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, 2017

OR

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

For the transition period from to

Commission file number 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 ☐ No ☒

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act 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 ☐

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 ☐

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. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act:

Large accelerated filer ☐	Accelerated filer ☒	Non-accelerated filer ☐ (Do not check if a smaller reporting company)	Smaller reporting company ☐	Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ 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, 2017 (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 $330,268,000.

Number of shares outstanding of the registrant's Common Stock, no par value, as of February 17, 2018: 51,768,424 shares.

Documents Incorporated by Reference

Portions of the Registrant's definitive Proxy Statement pertaining to the 2018 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 subsidiaries unless otherwise specified or the context otherwise requires.

Triferic®, CitraPure®, RenalPure® and SteriLyte® are registered trademarks of Rockwell.

Forward Looking Statements

We make, or incorporate by reference, “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, in this Annual Report on Form 10-K. 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,” “could,” “plan,” “potential,” “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 Annual Report, including without limitation in “Item 1A—Risk Factors.” Although it is not possible to identify all of these factors, they include, among others, the following:

- Acceptance of our products by doctors, patients or payors;
- Availability of reimbursement for our products;
- Ability to use existing inventory before shelf life expiration;
- Expectations regarding the safety and efficacy of our products;
- Expectations regarding the timing of submissions to, and decisions made by, the U.S. Food and Drug Administration, and other regulatory agencies, including foreign regulatory agencies;
- Ability to secure adequate protection for, and licensure of, our intellectual property;
- Estimates regarding the capacity of manufacturing and other facilities to support our products;
- Expectations or ability to enter into marketing and other partnership agreements;
- Ability to compete against other companies and research institutions;
- Ability to attract and retain key personnel;
- Expectations for increases or decreases in expenses;
- Expectations for incurring capital expenditures to expand our research and development and manufacturing capabilities;
- Expectations for generating revenue or becoming profitable on a sustained basis;
- Expectations regarding the effect of changes in accounting guidance or standards on our operating results;

- Impact of healthcare reform laws;
- Impact of potential shareholder activism; and
- Stock price and its volatility.

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.

Overview

Rockwell Medical, Inc. and Subsidiaries, (collectively, “we”, “our”, “us” or the “Company”) is a fully-integrated pharmaceutical company targeting end-stage renal disease (“ESRD”) and chronic kidney disease with innovative products and services for the treatment of iron deficiency, secondary hyperparathyroidism and hemodialysis (also referred to as “dialysis”). We were incorporated in the state of Michigan in 1996.

We are currently marketing and 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 also obtained licenses for certain dialysis related drugs which we are developing and planning to market globally.

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 manufacture, sell and distribute hemodialysis concentrates and other medical products and supplies used in the treatment of patients with ESRD. In 2017, we supplied approximately 25% of the United States domestic market with dialysis concentrates, and the majority of our sales were in the United States. We also supply dialysis concentrates to distributors serving a number of foreign countries, primarily in the Americas and the Pacific Rim.

We are regulated by the United States Food and Drug Administration (“FDA”) under the Federal Drug and Cosmetics Act, as well as by other federal, state and local agencies. We hold several FDA product approvals including both drugs and medical devices.

Our Market Opportunity – Hemodialysis

Hemodialysis is the primary treatment modality employed in the United States with over 90% of all dialysis patients receiving hemodialysis. The Company does not currently compete in the peritoneal or home dialysis segments. Hemodialysis treatments are primarily performed in freestanding clinics, as well as in some hospitals. The majority of dialysis services are performed by national and regional for profit dialysis chains. Based on data published by the United States Renal Data Systems (“USRDS”) we estimate that there are approximately 7,000 Medicare-certified treatment clinics in the United States. The two largest national for-profit dialysis chains service approximately 70% of the domestic hemodialysis market. According to the most recent statistics published by USRDS, there were approximately 479,000 dialysis patients in the United States as of the end of 2015.

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 3.2 million patients at the end of 2017 with the overall global patient population growing approximately 7-8% annually. According to the National Kidney Foundation, 10% of the worldwide population is affected by chronic kidney disease and millions die each year because they do not have access to affordable treatments. 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 United States dialysis population to grow approximately 3-4% annually over the next several years. The Asia-Pacific market is projected to experience rapid growth in both the incidence of kidney disease and by total treatment in the ESRD population over the decade ahead. One common side-effect of dialysis treatments is iron deficiency anemia for chronic patients.

The great majority of hemodialysis patients receive dialysis treatment three times per week, or approximately 156 times per year. Most patients 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 chronic 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 filter (called a 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, magnesium and potassium into the patient's blood while removing fluid and waste. Dialysate generally contains dextrose, sodium chloride, calcium, potassium, magnesium, sodium bicarbonate and 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 concentrate products every treatment, 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.

Our Solution

We are primarily focused on developing unique, proprietary renal drug therapies that we can commercialize or out-license, while also expanding our dialysis products business. 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.

The Only FDA-Approved Therapy to Replace Iron and Maintain Hemoglobin. As of now, Triferic is the only FDA-approved therapy indicated to replace iron and maintain hemoglobin in adult hemodialysis patients. We believe Triferic has the potential to capture significant market share due to its improved clinical and cost-saving benefits. Triferic is an innovative iron therapy that replaces the ongoing iron loss that occurs to patients during every hemodialysis treatment, via dialysate. If Triferic receives separate reimbursement from Centers for Medicare and Medicaid Services ("CMS") we anticipate dialysis providers will have greater incentive to adopt this new, innovative therapy and provide their patients wide-spread access to it. Effective January 1, 2016, Triferic received a CMS reimbursement code, commonly referred to as a J-Code.

Separate Reimbursement. While we cannot predict the outcome or timing of the CMS review, we anticipate that Triferic will receive separate reimbursement as a result of our extensive efforts in working with policy makers, Congress and stakeholders within the dialysis industry. We have had in-depth discussions with senior officials within the current administration, key members of Congress, patient advocacy groups and other industry stakeholders regarding the merits of Triferic and why this innovative therapy should receive separate reimbursement. Our efforts have received strong support. We have submitted information to CMS that highlights the improved clinical benefits that Triferic provides to patients, as well as the significant cost savings Triferic delivers to both Medicare and dialysis providers.

Develop Additional Clinical Indications and Product Presentations of Triferic. We are continuing development work on other clinical indications related to iron deficiency that address unmet patient needs and we are evaluating opportunities to in-license other products that will complement our product portfolio. We are also developing other presentations of Triferic.

International Opportunities. Our global strategy is to license Triferic to key partners to commercialize it internationally. We are actively pursuing international licensing opportunities in a number of countries and regions.

Enter into Generic Market. We are also working to begin marketing Calcitriol, a generic injectable vitamin-D, which is manufactured through contract manufacturing organizations ("CMOs"). In 2017, we engaged a new CMO in order to improve the manufacturing process of Calcitriol to ensure that Calcitriol is manufactured consistently and within specifications. We are awaiting FDA approval of a Prior Approval Supplement ("PAS") in order to market and commercialize Calcitriol. We received written notice from the FDA in October 2017 that the FDA needed additional time to review the data submitted by us. The notice contained no indication by the FDA of any deficiency with the data submitted. While we cannot predict the timing of the FDA's review of such data, we anticipate the FDA's review of such data to be completed during the second quarter of 2018. Following FDA approval, we plan to accelerate our commercial production volumes and to begin selling Calcitriol to hemodialysis providers in the United States.

Our Growth Strategies

Domestic Commercialization of Triferic. We are actively marketing Triferic in the United States hemodialysis market through our efforts to educate and to work together with clinics to evaluate their implementation of Triferic under our drug sample program. Feedback from clinics using Triferic in connection with our drug sample program has been positive and consistent with our clinical study results, which demonstrated stable maintenance of hemoglobin concentration and significant reduction in erythropoiesis stimulating agent ("ESA") and intravenous (IV) iron use. Until Triferic receives separate reimbursement from CMS, Triferic will be available through our drug sample program. The United States hemodialysis market is currently the largest market in the world for dialysis products. There are an estimated 470,000 dialysis patients in the United States or approximately 75 million treatments annually.

Domestic Commercialization of Calcitriol. Our generic injectable vitamin-D drug, Calcitriol, is indicated 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. Calcitriol (active vitamin D) injection is indicated in the management of hypocalcemia in patients undergoing chronic renal dialysis. Based on our analysis of information provided by industry sources, we estimate that there are currently over 52,000,000 vitamin D treatments per year in the ESRD market in the United States. We are awaiting FDA approval of a Prior Approval Supplement ("PAS") in order to market and commercialize Calcitriol. We received written notice from the FDA in October 2017 that the FDA needed additional time to review the data submitted by us. The notice contained no indication by the FDA of any deficiency with the data submitted. While we cannot predict the timing of the FDA's review of such data, we anticipate the FDA's review of such data to be completed during the second quarter of 2018. Following FDA approval, we plan to ramp up commercial production volumes and to begin marketing and selling Calcitriol to hemodialysis providers in the United States.

International Commercialization of Triferic and Calcitriol. We are working to commercialize both Triferic and Calcitriol globally. In 2016, we licensed the commercialization rights for Triferic for the Chinese market with a prominent Chinese pharmaceutical company. China is expected to become the largest ESRD market in the world over the next several years. Commercial sales activity in these markets will commence following regulatory or registration approval. We retain manufacturing responsibilities for both Triferic and Calcitriol. We have also executed a distribution agreement to market Triferic in Canada, where we anticipate commercial availability in 2019 after regulatory approval. We recently licensed Triferic to distributors in Chile and Peru. We are actively engaged in licensing negotiations for Triferic in a number of other regions and countries. We intend to leverage the development, regulatory and commercial presence and expertise of potential business partners to accelerate sales of our products throughout the world.

Obtain Separate Reimbursement for Triferic. We have been engaged in extensive efforts to obtain approval from CMS for separate reimbursement of Triferic. We have worked with policy makers, Congress and stakeholders within the dialysis industry. We have had in-depth discussions with senior officials within the current administration, key members of Congress, patient advocacy groups and other industry stakeholders regarding the merits of Triferic and why this innovative therapy should receive separate reimbursement. Our efforts have received strong support. We have submitted information to CMS that highlights the improved clinical benefits that Triferic provides to patients, as well as the significant cost savings Triferic delivers to both Medicare and dialysis providers. Notwithstanding our efforts, arguments and expectations, we cannot predict the outcome, or the timing of the CMS review.

Additional Potential Indications for Triferic. We are currently undertaking development of other clinical indications for Triferic. These clinical applications include peritoneal dialysis ("PD"), total parenteral nutrition ("TPN") and possibly treating cancer patients. We are also developing other methods for delivering and packaging Triferic, including intravenous delivery. Our drug product pipeline is summarized below by stage of development.

Expanding Out-Licensing. We have made significant progress with our international business development efforts for Triferic, including securing a licensing agreement with Wanbang Biopharmaceutical in 2016 for the rights to commercialize Triferic and Calcitriol for ESRD patients in the People's Republic of China. We are working with our partner to commence a clinical trial in China anticipated to commence in 2018. Under the terms of the Wanbang Agreement, we received an upfront payment of $4 million, which we are recognizing over the term of the agreement. Rockwell may also receive milestone payments of up to an additional $35 million over the life of the agreement in regulatory and revenue milestone payments plus ongoing earnings on product sales, and Wanbang is responsible for the cost of the clinical trial and regulatory approval in China. In the fourth quarter of 2017, we licensed Triferic to distributors in Chile and Peru. Our distributors are responsible for obtaining regulatory approvals in those markets. We are actively pursuing licensing transactions in a number of countries and regions. We believe that our intravenous form of Triferic will be the preferred method of delivery in a number of countries and will support our out-licensing efforts for those territories.

Current Drug Pipeline

We are currently developing Triferic for other clinical indications and presentations. We are developing an intravenous injection of Triferic primarily for use by hemodialysis patients in foreign markets and for use in other iron deficiency anemia indications, as well as other product presentations. Other clinical applications include peritoneal dialysis ("PD") and total parenteral nutrition ("TPN").

A new presentation and manufacturing process has been completed for infusing Triferic intravenously. A clinical equivalence study of Triferic IV infusion presentation has been completed. We expect to submit documentation for FDA approval of the Triferic IV presentation in 2018.

For our PD program, we completed a pharmacokinetic ("PK") study which showed iron transfer from peritoneal dialysate to blood. Additional Phase I/II safety and PK studies are required to establish dosing and are planned to commence in the third quarter of 2018.

We have met with experts in the TPN field to evaluate the TPN market. We are currently in the process of evaluating the TPN market. If the market opportunity appears favorable, clinical studies will commence following submission and approval of an Investigational New Drug ("IND") application with the FDA.

Our Drug Products

Triferic (Ferric Pyrophosphate Citrate)

The great majority of hemodialysis patients receive dialysis treatment three times per week, or approximately 156 times per year, and dialysis patients suffer from iron deficiency and anemia as a result of iron loss during their constant dialysis treatments. Triferic was designed specifically to treat this constant iron loss, and Triferic is the only FDA approved drug indicated to replace iron and maintain hemoglobin in hemodialysis patients. We believe Triferic will become the standard of care in anemia treatment for dialysis patients, addressing an important unmet need in the treatment of iron deficiency and anemia in ESRD patients.

Triferic is a novel iron therapy that replaces the small amount of iron patients lose during their hemodialysis treatment. It is innovative and convenient because it is delivered via dialysate Triferic's unique mode-of-action is what distinguishes it from other drug treatments because Triferic donates iron to transferrin, immediately, and completely, as soon as it enters the blood, where it then is transported to the bone marrow to make hemoglobin. Triferic delivers sufficient iron to the bone marrow and maintains hemoglobin without increasing iron stores (ferritin).

Intravenous (IV) iron was approved for use as a repletion therapy in the early 1990's, with a clinical indication to treat iron deficiency anemia – defined as a ferritin level < 200 ng/mL. At that time, the average ferritin level in dialysis patients in the U.S. was between 200 – 300 ng/mL. Ferritin is a marker of stored iron and inflammation in the body. IV iron has been the only viable therapy used during the last 30 years to attempt to treat dialysis patients for anemia . However, IV iron is not able to replace the continual iron loss that occurs at every dialysis treatment due to its mode-of-action. IV iron products are designed to metabolize in the patient's liver and then bind to transferrin. Due to the constant inflammation present in hemodialysis patients, a protein called hepcidin mobilizes and blocks the IV iron from leaving the liver, trapping most of it there. As a result, the average ferritin levels in dialysis patients have soared over the last 30 years, to approximately 750 ng/mL, according to US-DOPPS Practice Monitor published August 2017.

Triferic is distinctly different from IV iron and is specifically FDA approved to treat the small amount of iron patients lose during every hemodialysis treatment. Triferic is different in molecular structure, mode-of-action (bypassing liver storage) and FDA approved clinical indication (to replace iron and maintain hemoglobin). Triferic is an iron maintenance therapy approved to be given to patients every treatment whereas IV iron is a repletion or "rescue" therapy that should be given only when a patient experiences significant blood loss and has a ferritin level < 200 ng/mL. Triferic delivers iron and maintains hemoglobin without increasing iron stores (ferritin) and addresses an unmet need.

Triferic has demonstrated an excellent safety profile. We received FDA approval to market Triferic in liquid form in 2015 and in powder form in 2016.

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 every treatment using primarily one of two branded drugs or in some cases oral drugs. Clinical data shows Calcitriol to be clinically equivalent in safety and efficacy to the two branded drugs and Calcitriol is the most potent and physiological vitamin D therapy. We believe the lower cost of Calcitriol will provide incentive to dialysis providers to purchase it over current vitamin D options.

Dialysis Concentrate Products

We manufacture, sell, deliver and distribute hemodialysis concentrates, along with a full line of ancillary products abroad. As one of the two major suppliers in the United States, our dialysis concentrate products, as more fully described below, are used to maintain human life by removing toxins and replacing critical nutrients in the dialysis patient's bloodstream. We use Baxter Healthcare Corporation ("Baxter") as our exclusive marketer and distributor in the United States and in select foreign markets pursuant to an Exclusive Distribution Agreement, as amended (the "Distribution Agreement"). In June 2017, we settled arbitration proceedings with Baxter related to the Distribution Agreement and entered into the First Amendment to Exclusive Distribution Agreement with Baxter. See "Item 3 – Legal Proceedings."

