.1 is amended to add the following at the end of such section:

The Option is not intended to satisfy the requirements of or be exempt from Section 162(m) of the Internal Revenue Code of 1986.

2. Except as specifically modified herein, the remaining provisions of the Tranche B Grant Agreement remain in full force and effect.

3. This Amendment may be executed in any number of counterparts, all of which shall constitute one and the same Amendment. This Amendment may be executed by signatures delivered by facsimile or electronic mail, each of which shall be fully binding on the signing party.

IN WITNESS WHEREOF, the undersigned have caused this Amendment to be duly executed on this 17th day of February, 2015, effective as of October 1, 2014.

ROBERT L. CHIOINI, as Optionee

/s/ Robert L. Chioini

ROCKWELL MEDICAL, INC.

By: /s/ Thomas E. Klema
Thomas E. Klema
Vice President, Chief Financial Officer and Treasurer

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Exhibit 23.1

Plante & Moran, PLLC
Suite 300
19176 Hall Road
Clinton Township, MI 48038
Tel: 586.416.4900
Fax: 586.416.4901
plantemoran.com

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statements on Forms S-3 (Registration No.'s 333-135872, 333-148601, 333-160791, 333-160710 and 333-181003) and Forms S-8 (Registration No.'s 333-66791, 333-126627, 333-135896, 333-146817, 333-153046, 333-160135, 333-169003, 333-182043, and 333-189586) of Rockwell Medical, Inc. and Subsidiary of our reports dated February 27, 2015 on the consolidated financial statements and related financial statement schedule of Rockwell Medical, Inc. and Subsidiary as of December 31, 2014 and 2013 and for each of the years in the three-year period ended December 31, 2014 and on the effectiveness of the Company's internal control over financial reporting as of December 31, 2014, appearing in the Annual Report on Form 10-K of Rockwell Medical, Inc. and Subsidiary for the year ended December 31, 2014.

/s/ Plante & Moran, PLLC

Clinton Township, Michigan
March 3, 2015

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Exhibit 31.1

CERTIFICATION
PURSUANT TO RULE 13a-14(a)

I, Robert L. Chioini, certify that:

1. I have reviewed this annual report on Form 10-K of Rockwell Medical, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 3, 2015

/s/ ROBERT L. CHIOINI

Robert L. Chioini
Chairman, CEO and President

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Exhibit 31.2

CERTIFICATION
PURSUANT TO RULE 13a-14(a)

I, Thomas E. Klema, certify that:

1. I have reviewed this annual report on Form 10-K of Rockwell Medical, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 3, 2015

/s/ THOMAS E. KLEMA

Thomas E. Klema
Vice President & Chief Financial Officer

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EXHIBIT 32.1

CERTIFICATION OF 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

In connection with the Annual Report of Rockwell Medical, Inc. (the "Company") on Form 10-K for the year ending December 31, 2014 as filed with the Securities and Exchange Commission on the date hereof (the "Periodic Report"), I, Robert L. Chioini, Chief Executive Officer of the Company, and I, Thomas E. Klema, Chief Financial Officer of the Company, each certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

1. the Periodic Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. the information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 3, 2015

/s/ ROBERT L. CHIOINI

Robert L. Chioini
Chief Executive Officer

Dated: March 3, 2015

/s/ THOMAS E. KLEMA

Thomas E. Klema
Chief Financial Officer

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