Dialysate concentrates accounted for over 95% of our 2017 revenue with ancillary products accounting for most of 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 citrate-based, and 100% acetate-free, in contrast to the acetate-based products used for many years. Acetate promotes inflammation and the reduction in inflammation is beneficial to improving patient outcomes. Citrate acts as an anticoagulant 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 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. Dri-Sate is packaged as a dry powder acid concentrate for use with our Dry Acid Concentrate Mixer. Dri-Sate is packaged as dry acid concentrate in 25 gallon cases.

Renal Pure Liquid Acid Concentrate

Our RenalPure Liquid Concentrate is our original acetate-based product, and is 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 products and enables the clinic to mix acid concentrate on-site. Clinics using Rockwell's Dry Acid Concentrate products 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 and SteriLyte Bicarbonate Concentrate

RenalPure bicarbonate is a dry powder mixed on-site at the clinic and is packaged for bulk and individual treatment and SteriLyte bicarbonate is a 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 Distribution Agreement, Baxter is 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 ending October 2, 2024. We retain sales, marketing and distribution rights for our hemodialysis concentrate products for our 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. In June 2017, we settled arbitration proceedings with Baxter related to the Distribution Agreement and entered into the First Amendment to Exclusive Distribution Agreement with Baxter (the "Amendment". See "Item 3 – Legal Proceedings." The terms of the Amendment included, among other things, reduced pricing on certain accounts. While reducing pricing, the Amendment provides incentive to Baxter to pursue new customers and increase future sales.

Under the Distribution Agreement, Baxter purchases 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 calendar 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 continue to manage customer service, transportation and certain other functions for our current customers. Baxter pays us an amount equal to our related costs plus a slight mark-up for these services.

Upon the mutual determination of us and Baxter, the Distribution Agreement also provides that Baxter will pay us up to $10 million 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 non-compete 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 $20 million upfront fee and any paid portion of the 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 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.

Distribution and Delivery Operations

The majority of our domestic dialysis concentrate 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. Our drug products are generally delivered by third party drug distributors in the United States.

Sales and Marketing

The top ten dialysis providers treat approximately 400,000 hemodialysis patients in their centers according to an article published by Nephrology News in 2017. We believe this constitutes approximately 85% of the hemodialysis patients in the United States. Due to the concentrated nature of our customers, we expect to market our drug products using a team of skilled individuals, led and directed by our Chief Executive Officer who will handle much of the sales effort with our major accounts.

We market and advertise through trade publications, journals, product literature, industry trade conferences, and web-based applications. We target our sales and marketing efforts to senior and operating management of dialysis companies, dialysis service providers, nephrologists, clinic administrators, nurses, medical directors and technical and purchasing personnel.

Our dialysis concentrate products are sold to customers in the United States 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, and research and development resources than us. Fresenius operates approximately 1,700 clinics and treats approximately 36% of the dialysis patients in the United States. Fresenius also manufactures and sells a full range of renal products, including dialysis machines, dialyzers (artificial kidneys), concentrates and other supplies used in hemodialysis. 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. Fresenius and Rockwell are the two major dialysis concentrate suppliers in the United States.

Iron Delivery Market Competition

We believe Triferic has potential to become the standard of care for iron maintenance therapy for hemodialysis patients due to its unique mode of action, clinical benefits, ability to lower treatment cost for providers, ease of

administration and excellent safety profile. We are not aware of any other iron delivery products that compete with Triferic and its FDA approved clinical indication.

Historically, IV iron has been used to treat iron deficiency anemia, and currently, the drug Venofer® is generally regarded as having dominant market share over other IV iron drug products, such as Sanofi's Ferrlecit®. Venofer® is owned by Switzerland-based Galenica. Galenica also markets Ferinject® which is primarily used to treat anemia in a non-dialysis setting. Fresenius has a sublicense agreement that allows Fresenius to distribute Venofer® to the dialysis market in the United States and Canada. Other IV iron competitors include Watson's generic IV iron drug, Nulecit®. IV iron is a repletion therapy and not an iron maintenance therapy, and therefore, technically, Triferic and IV iron are not competing products as their molecular structure, mode-of-action and FDA approved clinical indication to treat anemia are different. Both therapies are needed to treat dialysis patients, where Triferic is administered every dialysis treatment and IV iron is administered sparingly when there is excessive blood loss in a patient. Accordingly, as Tiferic gains market share, we expect IV iron use will decline.

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 payers. Drugs approved by the FDA might not receive reimbursement from private insurers or government payers.

Prior to 2011, CMS had paid providers for dialysis treatments under the Medicare program in two parts: the composite rate and separately reimbursed drugs and services. The composite rate was a payment for the complete dialysis treatment except for physicians' professional services, separately billed laboratory services and separately billed drugs. CMS implemented a bundled reimbursement rate in 2011. 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, is an attractive therapy under this reimbursement landscape. When implementing the bundled rate, CMS conveyed that they would create a formal pathway for new innovative therapies to receive separate reimbursement for a 2-year period (called transitional payment) so that (a) dialysis providers would have incentive to make those therapies available to patients, (b) patients would not be denied access to new therapies and improved clinical outcomes and (c) innovation in the renal market would not be stifled. We believe Triferic is a new innovative therapy, and we are seeking separate reimbursement for Triferic.

Vitamin D Therapy Market Competition

We intend to market Calcitriol injection against two competitors with branded vitamin D products, against other generic drug competitors and against oral forms of vitamin D. 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 CMOs to manufacture and package our drug products for sale. These contract manufacturers are FDA registered 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, other Triferic indications and Calcitriol. The development and regulatory approval process for new drugs and additional indications for approved drugs includes preclinical testing and human clinical trials and is lengthy and uncertain. Before marketing any pharmaceutical or therapeutic product in the United States, the 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 the 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 (for which a PMA is not required), 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 new or 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 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 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.

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 scientifically 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 or in the process or procedures used to manufacture a 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. 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 exclusive worldwide rights to certain patents and information related to our Triferic® product. We licensed the rights 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 extended through 2016. Other patents are issued or pending in the United States, the European Union and Japan, as well as other foreign jurisdictions. As noted below in "Trademarks and Patents," the Company has also received a patent on the pharmaceutical grade formulation of the active pharmaceutical ingredient in Triferic product which extends until 2029. The license agreement requires us to obtain and pay the cost of obtaining FDA approval of our Triferic product and patent maintenance expenses in order to realize any benefit from commercialization of the product. In addition, we were obligated to make certain milestone payments during development of the product. As of December 31, 2017, there were no remaining milestones to be completed although we continue to be obligated to pay ongoing royalties upon sales of the Triferic product covered by the licensed rights.

Trademarks and Patents

We have several trademarks and service marks 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 service marks.

We were issued a United States patent on the synthesis and formulation of our pharmaceutical grade formulation of our Triferic product. The United States patent expires on April 17, 2029. Patents have also been granted in Europe, Japan and Canada. We have several other patents and patent applications connected to the Triferic product 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.

See Item 1A "Risk Factors" for a discussion of certain risks related to our intellectual property.

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 qualify and obtain regulatory approval for an additional CMO could be lengthy.

Customers

We operate in one market segment, the hemodialysis market, which involves the manufacture, sale and distribution of hemodialysis products to hemodialysis clinics, including pharmaceutical, dialysis concentrates, dialysis kits and other ancillary products used in the dialysis process. In October 2014, we entered into the Distribution Agreement with Baxter, which was amended in June 2017, pursuant to which Baxter received exclusive distribution rights for our concentrate products in the United States. Our domestic customer contracts for the supply of dialysis concentrate products that permitted assignment to Baxter without consent have been assigned to Baxter. As a result, for

2017, 2016 and 2015, our direct sales to Baxter aggregated approximately 27%, 24% and 28% of sales, respectively, and we had a receivable from Baxter of $1,863,412 and $2,430,159 as of December 31, 2017 and 2016, respectively.

One customer, DaVita Healthcare Partners, Inc., accounted for 50% of our sales in 2017, 52% of our sales in 2016 and 48% of our sales in 2015. Our accounts receivable from this customer were $2,411,367 and $2,224,046 as of December 31, 2017 and 2016, respectively. DaVita and Baxter and the accounts administered by Baxter are important to our business, financial condition and results of operations. The loss of any significant accounts could have a material adverse effect on our business, financial condition and results of operations. No other customers accounted for more than 10% of our sales in any of the last three years.

See Item 1A “Risk Factors” for a discussion of certain risks related to our key customers.

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 directly to foreign customers and distributors accounted for less than 5% of our total sales in 2017, 2016 and 2015. Our total international sales, including sales made through domestic distributors for resale outside the United States, aggregated 12%, 12% and 13%, of our overall sales in 2017, 2016 and 2015, respectively.

See Item 1A “Risk Factors” for a discussion of certain risks related to our foreign sales.

Employees

As of December 31, 2017, we had approximately 300 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. Since approval of Triferic, we have conducted additional clinical studies of Triferic for other indications, presentation in IV formulation and for a pediatric study of Triferic.

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 $6,321,000, $5,840,000 and $4,961,000, in 2017, 2016 and 2015, respectively. Future research and product development spending on the Triferic platform may include clinical testing in connection with peritoneal dialysis, total parenteral nutrition and a pediatric indication.

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 website 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 website is http://www.sec.gov.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk and there can be no assurance that future results will meet expectations. 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 these 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 been approved by the FDA, we may not be able to commercialize it successfully, especially if Triferic is not approved for separate reimbursement status by CMS.

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

- We are seeking separate reimbursement (separate payment outside of the ESRD bundled payment) for Triferic, and there can be no assurances as to whether or when such separate reimbursement will be approved by CMS. In the absence of separate reimbursement approval, dialysis service providers are likely to adopt Triferic at a much slower rate than if Triferic is granted such status due to the cost of conversion and lack of an immediate financial incentive to adopt Triferic;

- Even if separate reimbursement status is approved for Triferic, Triferic will have to compete against current iron therapies and possibly other future products;

- Even if separate reimbursement status is approved for Triferic, 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;

- Certain licensing royalties related to our sale of Triferic granted by us may reduce the profitability of our sales of Triferic;

- 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;

- Competitors may engage in aggressive marketing and pricing practices and other tactics to retain their market share;

- Avoidance of 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.

An adverse development with respect to any of the foregoing may have a material adverse effect on our ability to manufacture and market Triferic. We cannot assure you that we will be able to generate significant 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 of no value, our inventory of finished product may expire or become obsolete

(resulting in write-offs of such inventory), our licensing rights could be materially adversely affected and the price of our common stock could substantially decline. Even if we are successful in commercializing Triferic, due to the highly concentrated nature of the market, our continued success may depend on adoption of Triferic by the limited number of existing dialysis providers.

If we are unable to use our Triferic inventory before its shelf life expires, we will likely have to write-off such inventory, which will likely have a material adverse effect on our business, results of operations, financial position and cash flows.

We cannot predict when or if we will secure transitional separate reimbursement for Triferic or future usage of Triferic. As of December 31, 2017, we had invested approximately $13.5 million in Triferic inventory, including approximately $8.5 million in Triferic's active pharmaceutical ingredient and $5.0 million in finished goods inventory. We recorded an inventory reserve of $3.5 million related to our Triferic finished goods inventory. As a result of this reserve, our total Triferic inventory had a net book value of $10.0 million as of December 31, 2017. The Triferic inventory has an initial shelf life ranging from one to three years. If we are unable to utilize some or all of our Triferic inventory before its shelf life expires, some or all of our investment in Triferic inventory may not be saleable, reducing the inventory we have available for sale, requiring us to reserve for the reduction in value and likely requiring us to write-off the value of such inventory. We may also need to reserve for inventory that we estimate will not be sold before such inventory expires. Any such inventory reserve could have a material adverse effect on our business, results of operations and financial position.

Our ability to market Triferic and other FDA-approved drugs 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 Triferic and our other drug products.

Any new indication for an approved product requires FDA approval. Triferic is approved by the FDA for use in adult patients receiving hemodialysis treatments and has not yet been approved for other indications. We are not able to promote the products or encourage our customers to use the products for purposes other than those indications of use that are specifically approved by the FDA as safe and effective. If we are not able to obtain FDA approval for additional indications for Triferic, our ability to take full advantage of Triferic's market opportunity 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 an 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, debarment, exclusion and criminal prosecution. Any of these events could materially harm our business.

If we are unable to obtain and maintain adequate protection for our data, intellectual property and other proprietary rights, our business may be harmed.

Our success depends in part on our ability to obtain and defend patent and other intellectual property rights that are important to the commercialization of our drug products and drug candidates. The degree of patent protection that will be afforded to our products and processes in the U.S. and in other important markets remains uncertain and is dependent upon the scope of protection decided upon by the patent offices, courts, administrative bodies and lawmakers in these countries. We can provide no assurance that we will successfully obtain or preserve patent protection for the technologies incorporated into our products and processes, or that the protection obtained will be of sufficient breadth and degree to protect our commercial interests in all countries where we conduct business. If we cannot prevent others from exploiting our inventions, we will not derive the benefit from them that we currently expect. Furthermore, we can provide no assurance that our products will not infringe patents or other intellectual property rights held by third parties.

We also rely on regulatory exclusivity for protection of our products. Implementation and enforcement of regulatory exclusivity, which may consist of regulatory data protection and market protection, varies widely from country to country. Failure to qualify for regulatory exclusivity, or failure to obtain or maintain the extent or duration of such protections that we expect in each of the markets for our products due to challenges, changes or interpretations in the law or otherwise, could affect our revenues for our products or our decision on whether to market our products in a particular country or countries or could otherwise have an adverse impact on our results of operations.

Litigation, interferences, oppositions, inter partes reviews, administrative challenges or other similar types of proceedings are, have been and may in the future be necessary in some instances to determine the validity and scope of

certain of our proprietary rights, and in other instances to determine the validity, scope or non-infringement of certain patent rights claimed by third parties to be pertinent to the manufacture, use or sale of our products. We may also face challenges to our patent and regulatory protections covering our products by third parties, including manufacturers of generics and biosimilars that may choose to launch or attempt to launch their products before the expiration of our patent or regulatory exclusivity. Litigation, interference, oppositions, inter partes reviews, administrative challenges or other similar types of proceedings are unpredictable and may be protracted, expensive and distracting to management. The outcome of such proceedings could adversely affect the validity and scope of our patent or other proprietary rights, hinder our ability to manufacture and market our products, require us to seek a license for the infringed product or technology or result in the assessment of significant monetary damages against us that may exceed amounts, if any, accrued in our financial statements. An adverse determination in a judicial or administrative proceeding or a failure to obtain necessary licenses could prevent us from manufacturing or selling our products. Furthermore, payments under any licenses that we are able to obtain would reduce our profits derived from the covered products and services.

Defending our proprietary rights could be expensive, we may not always be successful in protecting our intellectual property, licenses and other proprietary rights and we could be prevented from selling products, forced to pay royalties and damages and compelled to defend against litigation if we infringe the rights of a third party.

Our success, competitive position and future revenues, particularly with respect to our drug products, will depend in part on our ability to obtain and maintain proprietary 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. There can be no assurance that these protections will prove commercially valuable.

We could incur substantial costs in seeking enforcement of our proprietary rights, and we cannot guarantee that we will prevail in any legal action seeking enforcement or that such rights will successfully preclude others from using technology that we rely upon. It is possible that we may infringe on proprietary rights of others, even if we are not aware of the infringement or believe our rights are otherwise valid. If a third party believes that one of our products infringes on the third party's rights, it may sue us even if we have received our own patent protection for the technology or otherwise believe we have valid proprietary rights. If we are found by a court to have infringed the rights of a third party, we could be prevented from manufacturing and selling products, forced to pay royalties and damages, compelled to license technology from the party claiming infringement and lose the opportunity to license our technology to others and collect royalty payments, any of which could have a material adverse effect on our business. In addition, if Baxter is prevented from selling 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.

We depend on contract manufacturing organizations to manufacture our drug products. If these organizations are unable or unwilling to manufacture our drug products, or if these organizations fail to comply with FDA or other applicable regulations or otherwise fail to meet our requirements, our drug business will be harmed.

We rely on CMOs to make Triferic and Calcitriol. If any are unable to make the product in sufficient quantities and on a consistent basis, or if they become unwilling to produce the product for us, we may not be able to supply our customers with product in a timely manner. The facilities and processes used by these CMOs to manufacture our drug products must be approved by the FDA and, where applicable, foreign regulators before the commercial products can be sold that were produced at a particular facility using a particular process. Even if approved, certain ongoing regulatory requirements for product testing and stability of our commercially marketed products must be met. We do not control the manufacturing processes of, and are dependent upon, these CMOs for compliance with current good manufacturing practices, referred to as cGMPs, and obtaining and maintaining their regulatory approval. If approval for a CMO is not received or ongoing testing does not continue to meet approved standards such that approval is withdrawn, the CMO's production would be delayed or suspended and we may be forced to find another capable CMO and/or shift production to another CMO that is already approved and under contract with us. Any such circumstance could significantly hamper our ability to supply our customers in a timely manner, which may have a material adverse effect on our business, results of operations, financial position and cash flows.

We rely on third party suppliers for raw materials and packaging components of our drug products. We may not be able to obtain the raw materials and proper components we need, or the cost of the materials or components may be higher than expected, any of which could impair our production or commercialization of drug products and have a material adverse effect on our business, results of operations and financial position.

We may not be able to obtain needed raw materials or packaging components, or the price of such materials or components may rise significantly, for a variety of reasons, including among others:

- Business interruption, such as due to a force majeure, cyber attack or labor strike at a supplier;
- Regulatory requirements or action by regulatory agencies or others against a supplier, including delays in receiving necessary approvals ;
- A supplier's failure to comply with cGMP standards which results in quality or product failures, adulteration, contamination and/or recall ;
- Adverse financial or other strategic developments at or affecting a supplier;
- Termination of the supply contract by a supplier;
- Unexpected demand for or shortage of raw materials or packaging components; and
- Unexpected increases in our product demand.

Some of the suppliers for our raw materials or packaging components may be single-source suppliers. Finding an alternative source can be expensive and take a substantial amount of time, especially when regulatory approval is required to qualify the supplier. If we are unable to obtain our raw materials and components and are not able to establish alternative supply sources, or if the prices for our raw materials or packaging components increase substantially, our CMOs may not be able to produce the desired quantities of our drug products or our expected gross profit margins may be materially adversely affected, any of which could be costly to us and have a material adverse effect on our business, results of operations, financial position and cash flows.

We may not be successful in obtaining foreign regulatory approvals or in arranging out-licensing partners capable of obtaining the approvals needed to effectively commercialize our drug products outside of the United States. Even if we are successful in out-licensing our drug products and obtaining the required regulatory approvals, the licensees or partners 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, should we attempt to develop international markets ourselves 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 is to license the rights to our drugs in markets outside the United States to partners who have resources to obtain regulatory approval. However, we may not be successful in finding partners in addition to those currently under contract, who will be willing to invest in our drugs outside the United States or our partners may be unable to obtain the necessary regulatory approvals. If we are not successful in out-licensing our drugs outside of the United States or entering into other arrangements with partners capable of obtaining the necessary regulatory approvals to commercialize our drug products, 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 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.

If our products are approved and marketed outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.

We may be subject to additional risks if our products are approved and marketed outside of the United States, including:

- Reduced protection for intellectual property rights;
- Unexpected changes in tariffs, trade barriers and regulatory requirements;
- Economic weakness, including inflation, or political instability in particular foreign economies and markets;
- Foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country; and
- Business interruptions resulting from geopolitical actions, including war and terrorism or natural disasters including earthquakes, typhoons, floods and fires.

We may not be successful in expanding our drug 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 drug 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. 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 at all, or result in an arrangement that will enable us to effectively integrate, develop and launch such products effectively.

In addition, the market potential for new drug products is highly uncertain and evaluation of such potential requires significant judgment and assumptions. There is a significant risk that any new drug product may not be able to be brought to market as profitably as expected or at all. If the results of any new drug product initiative are materially worse than expected, it could have a material adverse effect on our business, results of operations, financial position and cash flows.

Expansion of our drug business in the United States may require FDA approval of new drug candidates or indications for use. The process of obtaining FDA approval is a long and expensive process with no guarantee of success.

Expansion of our drug business will be dependent, in part, on our ability to successfully and timely develop, obtain regulatory approval for, and commercialize new drug candidates. The process of performing clinical trials for a potential new drug, filing an NDA with the FDA and receiving a decision from the FDA is expected to take several years, with no guarantee of approval. Clinical trials typically take years to complete and early promising clinical trial results may not necessarily be indicative of later results or demonstrate sufficient safety and efficacy to support an NDA filing. Clinical trials and the NDA approval process for any new drug candidate are also very expensive. Similarly, the FDA approval process for a new indication of Triferic would require us to pay substantial review fees, may require clinical trials and could take years to complete.

There is no guarantee the FDA will approve our new drug candidates. Once trials are completed and the NDA is submitted to the FDA, the FDA may find deficiencies that raise safety or efficacy concerns or may otherwise require additional clinical testing or impose other requirements, which could significantly delay approval or result in us not receiving approval at all. In addition, varying interpretations of the data obtained from testing could delay, limit or

prevent regulatory approval. If approval is not granted for any new products or new indications submitted for approval, our entire investment in the related products may be worthless, any licensing rights could be forfeited and our business could be materially adversely affected.

Our drug business depends 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. Congress continuously enacts a variety of changes to health insurance and reimbursement, some of which 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 business, results of operations, financial position 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, results of operations, financial position and cash flows.

The Trump administration and members of the U.S. Congress have introduced legislation in both the House of Representatives and Senate to repeal and/or replace all or part of the Patient Protection and Affordable Care Act, or PPACA, including potential changes or repeal of the Medicaid expansion, coverage for pre-existing coverages and insurance coverage minimum benefits. The likelihood of passage and the impact of this legislation is uncertain, but could potentially impact reimbursement by the Medicare and Medicaid programs for our drug products and dialysis and the ability of certain individuals to obtain coverage. Other federal and state healthcare reform measures could be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, or change the methods used by Medicare and Medicaid to reimburse providers, including the “bundled” payment model and the availability of transitional separate reimbursement, any of which could result in reduced demand for our products once approved or pricing pressures.

As a result of these changes to Medicare and Medicaid 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.

It may be difficult for us to capture market share for Calcitriol in the highly competitive generic drug market.

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-type product, which could have a material adverse effect on our future results of operations. Branded competitors may aggressively lower their prices to maintain market share. Dialysis service providers may seek alternative forms of treatment for this indication. Any of these outcomes could have an adverse effect on our ability to successfully commercialize Calcitriol.

Inventory obsolescence due to finite shelf lives could adversely affect our business.

To provide a high level of product availability to our distributors and customers, we generally maintain a considerable inventory of certain of our products. Our inventories of both raw materials and finished goods have finite shelf lives. If we overestimate the demand for our products or carry inventory in anticipation of certain future events, including the approval of reimbursements, we could experience significant write-downs of our inventory due to obsolescence. Such write-downs could have a material adverse effect on our business, results of operations and financial position.

We may not be able to commercialize our drug products without significant additional expenditures.

Our success, competitive position and future revenues, particularly with respect to our drug products, will depend, in part, on the effectiveness of our marketing and sales strategies and implementation of our commercialization efforts including our ability to execute our marketing strategy. Due to the concentrated nature of our customers, we expect to market our drug products using a team of skilled individuals, led and directed by our Chief Executive Officer who will handle much of the sales effort with our major accounts. As a result, we may not have sufficient sales and implementation resources in place to fully take advantage of any opportunities we may have to commercialize our drug products, and our sales and results of operation could fail to achieve our desired goals and objectives for sales and market penetration. Furthermore, we may need to add significant additional sales and implementation resources to achieve our desired goals and objectives.

RISKS RELATED TO OUR CONCENTRATE BUSINESS

We may be required to repay a portion of the upfront 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 includes, among other things, termination due to an uncured material breach by us. A Refund Trigger Event would obligate us to refund $6.6 million of the $20 million upfront fee (and any portion of the West Coast facility fee that may have been paid by Baxter) if termination occurs in 2018, and $5.0 million of the $20 million upfront fee (and any portion of the West Coast facility fee that may have been paid by Baxter) if termination occurs in 2019, 2020 or 2021.

If Baxter terminates the Distribution Agreement because it has been enjoined by a court of competent jurisdiction from selling in the United States 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. In any such event, our financial condition, results of operations, and cash reserves could be materially and adversely affected.

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 business, results of operations, financial position and cash flows.

Sales of our products are highly concentrated in a few customers. One customer accounted for nearly half of our sales in each of the last three years and for a substantial number of the clinics we serve. The loss of any of these significant customers could have a material adverse effect on our business, results of operations, financial position and cash flows.

We provided Baxter with certain pricing concessions to provide Baxter with incentive to increase its domestic concentrate business. Baxter may not be successful in increasing its domestic concentrate business. If Baxter is not successful in increasing its concentrate business, we may realize lower operating profit from concentrates as a result.

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

The primary competitor in the market for our concentrate products is Fresenius Medical Care NA, a large diversified company which has substantial financial, technical, manufacturing, marketing, research and management resources. We and our distributor, Baxter, may not be able to successfully compete with it. Fresenius has historically used product bundling and low pricing as a competitive strategy to capture market share of the concentrate products we sell. We and Baxter may be at a disadvantage in competing against its strategies to sell concentrate products. Furthermore, Fresenius is vertically integrated and is the largest provider of dialysis services in the United States, treating approximately 36% of all U.S. patients through its clinics. Fresenius has routinely acquired smaller clinic chain operations which we supply through Baxter, and it may acquire more of our customers in the future.

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 United States 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 has the option to terminate the Distribution Agreement and obtain a refund of a portion of the fees we received from Baxter. Any such termination or refund could have a material adverse effect on our business, results of operations, financial position and cash flows.

RISKS RELATED TO OUR BUSINESS AS A WHOLE

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

Our businesses are highly regulated. The testing, manufacture and sale of the products we manufacture directly or through third party CMOs 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 premarket 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 CMOs 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 non-compliant inventory is sold or 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. Our business could also be adversely affected by delays in obtaining necessary regulatory approvals and any restrictions placed by the DFA on our intended marketing or the use of our products.

Our failure to comply with applicable regulations could also result in product liability litigation against us. In addition, our failure to comply with respect to our concentrate products could constitute a breach by us of the Distribution Agreement, providing Baxter with various remedies that would be material and adverse to us. Moreover, changes in applicable regulatory requirements could significantly increase the costs of our operations, which, 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.

Our business could be impacted as a result of actions by activist shareholders, including as a result of a potential proxy contest for the election of directors at our annual meeting.

The Company was subjected to a proxy contest at the 2017 Annual Meeting of Shareholders (the "2017 Proxy Contest"), which resulted in the negotiation of changes to the Board of Directors and substantial costs were incurred. Ultimately, on November 22, 2017, the Company entered into a Settlement and Standstill Agreement (the "Standstill Agreement") with Richmond Brothers, Inc. ("RBI"), Mark H. Ravich, who currently serves as a director of the Company, and the other persons identified therein, to settle claims made by the parties in an action filed in the United States District Court for the Eastern District of Michigan arising in connection with the 2017 Proxy Contest. Among other items, the Settlement Agreement provided that the Board of Directors would add one additional director by

February 15, 2018 (the "Additional Director"), and in the event the Board of Directors did not add the Additional Director by that date, the persons identified in the Settlement Agreement as the "Richmond Group" would be entitled to nominate directors by February 28, 2018 for election at the 2018 Annual Meeting of Shareholders (the "2018 Meeting"). Our Board was unable to appoint the Additional Director by February 15, 2018. Accordingly, on February 27, 2018, RBI and David S. Richmond ("Richmond") delivered a letter to the Company nominating Lisa Colleran, Benjamin Wolin and Richmond for election to the Board of Directors at the 2018 Meeting. Thereafter, on March 7, 2018, we entered into a letter agreement with RBI and Richmond to memorialize the parties' mutual agreement on certain corporate governance matters (the "Letter Agreement"). The Letter Agreement provided, among other things, that: (a) by March 7, 2018, the Company's Board would increase the size of the Board from six directors to eight directors and would appoint: (i) Benjamin Wolin as (A) a Class I director to serve for a term expiring at the Company's 2019 Annual Meeting of Shareholders and (B) the lead independent director of the Board; and (ii) Lisa Colleran as a Class II director to serve for a term expiring at the Company's 2020 Annual Meeting of Shareholders; and (b) if the Company complied with the provisions of the Letter Agreement by March 7, 2018, then RBI would withdraw its proposal to separately nominate any directors for election at the 2018 Meeting. As a result, on March 9, 2018, RBI and Richmond withdrew their proposal to separately nominate directors for election at the 2018 Meeting.

A future proxy contest would require us to incur significant legal fees and proxy solicitation expenses and require significant time and attention by management and the Board of Directors. The potential of a proxy contest could interfere with our ability to execute our strategic plan, give rise to perceived uncertainties as to our future direction, adversely affect our relationships with customers, suppliers, investors, prospective and current team members and others, result in the loss of potential business opportunities or make it more difficult to attract and retain qualified personnel, any of which could materially and adversely affect our business and operating results.

We may also be subject, from time to time, to other legal and business challenges in the operation of our company due to actions instituted by activist shareholders. Responding to such actions, which may include publicity campaigns and, potentially, litigation, could be costly and time-consuming, divert the time and attention of our Board of Directors and management from our business, interfere with our ability to execute our strategic plan, give rise to perceived uncertainties as to our future direction, adversely impact our lobbying efforts, adversely affect our relationships with customers, suppliers, prospective and current team members and others, result in the loss of potential business opportunities or make it more difficult to attract and retain qualified personnel, any of which could materially and adversely affect our business and operating results. Disruption caused by a proxy contest could result in a negative impact on our efforts to obtain separate reimbursement for Triferic. We cannot predict, and no assurances can be given as to, the outcome or timing of any matters relating to actions by activist shareholders or the ultimate impact on our business, results of operations, financial position and cash flows.

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.

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 us directly or indirectly through the customers of our products. Our business, results of operations, financial position and cash flows and ability to commercialize our drug products could be materially adversely affected by the PPACA, future health care reform or reduced Medicare and Medicaid spending by the federal government. Legislative and administrative efforts to repeal or modify the PPACA are underway and in January 2017, President Trump signed an Executive Order directing federal agencies with authority and responsibility under PPACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the PPACA that would impose a fiscal or regulatory burden on states, individuals, health care providers, health insurers, or manufacturers of pharmaceuticals or medical devices. We cannot predict how repeal or replacement of PPACA, the Executive Order or other health care reform will affect our business and any such changes could substantially modify the methodology for reimbursing medical services, drugs and devices or the number of patients eligible for reimbursement or otherwise adversely affect our ability to successfully develop and commercialize our products.

Device and pharmaceutical manufacturers are required to report annually to the Department of Health and Human Services regarding certain financial relationships they have with physicians and teaching hospitals. This reporting requirement imposes governmental scrutiny on our contractual relationships with physicians and teaching hospitals and creates risk that inadvertent violations will result in liability under the federal fraud and abuse laws, which could have a material adverse effect on our business, results of operations, financial position and cash flows.

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

Our success depends upon the efforts of Robert L. Chioini, our founder and Chief Executive Officer, Dr. Raymond D. Pratt, our Chief Medical Officer, Dr. Ajay Gupta, our Chief Scientific Officer and Thomas E. Klema, our Chief Financial Officer, Secretary and Treasurer. Mr. Chioini is primarily responsible for making major corporate decisions, managing the overall operations and resources of the Company and leading the development and execution of the Company's long term strategy. Mr. Chioini has lead our government affairs efforts and has been the primary interface with Congress, Health & Human Services and CMS in Washington. Mr. Chioini also leads and directs our sales and marketing efforts with our key accounts. Dr. Pratt is primarily responsible for the clinical development, testing and regulatory approval of our products. Dr. Gupta is primarily responsible for discovery and development of new technologies. If we lose the services of Mr. Chioini, Dr. Pratt, Dr. Gupta or Mr. Klema, our business, customer relationships, government affairs efforts, product development efforts, financial condition and results of operations could be adversely affected.

Defending our intellectual property rights could be expensive, we may not always be successful in protecting our exclusive rights and 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, particularly with our drug products, 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. 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 manufacturing and selling products, forced to pay damages, compelled to license technology from the party claiming infringement and lose the opportunity to license our technology to others and collect royalty payments, any of which could have a material adverse effect on our business. If Baxter is prevented from selling 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.We may be subject to claims that our consultants or independent contractors have wrongfully used or disclosed alleged trade secrets of their other clients or former employers to it.

As is common in the biotechnology and pharmaceutical industry, we engage the services of consultants to assist us in the development of our product candidates. Many of these consultants were previously employed at, may have previously been, or are currently providing consulting services to, other biotechnology or pharmaceutical companies, including our competitors or potential competitors. As such, the Company advises consultants not to disclose, or use trade secrets, or proprietary information of their former employers or their former or current customers. Although no claims against us are currently pending, we may be subject to claims that these consultants or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers or their former or current customers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management and day-to-day business operations.

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 us by private litigants.

We maintain product liability insurance. 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 business reputation and marketing ability. Any such sanctions or litigation could also hurt our ability to retain product liability insurance or make such insurance more expensive. In any such event, our business, results of operations, financial position and cash flows could be materially adversely affected.

Our business and operations would suffer in the event of a security breach, system failure, invasion, corruption, destruction or interruption of our or our business partners' critical information technology systems or infrastructure.

In the ordinary course of business, we and our business partners store sensitive data, including intellectual property, proprietary business information, proprietary information of our customers and business partners in information technology systems and those of our current CMOs and other current or future contractors and consultants. Despite the implementation of security measures, these systems are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures due to employee error, malfeasance or other disruptions. We could experience a business interruption, intentional theft of confidential information or reputational damage from espionage attacks, malware, ransomware or other cyber-attacks, which may compromise our system infrastructure or lead to data leakage, either internally or at our contractors or consultants. While we have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our manufacturing activities and business operations. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could be subject to legal claims or proceedings, liability under personal privacy laws and regulatory penalties. In any such event, our business, results of operations, financial position and cash flows could be materially adversely affected.

We use biological and hazardous materials, and any claims relating to improper handling, storage or disposal of these materials could be time consuming or costly.

We use hazardous materials, including chemicals and biological agents and compounds, which could be dangerous to human health and safety or the environment. Our operations also produce hazardous waste products. Federal, state and local laws and regulations govern the use, generation, manufacture, storage, handling and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our pharmaceutical development efforts.

In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. If one of our employees was accidentally injured from the use, storage, handling or disposal of these materials or wastes, the medical costs related to his or her treatment would be covered by our workers' compensation insurance policy. However, we do not carry specific biological or hazardous waste insurance coverage and our property and casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could

be held liable for damages or penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended, or operations otherwise affected.

Our existing capital resources may not be adequate to finance our operating cash requirements for the length of time that we have estimated.

Our forecast of the period of time through which our existing capital resources will be adequate to support our current operations is a forward-looking statement that involves risks and uncertainties. The actual amount of funds we will need to operate is subject to many factors, some of which are beyond our control. These factors include, but are not limited to: (i) the timing and expenditures associated with the domestic and international commercialization of Triferic and Calcitriol and the timing and magnitude of cash received from product sales; (ii) the timing and expenditures associated with the build-up of inventory; (iii) the timing, design and conduct of, and results from, clinical trials that we may conduct; and (iv) the timing of the licensing, partnering and acquisition of new product opportunities. If our cash is insufficient to meet our future operating requirements, we will have to raise additional funds. Our capital raising activities may include, but may not be limited to, the issuance of common stock or other securities via private placement or public offerings or the issuance of debt. While we may seek capital through a number of means, there can be no assurance that additional financing will be available on acceptable terms, if at all. Furthermore, additional equity financings may be dilutive to our stockholders and debt financing, if available, may involve significant cash payment obligations and covenants that restrict our ability to operate as a business.

We may be unable to obtain secured debt financing in the future as a result of our Distribution Agreement 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 obtain this type of debt financing, our business and our future development and expansion strategies may be adversely affected.

Any adverse conclusions from our SEC inquiry could result in fines, criminal penalties and an adverse effect on our business.

We received letters dated February 13, 2017 and April 5, 2017 from the SEC informing us that the SEC was conducting an inquiry into our accounts receivable and inventory, calculation practices regarding such information, as well as disclosure regarding our dispute with Baxter and requesting that we voluntarily provide certain information and documents relating to our accounts receivable and inventory calculations and reporting practices, as well as information relating to the Baxter dispute. The SEC's letters stated that the SEC's inquiry should not be construed as an indication that any violation of any federal securities laws has occurred. We provided all of the requested information and documents to the SEC in March and April of 2017 and intend to continue to fully cooperate with the SEC inquiry. At this stage, we are unable to predict when the SEC's inquiry will conclude or what the consequences may be. We believe we are in compliance with all federal securities laws related to our accounts receivable and inventory calculations practices, as well as our disclosures regarding the Baxter dispute, which was settled in June of 2017. Nevertheless, any continuation of the SEC inquiry may cause a diversion of management's time and attention, which could have a material adverse effect on our business, results of operations, financial position and cash flows.

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, 2017, there were 6,333,168 shares issuable upon the exercise of the then-outstanding and exercisable stock options and 572,833 shares issuable upon the exercise of then-outstanding stock options that were not yet exercisable. 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 specialty pharmaceutical, 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.

Our ability to use our net operating loss carryforwards to offset potential taxable income and related income taxes that would otherwise be due may be limited.

We have substantial net operating loss carryforwards, or NOLs, available to reduce future taxable income. Our ability to use our NOLs to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income before the expiration dates of the NOLs. In addition to uncertainty regarding our future profitability, our use of the NOLs may be subject to annual limitations under the “ownership change” provisions of Section 382 of the Internal Revenue Code of 1986, as amended, which may result in the expiration of some or all of the NOLs before they can be used. In general, an “ownership change” occurs if, during a rolling three-year period, there is a greater than 50% change in the percentage ownership of the corporation by 5% owners (and persons treated as 5% owners), as defined in Section 382 and related regulations. We may experience an ownership change in the future as a result of future changes in our stock ownership. The inability to use our NOLs to reduce federal taxable income could result in increased future tax liability to us and reduce the cash that would otherwise be available to our business.

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, or ICFR, as of the end of each year, and to include a management report assessing the effectiveness of our ICFR in each Annual Report on Form 10-K. It is possible that we may identify control deficiencies in the future that constitute one or more material weaknesses. If our ICFR or disclosure controls and procedures are not effective, there may be errors in our financial statements and in our disclosure that could require restatements of our financial statements. In addition, if a restatement were to occur, investors may lose confidence in our reported financial information and in our disclosures, which could lead to a decline in our stock price.

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

Our Board of Directors has the authority, without shareholder approval, to issue shares of preferred stock, or rights to acquire preferred stock, having such rights, preferences and privileges our Board of Directors may determine. Any such issuance or potential 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 or our Board may take other actions which might also hinder or delay a change in control. Any such actions 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 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 only be removed for cause by a shareholder vote. 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 also 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 lease a 51,000 square foot facility and a 17,500 square foot facility in Wixom, Michigan under a lease expiring in August 2018. We also lease a 51,000 square foot facility in Grapevine, Texas under a lease expiring in December 2020. In addition, we lease a 57,000 square foot facility in Greer, South Carolina under a lease expiring in February 2020.

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.

Baxter Arbitration

On September 12, 2016, Baxter initiated an arbitration proceeding against us under the Distribution Agreement. Baxter alleged that we had breached the Distribution Agreement in various respects associated with our dealings with customers, our allocation of expenses and our true-up notices, and by improperly threatening to build a West Coast facility. Baxter sought declaratory relief giving Baxter the right to terminate the Distribution Agreement and recover up to $10 million of the upfront fee, injunctive relief to prevent us from establishing a West Coast facility, and unspecified damages.

We filed a response denying all of Baxter's claims of breach and wrongdoing, and counterclaimed that Baxter was itself in breach of the Distribution Agreement for failing to pay substantial accounts receivable and for repudiating its obligation to pay the West Coast facility fee of up to $10 million. We sought damages, declaratory, injunctive and other equitable relief, as well as interest, costs and attorney fees.

In addition, in October 2016, we gave notice to Baxter that it breached the minimum purchase requirement for the contract year ended October 2, 2016 and that we intended to cause our distribution rights to become non-exclusive unless Baxter cured the shortfall within the 30-day period specified in the Distribution Agreement. Baxter disputed the existence of a breach and failed to cure the deficiency. We subsequently provided Baxter with notice of loss of exclusivity due to its failure to cure as provided in the Distribution Agreement.

On June 23, 2017, we settled the arbitration with Baxter (the "Settlement"). The Settlement included a mutual release with respect to all known claims existing on the date of the Settlement and the arbitration was dismissed with prejudice. No payments were made by either party in connection with the Settlement.

In connection with the Settlement, on June 23, 2017, we entered into a First Amendment to Exclusive Distribution Agreement and a First Amendment to Investment Agreement, in each case, with Baxter. The terms of the Settlement included, among other things, reduced pricing on certain accounts that provides incentive to Baxter to pursue new customers and increase future sales. Our Settlement with Baxter is not expected to have a material impact on our business, results of operations, financial position or cash flows.

Richmond/Ravich Litigation

On March 8, 2017, we filed suit in the United States District Court for the Eastern District of Michigan against Richmond Brothers, Inc. and certain related entities, David S. Richmond, Mark H. Ravich and certain related trusts, Matthew J. Curfman ("Richmond/Ravich Defendants"), and three individual Rockwell shareholders: Jay F. Joliat, Chris Paxos and David Hagelstein (together with the "Richmond/Ravich Defendants," the "Rockwell Shareholders). Subsequently, we voluntarily dismissed our claims against two of the individual shareholders, Chris Paxos and David Hagelstein pursuant to settlement agreements with each of them. Our complaint alleged that the Rockwell Shareholders failed to timely file a Schedule 13D identifying themselves as a shareholder group and that Schedules 13D ultimately filed by the Richmond/Ravich Defendants contained various material misstatements and omissions, in violation of Section 13(d) of the Securities Exchange Act of 1934 (the "Exchange Act"), as amended, and the rules promulgated thereunder by the Securities and Exchange Commission. The complaint sought declaratory and injunctive relief relating to these alleged violations, including requiring the Rockwell Shareholders to file new or amended Schedules 13D disclosing the proper date of their shareholder group's formation and providing accurate information about the group's membership and activities, and issuing a declaratory judgment finding that the Rockwell Shareholders violated Section 13(d) of the Exchange Act.

On June 28, 2017, the Court denied the Richmond/Ravich Defendants' motion to dismiss this case, in which Defendant Jay F. Joliat had joined. On August 24, 2017, the Richmond/Ravich Defendants answered the Complaint, and Defendant Mark H. Ravich asserted counterclaims against us alleging that he was denied access to corporate books, not properly notified of a Board of Directors meeting, and that certain settlement agreements with former Defendant David Hagelstein and an unrelated third party violated Michigan law. On September 19, 2017, we moved for leave to amend the Complaint to add allegations regarding misstatements in the Richmond/Ravich Defendants' Schedule 13(d) concerning the voting power of Richmond Brothers, Inc. and Mr. Richmond. The Richmond/Ravich Defendants opposed this Motion. On September 28, 2017, we moved to dismiss Counts II-IV of Defendant Ravich's Counterclaims.

On November 22, 2017, we entered into a Settlement and Standstill Agreement with the Richmond/Ravich Defendants (the "Standstill Agreement") whereby the Richmond/Ravich Defendants agreed to support our recommendations and nominations in connection with any meeting of shareholders, including the 2018 Annual Meeting of shareholders (the "2018 Meeting") through December 31, 2018, and we agreed to add a seventh, independent director to our Board of Directors by February 15, 2018 and to reimburse the Richmond/Ravich Defendants for certain of their third-party expenses. Pursuant to the Standstill Agreement, we and Richmond/Ravich Defendants each released all claims against one another and jointly submitted a stipulation to the Court seeking to voluntarily dismiss the lawsuits. On November 30, 2017, the Court entered a Stipulated Order of Dismissal dismissing the entire case with prejudice.

Our Board of Directors was unable to appoint a seventh director by February 15, 2018. Accordingly, on February 27, 2018, Richmond Brothers, Inc. ("RBI") and David S. Richmond ("Richmond") delivered a letter to us nominating Lisa Colleran, Benjamin Wolin and Richmond for election to the Board of Directors at the 2018 Meeting. Thereafter, on March 7, 2018, we entered into a letter agreement with RBI and Richmond to memorialize the parties' mutual agreement on certain corporate governance matters (the "Letter Agreement"). The Letter Agreement provided, among other things, that: (a) by March 7, 2018, the Company's Board would increase the size of the Board from six directors to eight directors and would appoint: (i) Benjamin Wolin as (A) a Class I director to serve for a term expiring at the Company's 2019 Annual Meeting of Shareholders and (B) the lead independent director of the Board; and (ii) Lisa Colleran as a Class II director to serve for a term expiring at the Company's 2020 Annual Meeting of Shareholders; and (b) if the Company complied with the provisions of the Letter Agreement by March 7, 2018, then RBI would withdraw its proposal to separately nominate any directors for election at the 2018 Meeting. As a result, on March 9,2018, RBI and Richmond withdrew their proposal to separately nominate directors for election at the 2018 Meeting.

Other Proceedings

We are involved in certain other legal proceedings from time to time before various courts and governmental agencies. 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 these 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 2017 and 2016.

	Price Range	
	High	Low
2017		
Fourth Quarter	$ 8.63	$ 5.43
Third Quarter	8.70	6.00
Second Quarter	8.98	6.04
First Quarter	6.80	5.06
2016		
Fourth Quarter	$ 8.37	$ 3.55
Third Quarter	8.45	6.27
Second Quarter	10.58	6.86
First Quarter	10.50	5.47

As of February 28, 2018, there were 30 holders of record of our common shares.

Dividends

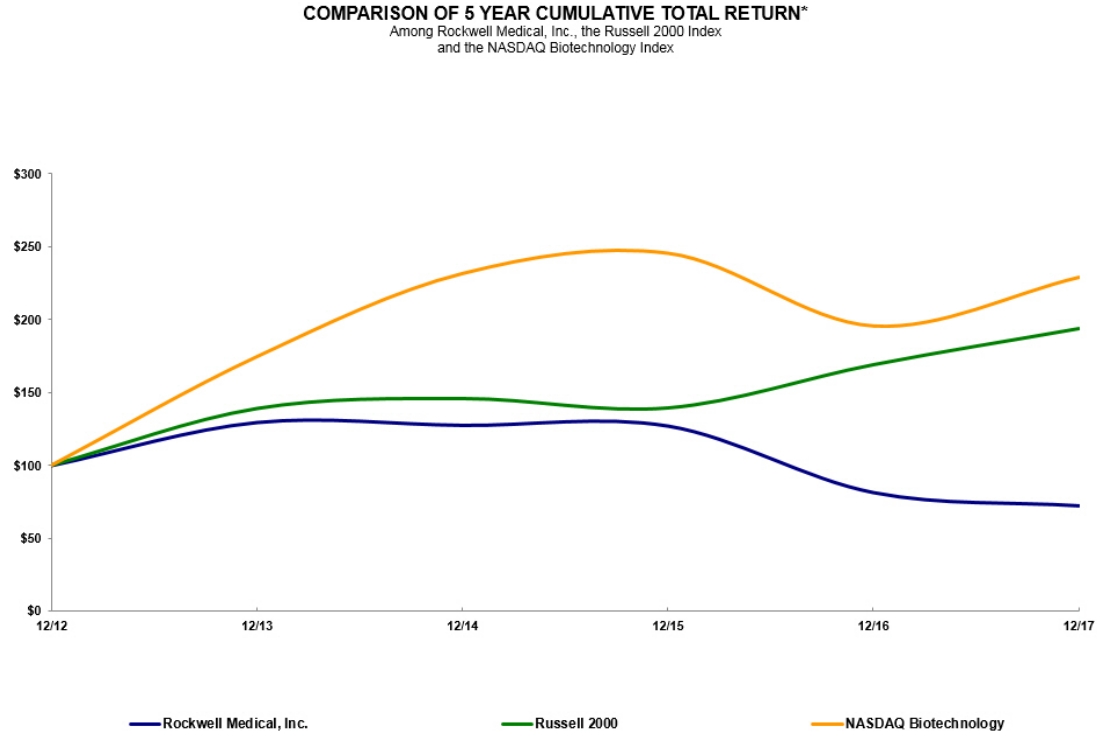
Our Board of Directors has discretion whether or not to pay dividends. Among the factors our Board of Directors considers when determining whether or not to pay dividends are our earnings, capital requirements, financial condition, future business prospects and business conditions. We have never paid 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 our 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, 2012 with relative performance tracked through December 31, 2017. The stock price performance included in this graph is not necessarily indicative of future stock price performance.



	12/31/2012	12/31/2013	12/31/2014	12/31/2015	12/31/2016	12/31/2017
Rockwell Medical, Inc.	**100.00**	**129.69**	**127.70**	**127.20**	**81.37**	**72.30**
Russell 2000	**100.00**	**138.82**	**145.62**	**139.19**	**168.85**	**193.58**
NASDAQ Biotechnology	**100.00**	**174.60**	**231.61**	**245.49**	**195.54**	**229.01**

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,				
	2017	2016	2015	2014	2013
Net sales	$ 57,300,281	$ 53,284,166	$ 55,350,702	$ 54,188,444	$ 52,379,543
Cost of sales	53,598,390	46,531,648	46,412,848	45,643,231	45,720,323
Gross profit	3,701,891	6,752,518	8,937,854	8,545,213	6,659,220
Income from continuing operations before interest expense and income taxes	(25,922,918)	(20,208,729)	(15,102,326)	(17,559,101)	(47,059,266)
Interest (expense) and Investment Income, net	892	810,340	681,876	(3,768,056)	(1,724,046)
Foreign Currency Gain (Loss)	742	—	—	—	—
Income from continuing operations before income taxes	(25,921,284)	(19,398,389)	(14,420,450)	(21,327,157)	(48,783,312)
Income taxes	—	404,527	—	—	—
Net income	(25,921,284)	(19,802,916)	(14,420,450)	(21,327,157)	(48,783,312)
Earnings per common share:					
Basic	$ (0.51)	$ (0.39)	$ (0.29)	$ (0.52)	$ (1.48)
Diluted	$ (0.51)	$ (0.39)	$ (0.29)	$ (0.52)	$ (1.48)
Weighted average number of common shares and common share equivalents					
Basic	51,067,412	50,676,180	50,068,129	41,404,999	32,882,333
Diluted	51,067,412	50,676,180	50,068,129	41,404,999	32,882,333

	2017	2016	2015	2014	2013
Total assets	$58,779,640	$83,153,638	$87,822,125	$97,999,716	$36,362,124
Current assets	48,828,318	78,509,195	84,626,316	94,707,149	31,917,774
Current liabilities	9,143,174	10,145,602	8,091,451	9,804,402	17,849,671
Working capital	39,685,144	68,363,593	76,534,865	84,902,747	14,068,103
Long term debt	—	—	—	—	17,916,914
Shareholders' equity(2)	32,913,148	52,956,299	62,319,822	68,702,794	595,539
Book value per outstanding common share	$ 0.66	$ 1.03	$ 1.21	$ 1.37	$ 0.01
Common shares outstanding	51,768,424	51,527,711	51,501,877	50,284,007	40,110,661

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

Overview and Recent Developments

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. In 2017, we supplied approximately 25% of the United States domestic market with dialysis concentrates, and the majority of our sales were in the United States. We also supplied dialysis concentrates to distributors serving a number of foreign countries, primarily in the Americas and the Pacific Rim. Substantially all of our sales in 2017 were concentrate products and related ancillary items.

Our business strategy is developing unique, proprietary renal drug therapies that we can commercialize or out-license, while also expanding our dialysis products business. 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.

Triferic is our lead branded drug. We believe it has the potential to capture significant market share due to its improved clinical and cost-saving benefits. Triferic received FDA approval in 2015, and is the only FDA-approved therapy indicated to replace iron and maintain hemoglobin in adult hemodialysis patients. Triferic received a reimbursement J-code on January 1, 2016. At about that time, we received clarification from CMS that Triferic would be included in the ESRD bundled payment, which initiated our pursuit of separate reimbursement, which is available for new, innovative therapies.

We have been engaged in extensive efforts to obtain approval from CMS for separate reimbursement of Triferic. We have worked with policy makers, Congress and stakeholders within the dialysis industry. We have had in-depth discussions with senior officials within the current administration, key members of Congress, patient advocacy groups and other industry stakeholders regarding the merits of Triferic and why this innovative therapy should receive separate reimbursement. Our efforts have received strong support. We have submitted information to CMS that highlights the improved clinical benefits that Triferic provides to patients, as well as the significant cost savings Triferic delivers to both Medicare and dialysis providers. Notwithstanding our efforts, arguments and expectations, we cannot predict the outcome, or the timing of the CMS review.

Until separate reimbursement is approved for Triferic, we do not anticipate realizing significant revenues from Triferic sales. In the meantime, we continue to make progress in marketing to, and educating our customers about, Triferic and the valuable benefits it delivers by improving patient outcomes and lowering costs. We also continue to provide Triferic to dialysis providers via a drug sample program, receiving favorable response to its positive clinical and cost saving benefits. Our marketing and selling efforts to nephrologists and nurses, as well as to patients, have been well received.

We have built significant inventory of Triferic in anticipation of receiving separate reimbursement status. However, if we are unable to successfully commercialize Triferic and achieve sufficient sales volumes over the next one to two years, we may have to write off a significant portion of our inventory investment in Triferic, which would have an adverse effect on our business, results of operations and financial position. We have classified $6.0 million of Triferic Active Pharmaceutical Ingredient ("API") as non-current inventory as of December 31, 2017. We have produced sufficient supplies of Triferic API to meet expected prospective demand in 2018 and 2019, assuming we can start commercial sales under separate reimbursement status in the first half of 2018. As of December 31, 2017, we also had $5.0 million of Triferic finished goods inventory that could expire within the next twelve months and against which we have reserved $3.5 million and expensed in 2017 as a result of the uncertainty regarding separate reimbursement for Triferic. If CMS does not award separate reimbursement for Triferic or further extends its review of Triferic for separate reimbursement, some or all of our current investment in Triferic finished goods inventory could be written off which would have an adverse impact on our results of operations.

Our global strategy is to license Triferic to key partners to commercialize internationally. We are actively pursuing international licensing opportunities in a number of countries and regions. Additionally, we are continuing

development work on other clinical indications related to iron deficiency that address unmet patient needs and we are evaluating opportunities to in-license other products that will complement our product portfolio.

We are also working to begin marketing Calcitriol, generic injectable vitamin-D, which is manufactured through contract manufacturing organizations ("CMOs"). We received written notice from the FDA in October 2017 that the FDA needed additional time to review the data submitted by us supporting manufacturing changes to Calcitriol. The notice contained no indication by the FDA of any deficiency with the data submitted. We expect to begin marketing Calcitriol following FDA approval of the submission.

We also sell our dialysis concentrates in the United States and certain foreign markets under the Distribution Agreement with Baxter. We receive a pre-defined gross profit margin on our concentrate products sold pursuant to the Distribution Agreement, subject to an annual true-up of costs. As discussed in more detail in Note 6 to our condensed consolidated financial statements, we settled our contractual dispute with Baxter in June of 2017, and, as part of our settlement, reduced pricing on certain accounts was agreed upon that provides incentive to Baxter to pursue new customers and increase future sales.

Results of Operations

For the year ended December 31, 2017 compared to the year ended December 31, 2016

Sales

In 2017, our sales were $57.3 million compared to $53.3 million in 2016, an increase of $4.0 million, or 7.5%. Our domestic concentrate revenue increased $3.6 million, or 7.7 %, compared to 2016. Our international concentrate revenue for 2017 increased $0.4 million, or 5.8%, compared to 2016, due to increased order volumes. We recognized deferred license revenue related to the Baxter Distribution Agreement of $2.1 million in both 2017 and 2016.

Our domestic concentrate revenue increase was partially due to the addition of new business following pricing concessions provided to Baxter in order to increase dialysis concentrate business. Increased pass through billings for delivery services represented approximately 17% of the concentrate business revenue increase with Baxter.

We continue to market to and educate our customers on Triferic while seeking to obtain separate reimbursement status for Triferic. Until the reimbursement issue is resolved with CMS, however, we do not expect our Triferic sales to be significant.

Our drug business revenue was not significant in 2017. We recognized $0.2 million in deferred revenue related to Triferic licensing agreements in 2017.

Gross Profit

Our gross profit was $3.7 million in 2017, a decrease of $3.0 million compared to 2016. Our gross profit margin was 6.5% in 2017, compared to 12.7% in 2016.

Our drug gross profit was a loss of $3.6 million in 2017 compared to a loss of $1.7 million in 2016. Our inventory reserves and write-offs of Triferic finished goods inventory aggregated $3.5 million in 2017, an increase of $2.9 million over 2016. If we do not receive separate reimbursement status for Triferic in the first half of 2018, we will likely need to write-off and reserve against additional amounts of our Triferic inventory. Other expenses associated with our drug products decreased approximately $1.0 million in 2017 over 2016 and included direct operating, regulatory, material, inventory and finished product expenses associated with our drug products.

Our concentrate business gross profit decreased $1.0 million in 2017 compared to 2016 as a result of our settlement with Baxter under which we provided certain pricing concessions on current and prospective business. Business added subsequent to the settlement agreement has been at a lower pricing and margin level than other business. In addition, a significant portion of the revenue increase has been in the form of a pass through of freight costs related to delivery of products under the new contracts. Additionally, we have experienced higher costs to deliver our concentrate products and those higher costs have not been recovered in price increases to certain of our customers.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $23.3 million in 2017 compared to $21.1 million in 2016, an increase of $2.2 million. The increase was primarily due to an increase in legal and professional costs related to litigation, the settlement with Baxter and our contested 2017 annual meeting of shareholders. Equity compensation costs decreased by $3.2 million. Marketing related costs for Triferic increased $0.6 million. We recognized uncollectible accounts receivable of $0.4 million in our settlement with Baxter.

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 $6.3 million and $5.8 million in 2017 and 2016, respectively. Costs incurred in 2017 and 2016 were largely related to testing and development of Triferic for other indications and presentations.

Interest Income, Net

Our net interest and investment income was nominal in 2017 compared to income of $0.8 million in 2016. All of our net interest and investment income was offset by realized losses on repositioning our portfolio during 2017.

Income Tax Expense

We have substantial tax loss carryforwards from our losses in previous years. 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, 2016 compared to the year ended December 31, 2015

Sales

In 2016, our sales were $53.3 million compared to $55.4 million in 2015 a decrease of $2.1 million, or 3.7%. Our domestic concentrate revenue increased $0.1 million, or 0.2 %, compared to 2015. Our international concentrate revenue for 2016 decreased $0.6 million, or 8.0%, compared to 2015 due to lower order volume. Third party contract manufacturing sales decreased $1.6 million compared to 2015 due to the completion of a manufacturing contract in 2015. We recognized deferred license revenue related to the Baxter Distribution Agreement of $2.1 million in both 2016 and 2015.

Gross Profit

Our gross profit was $6.8 million in 2016, a decrease of $2.2 million compared to 2015. Our gross profit margin was 12.7% in 2016 compared to 16.1% in 2015. Gross profit decreased by $1.7 million primarily due to approximately $1.5 million related to direct operating, regulatory, material, inventory and finished product expenses associated with our drug products. We also expensed $0.2 million in value added taxes paid on the $4 million in licensing payments received in connection with the Wanbang agreement. The remainder of the decrease in gross profit was due to lower unit volumes on contract manufacturing sales and on international business.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $21.1 million in 2016 compared to $19.1 million in 2015 an increase of $2.0 million. The increase was primarily due to an increase in non-cash equity compensation charges of $1.5 million related to equity grants in prior years as no equity compensation plan grants were made to directors and officers in 2016 other than a grant to a new director. Other significant cost increases included increased legal fees of $0.7 million related to litigation expenses and increased marketing costs related to Triferic of $0.2 million. The increase was

partially offset by the moratorium on medical device taxes for 2016 and 2017, resulting in a decrease of $0.4 million in 2016 compared to 2015.

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 $5.8 million and $5.0 million in 2016 and 2015, respectively. Costs incurred in 2016 and 2015 were largely related to testing of Triferic and included pharmacokinetic testing of Triferic for use in other indications, pediatric indications of Triferic, peritoneal dialysis, an orphan indication for Triferic, additional presentations of Triferic as well as other testing and development costs.

Interest Income, Net

Our net interest income was $0.8 million compared to net interest income of $0.7 million in 2015.

Income Tax Expense

We recognized approximately $0.4 million in income tax expense in 2016 compared to no income tax expense in 2015. Our income tax expense pertained to foreign income taxes paid related to license payments received under the Wanbang Agreement. The amount of foreign income tax paid can be credited against future United States tax liabilities and carried forward to offset future United States income tax liabilities.

We have substantial tax loss carryforwards from our losses in previous years. 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.

Liquidity and Capital Resources

We believe we currently have adequate capital resources and liquidity to pursue our business strategy in 2018. In addition to operating our concentrate business, our business strategy is centered on developing, marketing and licensing high potential drug products, in particular Triferic. The actual amount of cash that we will need to execute our business strategy is subject to many factors, including, but not limited to, the timing and magnitude of cash received from drug product sales, the timing and expenditures associated with the commercialization of Triferic and Calcitriol, the timing and expenditures associated with the build-up of related inventory and whether, and to what extent, separate reimbursement for Triferic is approved by CMS.

As of December 31, 2017, we had approximately $33.1 million in cash and investments and $39.7 million in working capital. Our uses of cash have primarily been for funding our operating activities. Cash used in operating activities during 2017 was $21.1 million which included research and development of $6.3 million in 2017. Our 2017 operating expenses included substantial amounts for legal and professional fees related to litigation, the settlement with Baxter and the contested 2017 director election which were $2.7 million higher than in 2016.

We have also invested in inventories in preparation for commercial sales of Triferic in anticipation of separate reimbursement of Triferic. As of December 31, 2017, we have invested approximately $10 million in Triferic inventory, including $1.5 million for finished goods presentations of Triferic and $8.5 million in active pharmaceutical ingredient (“API”) of Triferic. We have built substantial inventory of Triferic API, which we believe will be adequate to meet prospective product demand upon CMS awarding a separate reimbursement for Triferic in 2018. We have classified a significant amount of our Triferic API inventory as non-current, which we believe will supply a portion of our future API requirements after 2018. All of the $1.5 million of Triferic finished goods inventory will expire during the second half of 2018. If we are delayed in receiving separate reimbursement for Triferic or if we do not receive separate reimbursement for Triferic, we may need to write-off some or all of our investment in Triferic finished goods inventory which would have a negative impact on our reported results of operations during 2018.

We have no long term debt as of December 31, 2017 and do not expect to incur interest expense in 2017. Our capital expenditures were $1.7 million in 2017 but are not expected to materially exceed depreciation expense in 2018.

We anticipate that our accounts receivable will increase as we increase our drug product sales and that our inventories will increase to a more modest degree, if, and to the extent, we commercialize Triferic and Calcitriol. We also expect to continue investing in research and product development. Our future spending on research and development activities in the year ahead is expected to be in approximately the same range as incurred in the last two years. We believe that we have adequate capital resources to make these investments in accounts receivable, inventory and research and product development. We expect to generate positive cash flow from operations when our drug products generate substantial sales.

We are in discussions with multiple potential business development partners to out-license rights to Rockwell's drug products outside the United States. Such licensing arrangements often include upfront fees, developmental milestone payments and royalties. If such licensing arrangements are negotiated for certain markets, we may receive such consideration in the future in addition to that which we are already entitled to receive under existing agreements. We are also 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.

We are currently using cash to fund our operations and while we believe we have sufficient cash to fund our operations for at least the year ahead, if we are unable to generate sufficient cash from our commercial business activities, we may need to seek additional financing to provide the cash necessary to execute our business strategy, including working capital needs. Our capital raising activities may include, but may not be limited to, the issuance of common stock or other securities via private placement or public offerings or the issuance of debt. While we may seek capital through a number of means, there can be no assurance that additional financing will be available on acceptable terms, if at all. In particular, our distribution agreement with Baxter prohibits us from entering into a contract encumbering the assets used in our concentrate business without the prior written consent of Baxter. Due to the fact that the assets used in our concentrate business currently constitute a substantial portion of the tangible assets we own other than our drug inventory, we may not be able to obtain debt financing without the consent of Baxter. Furthermore, additional equity financings may be dilutive to our stockholders and debt financing, if available, may involve significant cash payment obligations and covenants that restrict our ability to operate as a business.

Contractual Obligations

The following table details our contractual obligations as of December 31, 2017:

	Payments due by period				
Contractual Obligations	**Total**	**Less than 1 year**	**1 - 3 years**	**3 - 5 years**	**More than 5 years**
Operating leases	$ 4,320,190	1,917,356	2,141,513	261,321	—
Purchase obligations	—	—	—	—	—
All other long term liabilities	—	—	—	—	—
Total	$ 4,320,190	$ 1,917,356	$ 2,141,513	$ 261,321	$ —

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.

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, inventory reserves, share based compensation, 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

Our policy is to recognize revenue consistent with authoritative guidance for revenue recognition including the provisions of the Financial Accounting Standards Board Accounting Standards Codification. We recognize revenue when all of the following criteria are met: (i) persuasive evidence of an arrangement exists, (ii) delivery (or passage of title) has occurred or services have been rendered, (iii) the seller's price to the buyer is fixed or determinable, and (iv) collectability is reasonably assured.

Consistent with these guidelines we recognize revenue at the time we transfer title to our products to our customers which generally occurs 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.

We apply judgment as we analyze each element of our contractual agreements to determine appropriate revenue recognition. The terms of our contractual agreements may include milestone payments if specified research and development objectives are achieved, non-refundable licensing fees, milestone payments on sales or royalties from product sales.

When entering into an arrangement, we first determine whether the arrangement includes multiple deliverables and is subject to the accounting guidance in ASC subtopic 605-25, Multiple-Element Arrangements. If we determine that an arrangement includes multiple elements, we determine whether the arrangement should be divided into separate units of accounting and how the arrangement consideration should be measured and allocated among the separate units of accounting. An element qualifies as a separate unit of accounting when the delivered element has standalone value to the customer. Our arrangements do not include a general right of return relative to delivered elements. Any delivered elements that do not qualify as separate units of accounting are combined with other undelivered elements within the arrangement as a single unit of accounting. If the arrangement constitutes a single combined unit of accounting, we determine the revenue recognition method for the combined unit of accounting and recognize the revenue either on a straight-line basis or on a modified proportional performance method over the period from inception through the date the last deliverable within the single unit of accounting is delivered.

Non-refundable upfront license fees are recorded as deferred revenue and recognized into revenue over the estimated period of our substantive performance obligations. If we do not have substantive performance obligations, we recognize non-refundable upfront fees into revenue through the date the deliverable is satisfied. Analyzing the arrangement to identify deliverables requires the use of judgment and each deliverable may be an obligation to deliver services, a right or license to use an asset, or another performance obligation. In arrangements that include license rights and other non-contingent deliverables, such as participation in a steering committee, these deliverables do not have standalone value because the non-contingent deliverables are dependent on the license rights. That is, the non-contingent deliverables would not have value without the license rights, and only we can perform the related services. Upfront license rights and non-contingent deliverables, such as participation in a steering committee, do not have standalone value as they are not sold separately and they cannot be resold. In addition, when non-contingent deliverables are sold with upfront license rights, the license rights do not represent the culmination of a separate earnings process. As such, we account for the license and the non-contingent deliverables as a single combined unit of accounting. In such instances, the license revenue in the form of non-refundable upfront payments is deferred and recognized over the applicable relationship period.

For milestone payments based on sales and for royalties based on sales, we recognize revenue in the quarter that the information related to the sales becomes available and collectability is reasonably assured.

We generally recognize licensing fees over the term of the related license agreement. We received an upfront payment of $4 million pursuant to our license agreement with Wanbang Biopharmaceutical Co., Ltd. in February 2016. Deferred license revenue for our license agreements is being recognized over the term of the license agreement.

The initial payment of $20 million received pursuant to our Distribution Agreement with Baxter in October 2014 has been accounted for 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 recognize other revenues at the time the related fees and or payments are earned.

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.

Inventories

Inventory is stated at the lower of cost or net realizable value. Cost is determined on the first-in first-out (FIFO) method. Our policy is to reserve for our drug product inventory that we determine is unlikely to be sold to, or if sold, unlikely to be utilized by our customers on or before its expiration date.

We evaluate how much of our current inventory we are likely to convert into cash over the next twelve months. If we have inventory that is in excess of our expectations to convert into cash over the next twelve months we will classify such inventory as non-current. We will evaluate such inventory for its net realizable value considering such factors as potential future product sales, marketability and future shelf life.

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.

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.

Tax Cuts and Jobs Act (TCJA) tax reform legislation enacted on December 22, 2017 makes major changes to the U.S. corporate income tax system, including lowering the U.S. federal corporate income tax rate to 21 percent from 35 percent. TCJA resulted in a reduction in the deferred tax asset, before valuation allowance, as a result of the lower corporate income tax rate in the Company's fourth quarter 2017 income tax provision.

New Accounting Pronouncements

New accounting pronouncements are issued by the Financial Accounting Standards Board or other standard setting bodies that are adopted by us as of the specified effective date. Unless otherwise discussed, we believe that the impact of recently issued standards that are not yet effective will not have a material impact on our financial position or results of operations upon adoption. For further discussion on recent accounting pronouncements, please see Note 2, "*New Accounting Pronouncements*," to our consolidated financial statements included in this Annual Report on Form 10-K for additional information.

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

Interest Rate Risk

We have invested $24.6 million in available for sale securities that are invested in short term bonds which typically yield higher returns than the interest realized in money market funds. While these bonds are of shorter 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 bonds. If we liquidate our position in these bonds, those unrealized losses may result in realized losses which may or may not exceed the interest and dividends earned from those bonds. However, due to the short duration of these short term bonds, 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 investments.

Foreign Currency Exchange Rate Risk

Our international business is conducted in U.S. dollars with the exception of transactions by our subsidiary in India, which conducts business in Indian rupees and has had only minor transactional activity to date. 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 and Supplementary Data.

The Consolidated Financial Statements of the Registrant and other information required by this item are set forth on pages F-1 through F-23 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 December 31, 2017, 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

Our 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, our management evaluated the effectiveness of our internal control over financial reporting as of December 31, 2017. In making their assessment of internal control over financial reporting, our 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 our internal control over financial reporting was effective as of December 31, 2017.

Attestation Report of Independent Registered Public Accounting Firm

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, 2017. Plante & Moran, PLLC's report, which expresses an unqualified opinion on the effectiveness of our internal control over financial reporting, is included herein.

The attestation report required under this Item 9A can be found on page F-3 in Consolidated Financial Statements for Rockwell Medical, Inc. and Subsidiaries found at the end of this Annual Report on Form 10-K under the heading "Report of Independent Registered Public Accounting Firm."

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, 2017 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.

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics that applies to all of our directors, employees and officers, including our principal executive officer, our principal financial officer and persons performing similar functions. Our Code of Business Conduct and Ethics is available on our website at www.rockwellmed.com. Future material amendments or waivers relating to the Code of Business Conduct and Ethics will be disclosed on our web site referenced in this paragraph with four business days following the date of such amendment or waiver.

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, 2017:

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	6,906,001	$ 7.92	—
Equity compensation plans not approved by security holders	—	—	—
Total	6,906,001	$ 7.92	—

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 Accounting 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, 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 March 13, 2018).
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 21, 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).
*10.54	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).
10.57	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) (Company's Form 10-K filed March 3, 2015).
10.58	Investment Agreement, dated as of October 2, 2014, between the Company and Baxter Healthcare Corporation (Company's Form 10-K filed March 3, 2015).
*10.59	Amendment to October 1, 2014 Stock Option Agreement with Robert L. Chioini (Company's Form 10-K filed March 3, 2015).
*10.60	Rockwell Medical, Inc. Amended and Restated 2007 Long Term Incentive Plan, as amended effective May 21, 2015 (Company's Proxy Statement for the 2015 Annual Meeting of Shareholders filed on April 13, 2015).
*10.61	Amendment to October 2, 2015 Stock Option Agreement with Robert L. Chioini (Company's Form 10 K filed February 29, 2016).
*10.62	Form of Restricted Stock Award Agreement October 2015 (Director Version) (Company's Form 10 K filed February 29, 2016).
10.64	Form of Performance Share Award Agreement March 2017 (Executive Version) (Company's Form 10-Q filed May 9, 2017).
10.65	Form of Performance Share Award Agreement March 2017 (Director Version) (Company's Form 10-Q filed May 9, 2017).
10.68	First Amendment to Exclusive Distribution Agreement, dated as of June 23, 2017, by and between the Company and Baxter Healthcare Corporation (with certain portions redacted pursuant to a confidential treatment request) (Company's form 10-Q filed August 9, 2017).
10.69	First Amendment to Investment Agreement, dated as of June 23, 2017, by and between the Company and Baxter Healthcare Corporation. (Company's form 10-Q filed August 9, 2017).
10.70	Form of Director and Officer Indemnification Agreement September 2017. (Company's Form 10-Q filed November 8, 2017).

10.71	Stock Appreciation Right Agreement, dated September 5, 2017, between the Company and John G. Cooper. (Company's Form 10-Q filed November 8, 2017).
10.72	Settlement and Standstill Agreement with Richmond Brothers, Inc., Mark H. Ravich, and other persons collectively referred to as the "Shareholder Group" and the Company. (Company's Form 8-K filed November 29, 2017).
10.73	Letter Agreement, dated March 7, 2018, by and among the Company, Richmond Brothers, Inc. and David S. Richmond. (Company's Form 8-K filed on March 13, 2018).
*10.74	Executive Employment Agreement, dated March 7, 2018, between Rockwell Medical, Inc. and Robert L. Chioini. (Company's Form 8-K filed on March 13, 2018).
*10.75	Executive Employment Agreement, dated March 7, 2018, between Rockwell Medical, Inc. and Thomas E. Klema. (Company's Form 8-K filed on March 13, 2018).
11.1	Computation of per share earnings (contained in Note 16 of "Notes to Consolidated Financial Statements" of the Company's Annual Report on Form 10-K for the year ended December 31, 2017).
21.1	List of Subsidiaries.
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.

Item 16. Form 10-K Summary.

Not Applicable

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 15, 2018

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 15, 2018
/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 15, 2018
/s/ Patrick J. Bagley Patrick J. Bagley	Director	March 15, 2018
/s/ Ronald D. Boyd Ronald D. Boyd	Director	March 15, 2018
/s/ JOHN G. COOPER John G. Cooper	Director	March 15, 2018
/s/ Robin L. Smith Robin L. Smith	Director	March 15, 2018
/s/ MARK H. RAVICH Mark H. Ravich	Director	March 15, 2018

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Shareholders and Board of Directors of Rockwell Medical, Inc. and Subsidiaries

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Rockwell Medical, Inc. and Subsidiaries (the "Company") as of December 31, 2017 and 2016, the related statements of income, comprehensive income, shareholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2017, and the related notes and schedule (collectively referred to as the "financial statements"). In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2016, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2017, in conformity with accounting principles generally accepted in the United States of America.

We also have audited the Company's internal control over financial reporting as of December 31, 2017, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), based on criteria established in *Internal Control-Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Our report dated March 15, 2018, expresses an unqualified opinion.

Basis for Opinion

The Company's management is responsible for these financial statements. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Plante & Moran, PLLC

We have served as the Company's auditor since 1998.

Clinton Township, Michigan

March 15, 2018

Report of Independent Registered Public Accounting Firm

To the Shareholders and Board of Directors of Rockwell Medical, Inc. and Subsidiaries

Opinion on Internal Control over Financial Reporting

We have audited the internal control over financial reporting as of December 31, 2017 of Rockwell Medical, Inc. and Subsidiaries (the "Company"), based on criteria established in *Internal Control-Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (the "COSO framework"). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2017, based on criteria established in the COSO framework.

We also have audited the accompanying balance sheets of the Company as of December 31, 2017 and 2016, the related statements of income, comprehensive income, shareholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2017, and the related notes and schedule (collectively referred to as the "financial statements"), in accordance with the standards of the Public Company Accounting Oversight Board (United States). Our report dated March 15, 2018, expresses an unqualified opinion.

Basis for Opinion

The Company's 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 are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. 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. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

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.

/s/ Plante & Moran, PLLC

We have served as the Company's auditor since 1998.

Clinton Township, Michigan

March 15, 2018

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

As of December 31, 2017 and 2016

	December 31, 2017	December 31, 2016
ASSETS		
Cash and Cash Equivalents	$ 8,406,917	$ 17,180,594
Investments Available for Sale	24,648,459	40,759,703
Accounts Receivable, net of a reserve of $11,000 in 2017 and $5,000 in 2016	6,355,566	6,393,228
Inventory	7,637,384	12,141,072
Other Current Assets	1,779,992	2,034,598
Total Current Assets	48,828,318	78,509,195
Property and Equipment, net	2,548,978	1,391,575
Inventory, Non-Current	5,986,752	1,826,554
Intangible Assets	4,028	4,382
Goodwill	920,745	920,745
Other Non-current Assets	490,819	501,187
Total Assets	$ 58,779,640	$ 83,153,638
LIABILITIES AND SHAREHOLDERS' EQUITY		
Accounts Payable	$ 4,222,159	$ 5,858,234
Accrued Liabilities	4,715,712	4,210,151
Customer Deposits	205,303	77,217
Total Current Liabilities	9,143,174	10,145,602
Deferred License Revenue	16,723,318	20,051,737
Shareholders' Equity:		
Common Shares, no par value, 51,768,424 and 51,527,711 shares issued and outstanding	273,210,907	268,199,939
Accumulated Deficit	(240,262,376)	(214,341,092)
Accumulated Other Comprehensive Income	(35,383)	(902,548)
Total Shareholders' Equity	32,913,148	52,956,299
Total Liabilities And Shareholders' Equity	$ 58,779,640	$ 83,153,638

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

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED INCOME STATEMENTS

For The Years Ended December 31, 2017, 2016 and 2015

	2017	2016	2015
Sales	$ 57,300,281	$ 53,284,166	$ 55,350,702
Cost of Sales	53,598,390	46,531,648	46,412,848
Gross Profit	3,701,891	6,752,518	8,937,854
Selling, General and Administrative	23,303,409	21,120,901	19,078,867
Research and Product Development	6,321,400	5,840,346	4,961,313
Operating Income (Loss)	(25,922,918)	(20,208,729)	(15,102,326)
Interest and Investment Income	892	810,340	681,876
Interest (Expense)	—	—	—
Foreign Currency Gain (Loss)	742	—	—
Income (Loss) Before Income Taxes	(25,921,284)	(19,398,389)	(14,420,450)
Income Tax Expense	—	(404,527)	—
Net Income (Loss)	$ (25,921,284)	$ (19,802,916)	$ (14,420,450)
Basic Earnings (Loss) per Share	$ (0.51)	$ (0.39)	$ (0.29)
Diluted Earnings (Loss) per Share	$ (0.51)	$ (0.39)	$ (0.29)

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

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

For The Years Ended December 31, 2017, 2016 and 2015

	2017	2016	2015
Net Income (Loss)	**$ (25,921,284)**	**$ (19,802,916)**	**$ (14,420,450)**
Unrealized Gain (Loss) on Available-for-Sale Investments	866,031	13,619	(717,827)
Foreign Currency Translation Adjustments	1,134	(671)	—
Comprehensive Income (Loss)	**$ (25,054,119)**	**$ (19,789,968)**	**$ (15,138,277)**

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

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY

For The Years Ended December 31, 2017, 2016 and 2015

	COMMON SHARES		ACCUMULATED	ACCUMULATED OTHER COMPREHENSIVE	TOTAL SHAREHOLDER'S
	SHARES	AMOUNT	DEFICIT	INCOME (LOSS)	EQUITY
Balance as of December 31, 2014	50,284,007	$ 249,018,189	$ (180,117,726)	$ (197,669.)	$ 68,702,794
Net Loss	—	—	(14,420,450)	—	(14,420,450)
Unrealized Gain on Available-for-Sale Investments	—	—	—	(717,827)	(717,827)
Issuance of Common Shares	1,644,248	4,132,250	—	—	4,132,250
Stock Tendered in Satisfaction of Tax Liabilities	(426,378)	(4,264,922)	—	—	(4,264,922)
Exercise of Purchase Warrants	—	—	—	—	—
Expiration of Purchase Warrants	—	—	—	—	—
Purchase Warrants Expense	—	—	—	—	—
Stock Option Based Expense	—	5,193,481	—	—	5,193,481
Restricted Stock Amortization	—	3,694,496	—	—	3,694,496
Balance as of December 31, 2015	51,501,877	$ 257,773,494	$ (194,538,176)	$ (915,496)	$ 62,319,822
Net Loss	—	—	(19,802,916)	—	(19,802,916)
Unrealized Gain on Available-for-Sale Investments	—	—	—	13,619	13,619
Foreign Currency Rate Changes				(671)	(671)
Issuance of Common Shares	25,834	80,161	—	—	80,161
Stock Tendered in Satisfaction of Tax Liabilities	—	—	—	—	—
Stock Option Based Expense	—	5,984,524	—	—	5,984,524
Restricted Stock Amortization	—	4,361,760	—	—	4,361,760
Balance as of December 31, 2016	51,527,711	$ 268,199,939	$ (214,341,092)	$ (902,548)	$ 52,956,299
Net Loss	—	—	(25,921,284)	—	(25,921,284)
Unrealized Gain on Available-for-Sale Investments	—	—	—	866,031	866,031
Foreign Currency Rate Changes	—	—	—	1,134	1,134
Issuance of Common Shares	508,384	123,603	—	—	123,603
Shares Issued in Exchange for Services	50,000	228,847			228,847
Stock Option Based Expense	—	3,858,502	—	—	3,858,502
Stock Tendered in Satisfaction of Tax Liabilities	(317,671)	(2,287,231)	—	—	(2,287,231)
Restricted Stock Amortization	—	3,087,247	—	—	3,087,247
Balance as of December 31, 2017	51,768,424	$ 273,210,907	$ (240,262,376)	$ (35,383)	$ 32,913,148

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

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

For the years ended December 31, 2017, 2016 and 2015

	2017	2016	2015
Cash Flows From Operating Activities:			
Net (Loss)	**$ (25,921,284)**	**$ (19,802,916)**	**$ (14,420,450)**
Adjustments To Reconcile Net Loss To Net Cash Used In Operating Activities:			
Depreciation and Amortization	514,362	762,368	822,294
Share Based Compensation—Non-employee	228,847	—	—
Share Based Compensation—Employees	6,945,749	10,346,284	8,887,977
Loss on Disposal of Assets	10,777	8,168	5,281
Loss on Sale of Investments Available for Sale	792,207	26,820	58,095
Changes in Assets and Liabilities:			
(Increase) in Accounts Receivable	(962,338)	(1,162,469)	(574,731)
(Increase) in Inventory	343,490	(6,095,846)	(3,951,595)
(Increase) in Other Assets	264,975	(1,230,084)	(360,303)
(Decrease) Increase in Accounts Payable	(1,636,840)	1,863,018	(1,299,299)
(Decrease) Increase in Other Liabilities	634,238	191,134	(413,652)
(Decrease) in Deferred License Revenue	(2,099,028)	(2,065,785)	(2,081,668)
(Decrease) Increase in Deferred Drug License Revenue	(229,390)	4,706,670	—
Changes in Assets and Liabilities	(3,684,893)	(3,793,362)	(8,681,248)
Cash (Used In) Operating Activities	**(21,114,235)**	**(12,452,638)**	**(13,328,051)**
Cash Flows From Investing Activities:			
Purchase of Investments Available for Sale	(35,733,677)	(25,781,853)	(21,800,000)
Sale of Investments Available for Sale	51,918,745	24,491,677	1,468,656
Purchase of Equipment	(1,682,913)	(355,264)	(815,002)
Proceeds on Sale of Assets	725	1,000	4,800
Cash Provided by (Used In) Investing Activities	**14,502,880**	**(1,644,440)**	**(21,141,546)**
Cash Flows From Financing Activities:			
Proceeds from Issuance of Common Shares	123,603	80,161	2,780,187
Restricted Stock Retained in Satisfaction of Tax Liabilities	(2,287,231)	—	(2,912,859)
Cash (Used In) Provided By Financing Activities	**(2,163,628)**	**80,161**	**(132,672)**
Effects of exchange rate changes	1,306	(671)	—
(Decrease) In Cash	(8,773,677)	(14,017,588)	(34,602,269)
Cash At Beginning Of Period	17,180,594	31,198,182	65,800,451
Cash At End Of Period	**$ 8,406,917**	**$ 17,180,594**	**$ 31,198,182**

Supplemental Cash Flow Information:

	2017	2016	2015
Income Taxes Paid	$ —	$ 404,527	$ —

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

1. DESCRIPTION OF BUSINESS

Rockwell Medical, Inc. and Subsidiaries, (collectively, “we”, “our”, “us” or the “Company”) is a fully-integrated pharmaceutical company targeting end-stage renal disease (“ESRD”) and chronic kidney disease with innovative products and services for the treatment of iron deficiency, secondary hyperparathyroidism and hemodialysis (also referred to as “dialysis”). Rockwell Medical, Inc. was incorporated in the state of Michigan in 1996.

We are currently marketing and 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 also obtained licenses for certain dialysis related drugs which we are developing and planning to market globally.

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 manufacture, sell and distribute hemodialysis concentrates and other medical products and supplies used in the treatment of patients with ESRD. In 2017, we supplied approximately 25% of the United States domestic market with dialysis concentrates, and the majority of our sales were in the United States. We also supplied dialysis concentrates to distributors serving a number of foreign countries, primarily in the Americas and the Pacific Rim.

We are regulated by the United States Food and Drug Administration (“FDA”) under the Federal Drug and Cosmetics Act, as well as by other federal, state and local agencies. We hold several FDA product approvals including both drugs and medical devices.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

Our consolidated financial statements include our accounts and the accounts for our wholly owned subsidiaries, Rockwell Transportation, Inc. and Rockwell Medical India Private Limited. Rockwell Medical India Private Limited was formed in 2016 for the purpose of conducting certain commercial activities in India.

All intercompany balances and transactions have been eliminated in consolidation.

Revenue Recognition

Our policy is to recognize revenue consistent with authoritative guidance for revenue recognition including the provisions of the Financial Accounting Standards Board Accounting Standards Codification. We recognize revenue when all of the following criteria are met: (i) persuasive evidence of an arrangement exists, (ii) delivery (or passage of title) has occurred or services have been rendered, (iii) the seller's price to the buyer is fixed or determinable, and (iv) collectability is reasonably assured.

Consistent with these guidelines we recognize revenue at the time we transfer title to our products to our customers which generally occurs 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.

We apply judgment as we analyze each element of our contractual agreements to determine appropriate revenue recognition. The terms of our contractual agreements may include milestone payments if specified research and development objectives are achieved, non-refundable licensing fees, milestone payments on sales or royalties from product sales.

When entering into an arrangement, we first determine whether the arrangement includes multiple deliverables and is subject to the accounting guidance in ASC subtopic 605-25, Multiple-Element Arrangements. If we determine that an arrangement includes multiple elements, we determine whether the arrangement should be divided into separate units of accounting and how the arrangement consideration should be measured and allocated among the separate units of accounting. An element qualifies as a separate unit of accounting when the delivered element has standalone value to the customer. Our arrangements do not include a general right of return relative to delivered elements. Any delivered elements that do not qualify as separate units of accounting are combined with other undelivered elements within the arrangement as a single unit of accounting. If the arrangement constitutes a single combined unit of accounting, we determine the revenue recognition method for the combined unit of accounting and recognize the revenue either on a straight-line basis or on a modified proportional performance method over the period from inception through the date the last deliverable within the single unit of accounting is delivered.

Non-refundable upfront license fees are recorded as deferred revenue and recognized into revenue over the estimated period of our substantive performance obligations. If we do not have substantive performance obligations, we recognize non-refundable upfront fees into revenue through the date the deliverable is satisfied. Analyzing the arrangement to identify deliverables requires the use of judgment and each deliverable may be an obligation to deliver services, a right or license to use an asset, or another performance obligation. In arrangements that include license rights and other non-contingent deliverables, such as participation in a steering committee, these deliverables do not have standalone value because the non-contingent deliverables are dependent on the license rights. That is, the non-contingent deliverables would not have value without the license rights, and only we can perform the related services. Upfront license rights and non-contingent deliverables, such as participation in a steering committee, do not have standalone value as they are not sold separately and they cannot be resold. In addition, when non-contingent deliverables are sold with upfront license rights, the license rights do not represent the culmination of a separate earnings process. As such, we account for the license and the non-contingent deliverables as a single combined unit of accounting. In such instances, the license revenue in the form of non-refundable upfront payments is deferred and recognized over the applicable relationship period.

For milestone payments based on sales and for royalties based on sales, we recognize revenue in the quarter that the information related to the sales becomes available and collectability is reasonably assured.

We recognize drug licensing fees over the term of the related license agreement. We received an upfront payment of $4 million pursuant to our license agreement with Wanbang Biopharmaceutical Co., Ltd. (“Wanbang”), a subsidiary of Shanghai Fosun Pharmaceutical (Group) Co., Ltd. Deferred drug license revenue for our drug license agreement is being recognized over the term of those license agreements and we recognized drug license revenue of $0.2 million in 2017.

The initial payment of $20 million received pursuant to our long-term Exclusive Distribution Agreement (the “Distribution Agreement”) with Baxter Healthcare Corporation (“Baxter”) in October 2014 has been accounted for 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 recognize other revenues at the time the related fees and or payments are earned.

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.

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.

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. Inventory that is not expected to be converted to cash over the next year is classified as non-current. Our policy is to reserve for our drug product inventory that we determine is unlikely to be sold to, or if sold, unlikely to be utilized by our customers on or before its expiration date.

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.

Licensing Fees

License fees related to the technology, intellectual property and marketing rights for Triferic 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.

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 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 carryforward, will be disallowed by a taxing authority. The amount of unrecognized tax benefits related to current tax positions is insignificant. The Company recognizes interest and penalties accrued related to unrecognized tax benefits as income tax expense.

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 and for other indications of Triferic, aggregating approximately $6,321,000, $5,840,000 and $4,961,000 in 2017, 2016 and 2015, 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 compute 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:

	2017	2016	2015
Basic Weighted Average Shares Outstanding	51,067,412	50,676,180	50,068,129
Effect of Dilutive Securities	—	—	—
Diluted Weighted Average Shares Outstanding	51,067,412	50,676,180	50,068,129

For 2017, 2016 and 2015, 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 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.

	2017	2016	2015
Stock Options	6,906,001	7,691,501	7,759,002
Range of Exercise Prices of Stock Options	$3.09 - $11.49	$3.09 - $11.49	$3.09 - $11.49
Unvested Restricted Common Shares	480,000	850,000	850,000

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 almost entirely of unrealized gains and losses on available-for-sale investment securities. We also record foreign currency translation adjustments to Other Comprehensive Income (Loss). However, such amounts were insignificant in 2017.

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.

New Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board issued Accounting Standards Update (“ASU”) No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which will supersede the current revenue recognition requirements in Topic 605, *Revenue Recognition*. The standard’s core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The new guidance is effective for the year beginning January 1, 2018. The standard permits the use of either the retrospective or cumulative effect transition method. The Company has evaluated the impact of the new standard and has elected the cumulative effect transition method. The adoption of the standard will not have a material impact on our financial position or results of operations. We have finalized and implemented our accounting policy and our internal controls under the new standard without significant issues. The new standard will also require expanded disclosures surrounding revenue in the notes to the financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*. The amendments in this ASU revise the accounting related to lessee accounting. Under the new guidance, lessees will be required to recognize a lease liability and a right-of-use asset for all leases. The amendments in this ASU are effective for the Company beginning on

January 1, 2019 and should be applied through a modified retrospective transition approach for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements. Early adoption is permitted. We anticipate this standard will have a material impact on our consolidated balance sheets. However, we do not believe adoption will have a material impact on our consolidated income statements. Upon implementation, the Company's lease payment obligations will be recognized at their estimated present value along with a corresponding right-of-use asset. Lease expense recognition will be generally consistent with current practice.

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 balance sheets for cash and cash equivalents are deemed to approximate fair value

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

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.

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, 2017					
Financial assets					
Cash and cash equivalents	$ 8,407	$ 8,407	$ 8,407	$ —	$ —
Investment securities available for sale	24,648	24,648	24,648	—	—
As of December 31, 2016					
Financial assets					
Cash and cash equivalents	$ 17,181	$ 17,181	$ 17,181	$ —	$ —
Investment securities available for sale	40,760	40,760	40,760	—	—

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 2017 or 2016.

4. INVESTMENTS IN AVAILABLE FOR SALE SECURITIES

As of December 31, 2017, we held investments in available for sale securities with a market value of $24,648,459. These investments consisted primarily of high quality short term debt instruments. These debt instruments were subject to changes in fair market value due to changes in interest rates. In 2017, we repositioned our investment portfolio and sold securities with a market value of $51,918,745 with an average cost basis of $52,711,407. In 2017, we had realized gains of $12,927 and realized losses of $805,134.

As of December 31, 2016, 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 $40,759,703 as of December 31, 2016. In 2016, we purchased securities with a market value of $25,781,853 and had unrealized losses of $901,877 as of December 31, 2016. In 2016, we sold securities with a market value of $24,491,677 with an average cost basis of $24,518,497. We had realized gains of $156,461 and realized losses of $183,281.

5. SIGNIFICANT MARKET SEGMENTS AND CUSTOMERS

We operate in one market segment, the hemodialysis market, which involves the manufacture, sale and distribution of hemodialysis products to hemodialysis clinics, including pharmaceutical, dialysis concentrates, dialysis kits and other ancillary products used in the dialysis process. In October 2014, we entered into the Distribution Agreement with Baxter, which was amended in June 2017, pursuant to which Baxter received exclusive distribution rights for our concentrate products in the United States. Our domestic customer contracts for the supply of dialysis concentrate products that permitted assignment to Baxter without consent have been assigned to Baxter. As a result, for 2017, 2016 and 2015, our direct sales to Baxter aggregated approximately 27%, 24% and 28% of sales, respectively, and we had a receivable from Baxter of $1,863,412 and $2,430,159 as of December 31, 2017 and 2016, respectively.

One customer, DaVita Healthcare Partners, Inc., accounted for 50% of our sales in 2017, 52% of our sales in 2016 and 48% of our sales in 2015. Our accounts receivable from this customer were $2,411,367 and $2,224,046 as of December 31, 2017 and 2016, respectively. DaVita and Baxter and the accounts administered by Baxter are important to our business, financial condition and results of operations. The loss of any significant accounts could have a material adverse effect on our business, financial condition and results of operations. No other customers accounted for more than 10% of our sales in any of the last three years.

The majority of our international sales in each of the last three years were sales to domestic distributors that were resold to end users outside the United States. Our sales directly to foreign customers and distributors accounted for less than 5% of our total sales in 2017, 2016 and 2015. Our total international sales, including sales made through domestic distributors for resale outside the United States, aggregated 12%, 12% and 13%, of our overall sales in 2017, 2016 and 2015, respectively.

6. DISTRIBUTION AGREEMENT

As of October 2, 2014, we entered into the Distribution Agreement with Baxter, pursuant to which Baxter became our exclusive agent for sales, marketing and distribution activities for our hemodialysis concentrate and ancillary products in the United States and various foreign countries for an initial term of 10 years ending on October 2, 2024. The Distribution Agreement does not include any of our drug products. We will retain sales, marketing and distribution rights for our hemodialysis concentrate products in specified foreign 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.

Pursuant to the Distribution Agreement, Baxter paid us $20 million in cash in October 2014 (the “Upfront Fee”). The Upfront Fee has been deferred and is being 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. We recognized revenue associated with the Upfront Fee totaling $2,099,028 for the year ended December 31, 2017, $2,065,785 for the year ended December 31, 2016 and $2,081,668 for the year ended December 31, 2015.

Under the Distribution Agreement, Baxter purchases products from us at established gross margin-based prices per unit, adjusted each year during the term. We continue to manage customer service, transportation and certain other

functions for our current customers on Baxter's behalf, in exchange for which Baxter will pay us an amount equal to our 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, our obligations to maintain specified manufacturing capacity and quality levels, remedies, as well as representations, warranties and indemnification obligations of the parties.

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 non-compete 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 (described below) as follows: 33% if the event occurs in 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 us to prepay our outstanding secured long-term indebtedness within 180 days and prohibits us from entering into a subsequent contract encumbering the assets used in our concentrate business without the prior written consent of Baxter.

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.

On September 12, 2016, Baxter initiated an arbitration proceeding against us under the Distribution Agreement alleging various breaches of the Distribution Agreement, and we counterclaimed alleging various breaches by Baxter. On June 23, 2017, we settled the arbitration with Baxter (the "Settlement"). The Settlement included a mutual release with respect to all known claims existing on the date of the Settlement and the arbitration was dismissed with prejudice. No payments were made by either party in connection with the Settlement.

In connection with the Settlement, on June 23, 2017, we entered into a First Amendment to Exclusive Distribution Agreement and a First Amendment to Investment Agreement, in each case, with Baxter. The terms of the Settlement included, among other things, reduced pricing on certain accounts that provides incentive to Baxter to pursue new customers and increase future sales.

7. INVENTORY

Components of inventory as of December 31, 2017 and 2016 are as follows:

	December 31, 2017	December 31, 2016
Raw Materials	$ 10,604,232	$ 10,903,084
Work in Process	212,505	86,452
Finished Goods	2,807,399	2,978,090
Total	$ 13,624,136	$ 13,967,626

As of December 31, 2017, we classified $5,986,752 of inventory as non-current all of which related to the active pharmaceutical ingredient for Triferic.

8. PROPERTY AND EQUIPMENT

Major classes of property and equipment, stated at cost, as of December 31, 2017 and 2016 are as follows:

	2017	2016
Leasehold Improvements	$ 824,087	$ 728,151
Machinery and Equipment	7,893,566	7,169,223
Information Technology & Office Equipment	2,327,524	2,293,587
Laboratory Equipment	631,666	610,767
Transportation Equipment	242,277	265,198
	11,919,120	11,066,926
Accumulated Depreciation	(9,370,142)	(9,675,351)
Net Property and Equipment	$ 2,548,978	$ 1,391,575

Below is a summary of depreciation expense by period:

	2017	2016	2015
Depreciation expense	$ 514,009	$ 601,093	$ 655,265

9. GOODWILL AND INTANGIBLE ASSETS

Total goodwill was $920,745 at December 31, 2017 and 2016. We completed our annual impairment tests as of November 30, 2017 and 2016, 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. We have capitalized certain patent approval costs.

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 were amortized over a five year period ending December 31, 2016.

	2017	2016	2015
Capitalized Licensing Fees	$ 1,070,126	$ 1,070,126	$ 1,070,126
Accumulated Amortization	(1,066,098)	(1,065,744)	(904,469)
Capitalized Licensing Fees, Net of Amortization	$ 4,028	$ 4,382	$ 165,657
Amortization Expense	$ 353	$ 161,275	$ 167,029

Our policy is to amortize licensing fees over the life of the patents pertaining to certain licensing agreements and to amortize patent costs over the life of the patent. Estimated amortization expense for amortization of capitalized patent costs in 2018 is approximately $353. In 2015, we recognized expenses related to milestone achievements of $275,000.

10. ACCRUED LIABILITIES

We had the following accrued liabilities as of December 31, 2017 and 2016:

	2017	2016
Accrued Research & Development Expense	$ 400,024	$ 193,638
Accrued Compensation and Benefits	1,991,874	2,002,767
Other Accrued Liabilities	2,323,814	2,013,746
Total Accrued Liabilities	$ 4,715,712	$ 4,210,151

11. 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 2018. We also occupy a 51,000 square foot facility in Grapevine, Texas under a lease expiring in December 2020. In addition, we lease a 57,000 square foot facility in Greer, South Carolina under a lease expiring February 2020.

	2017	2016	2015
Rent Expense Recognized Under Operating Leases	$ 2,463,145	$ 2,369,101	$ 2,301,930

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

Year ending December 31, 2018	$ 1,917,356
Year ending December 31, 2019	1,456,164
Year ending December 31, 2020	685,349
Year ending December 31, 2021	206,595
Year ending December 31, 2022	54,726
Year ending December 31, 2023 and thereafter	—
Total	$ 4,320,190

12. INCOME TAXES

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

	2017	2016	2015
Tax Expense (Benefit) Computed at 34 % of Pretax Income (Loss)	$ (8,813,237)	$ (6,595,452)	$ (4,903,000)
Changes in Tax Laws	29,450,000	—	—
Foreign Income Tax Expense	—	(404,527)	—
Effect of Change in Valuation Allowance	20,636,763	(6,595,452)	(4,903,000)
Total Income Tax Expense	$ —	$ 404,527	$ —

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

	December 31,	
	2017	2016
Deferred tax assets:		
Net Operating Loss Carryforward	$ 35,030,000	$ 51,463,000
Stock Based Compensation	5,030,000	7,704,000
Deferred Revenue	3,512,000	6,478,000
General Business Credit	6,872,000	6,146,000
Accrued Expenses	341,000	605,000
Inventories	909,000	494,000
Book over Tax Depreciation	32,000	61,000
Allowance for Doubtful Accounts	2,000	2,000
Total Deferred Tax Assets	51,728,000	72,953,000
Deferred Tax Liabilities:		
Goodwill & Intangible Assets	98,000	137,000
Prepaid Expenses	136,000	182,000
Total Deferred Tax Liabilities	234,000	319,000
Subtotal	51,494,000	72,634,000
Valuation Allowance	(51,494,000)	(72,634,000)
Net Deferred Tax Asset	$ —	$ —

TCJA tax reform legislation enacted on December 22, 2017 makes major changes to the U.S. corporate income tax system, including lowering the U.S. federal corporate income tax rate to 21 percent from 35 percent, limiting or eliminating certain existing tax deductions, credits and incentives, allowing immediately expensing of capital expenditures through 2022, and eliminating the expiration of net operating loss carryforwards for losses generated in 2018 or after. ASC 740 requires companies to recognize the effects of tax law changes in the period of enactment, which for us was the fourth quarter of 2017, even though the effective date of most provisions of the TCJA is January 1, 2018. TCJA resulted in significant changes to the our fourth quarter 2017 income tax provision most notably a reduction in our deferred tax asset, before valuation allowance, as a result of the lower corporate income tax rate.

Deferred tax assets result primarily from net operating loss carryforwards. For tax purposes, we have net operating loss carryforwards of approximately $166,800,000 that expire between 2018 and 2037.

In assessing the potential for realization 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, 2017 and 2015. We recognized $404,527 in foreign income taxes paid for the year ended December 31, 2016. While we anticipate generating income within the next year or two, we expect to incur operating losses until our drug products are marketed and generating sufficient profits to offset our operating expenses. Considered together with our limited history of operating income and our net losses in 2017, 2016 and 2015, management has placed a full valuation allowance against the net deferred tax assets as of December 31, 2017 and 2016. 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 $3.0 million.

We account for our 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, 2017 and 2016.

13. CAPITAL STOCK

Our authorized capital stock consists of 2,000,000 preferred shares, none of which were issued or outstanding at December 31, 2017, 2016 and 2015, and 120,000,000 common shares, no par value per share, of which the following shares were outstanding:

	2017	2016	2015
Shares outstanding as of December 31,	51,768,424	51,527,711	51,501,877
Summary of Share Issuances:			
Share Issuances related to Equity Compensation:			
Shares issued upon exercise of stock options by employees	28,384	25,834	657,998
Proceeds realized from stock option exercises	$ 123,603	$ 80,161	$ 2,780,188
Average exercise price of options exercised	$ 4.35	$ 3.10	$ 4.23
Restricted Stock Grants	530,000	—	850,000

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 our Articles of Incorporation without further shareholder action, subject to applicable stock exchange rules.

14. 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 (“2007 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 and no options remained outstanding as of December 31, 2016. The 2007 LTIP expired on April 11, 2017 and no equity awards were granted under the 2007 LTIP following its expiration. There were 11,500,000 common shares reserved for issuance under the 2007 LTIP. The Compensation Committee of the Board of Directors (the “Committee”) is responsible for the administration of the 2007 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 during 2017, 2016 and 2015 and restricted stock grants in 2017 and 2015. 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 530,000 and 850,000 restricted shares in 2017 and 2015, respectively under the 2007 LTIP. There were no grants of restricted stock during 2016. These restricted stock grants were valued at the market price on the date of grant.

During 2017, 480,000 performance based restricted shares were granted. Vesting is conditioned upon achievement of certain performance measures which were originally estimated to be approximately seventeen months following the grant date and may also vest based on a market performance measure. Evaluation of the expected vesting period is reviewed quarterly. During 2017, 50,000 restricted shares were granted in consideration for consulting services.

During 2015, restricted stock grants aggregating 850,000 common shares were granted in October 2015 with a vesting date of approximately twenty months following the grant date. Vesting is conditioned upon continued employment with the Company.

	2017	2016	2015
Restricted Shares Granted	530,000	-	850,000
Average Market Value Per Share on Grant Date	$ 5.72	$ -	$ 8.23
Expense related to All Restricted Shares	$ 3,316,093	$ 4,361,760	$ 3,694,496
Unearned Stock Based Compensation for All Restricted Stock Awards Attributable to Future Periods.	$ 1,266,666		

Stock Option Grants

Our standard stock option agreement under the 2007 LTIP 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 2007 LTIP 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 2017, 2016 and 2015, we received cash proceeds of $123,603, $80,161 and $2,780,188 respectively, in exchange for shares issued upon the exercise of options during the year. No income tax benefits were recognized during 2017, 2016 and 2015 related to stock option activity as we have a full valuation allowance recorded against its deferred tax assets. However, tax benefits (expense) for the excess of the value of the shares issued over the price paid of $1,209,000, $20,000 and ($943,000) were created in 2017, 2016, and 2015. The cumulative excess tax benefit at December 31, 2017 is $3.0 million, which when realized, will be credited directly to shareholders' equity.

A summary of the status of the 2007 LTIP and the Old Plan is as follows:

	SHARES	WEIGHTED AVERAGE EXERCISE PRICE	AGGREGATE INTRINSIC VALUE
Outstanding at December 31, 2014	6,885,083	7.41	$ 19,730,211
Granted	1,697,500	8.30	
Exercised	(794,248)	3.50	$ 2,780,188
Forfeited	(29,333)	6.91	
Outstanding at December 31, 2015	7,759,002	7.84	$ 18,648,477
Granted	30,000	6.54	
Exercised	(25,834)	4.35	$ 112,280
Forfeited	(71,667)	9.33	
Outstanding at December 31, 2016	7,691,501	7.83	$ 1,821,384
Granted	15,000	6.09	
Exercised	(433,500)	6.45	$ 109,847
Forfeited	(367,000)	7.85	
Outstanding at December 31, 2017	6,906,001	7.92	$ 976,335

	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	389,500	1.0-5.5 yrs.	$ 3.31	389,500	$ 3.31
$5.86 to $7.13	1,922,500	.4-8.7 yrs.	$ 6.43	1,887,500	$ 6.43
$8.23 to 11.49	4,594,001	1.8-7.8 yrs.	$ 8.93	4,056,168	$ 9.02
Total	6,906,001	5.1 yrs.	$ 7.92	6,333,168	$ 7.90
Intrinsic Value	$ 976,335			$ 976,335	

	NUMBER OF UNVESTED OPTIONS	WEIGHTED AVERAGE FAIR MARKET VALUE AT GRANT DATE
As of December 31, 2014	2,580,500	
Granted	1,697,500	$ 4.56
Forfeited	(28,333)	
Vested	(1,135,056)	
As of December 31, 2015	3,114,611	
Granted	30,000	$ 3.85
Forfeited	(71,667)	
Vested	(1,370,778)	
As of December 31, 2016	1,702,166	
Granted	15,000	$ 3.70
Forfeited	(367,000)	
Vested	(777,333)	
As of December 31, 2017	572,833	

We value stock options awarded using the Black-Scholes method. Assumptions used in the stock option valuations were:

	2017	2016	2015
Volatility of share price	66%	64 - 65 %	58 - 61 %
Risk free interest rate	2.00%	1.3-1.6 %	1.5 - 1.7 %
Expected option life	6 yrs.	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, 2017, 2016 and 2015, we recognized compensation expense of $3,858,503 $5,984,524, and $5,193,481 respectively related to options granted to employees under the 2007 LTIP with a corresponding credit to common stock. At December 31, 2017, the amount of unrecorded stock-based compensation expense for stock options attributable to future periods was approximately $1,944,342 which is expected to be amortized to expense over the remaining vesting periods of the options of 8 to 25 months.

15. 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, our self-insurance retention is $350,000 per occurrence and $707,898 in aggregate coverage for the policy year ending July 1, 2018. The total amount at

December 31, 2017 by which retention limits exceed the claims paid and accrued is approximately $569,000 for the policy year ending July 1, 2018. Estimated additional future claims subject to our payment of approximately $116,000 have been accrued for the year ended December 31, 2017.

At December 31, 2017, approximately $300,000 was held in cash collateral and escrow by the insurance carrier for workers' compensation insurance. At December 31, 2017 amounts held in cash collateral and escrow are included in prepaid expenses and other non-current assets in the consolidated financial statements.

16. QUARTERLY RESULTS OF OPERATIONS

The following is a summary of the quarterly results of operations for the years ended December 31, 2017 and 2016.

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
2017				
Sales	$ 14,592,254	$ 13,243,107	$ 14,626,904	$ 14,838,016
Cost of Sales	12,234,782	11,744,819	13,555,853	16,062,936
Gross Profit	2,357,472	1,498,288	1,071,051	(1,224,920)
Selling, General and Administrative	6,100,715	6,541,179	4,791,636	5,869,879
Research and Product Development	1,214,851	1,675,494	1,304,658	2,126,397
Operating Income (Loss)	(4,958,094)	(6,718,385)	(5,025,243)	(9,221,196)
Interest and Investment Income, net	216,071	(364,599)	(31,751)	181,171
Foreign Currency Gain (Loss)	—	—	—	742
Income (Loss) Before Income Taxes	(4,742,023)	(7,082,984)	(5,056,994)	(9,039,283)
Income Tax Expense	—	—	—	—
Net Income (Loss)	$ (4,742,023)	$ (7,082,984)	$ (5,056,994)	$ (9,039,283)
Basic And Diluted Earnings (Loss) Per Share	$ (0.09)	$ (0.14)	$ (0.10)	$ (0.18)

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
2016				
Sales	$ 13,627,048	$ 13,452,517	$ 12,814,815	$ 13,389,786
Cost of Sales	11,932,122	11,962,989	11,234,934	11,401,603
Gross Profit	1,694,926	1,489,528	1,579,881	1,988,183
Selling, General and Administrative	4,986,741	5,014,370	5,070,127	6,049,663
Research and Product Development	1,314,430	2,063,324	1,261,863	1,200,729
Operating Income (Loss)	(4,606,245)	(5,588,166)	(4,752,109)	(5,262,209)
Interest and Investment Income, net	186,562	227,020	188,847	207,911
Interest Expense	—	—	—	—
Income (Loss) Before Income Taxes	(4,419,683)	(5,361,146)	(4,563,262)	(5,054,298)
Income Tax Expense	(404,527)	—	—	—
Net Income (Loss)	$ (4,824,210)	$ (5,361,146)	$ (4,563,262)	$ (5,054,298)
Basic And Diluted Earnings (Loss) Per Share	$ (0.10)	$ (0.11)	$ (0.09)	$ (0.10)

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, 2017	$ 5,231	$ 11,711	$ (5,864)	$ 11,078
Year ended December 31, 2016	$ 75,160	$ 13,348	$ (83,277)	$ 5,231
Year ended December 31, 2015	$ 52,213	$ 72,877	$ (49,930)	$ 75,160
Inventory Reserve:				
Year ended December 31, 2017	$ 563,815	$ 5,330,198	$ (2,424,566)	$ 3,469,447
Year ended December 31, 2016	$ 10,662	$ 564,451	$ (11,298)	$ 563,815
Year ended December 31, 2015	$ 27,274	$ 59,581	$ (76,193)	$ 10,662
Deferred Tax Asset Valuation Allowance:				
Year ended December 31, 2017	$ 72,634,000	$ —	$ (21,140,000)	$ 51,494,000
Year ended December 31, 2016	$ 69,014,000	$ 3,620,000	$ —	$ 72,634,000
Year ended December 31, 2015	$ 69,307,000	$ —	$ (293,000)	$ 69,014,000

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

Exhibit 21.1

Subsidiaries of Rockwell Medical, Inc.

Rockwell Medical, Inc.'s subsidiaries as of December 31, 2017 is listed below:

Subsidiaries	**Jurisdiction of Organization**
Rockwell Transportation, Inc.	Michigan
Rockwell Medical India Private Limited	India

4836-6841-4047.1

Exhibit 23.1

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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 March 15, 2018 on the consolidated financial statements and related financial statement schedule of Rockwell Medical, Inc. and Subsidiary as of December 31, 2017 and 2016 and for each of the years in the three-year period ended December 31, 2017 and on the effectiveness of the Company's internal control over financial reporting as of December 31, 2017, appearing in the Annual Report on Form 10-K of Rockwell Medical, Inc. and Subsidiary for the year ended December 31, 2017.

/s/ Plante & Moran, PLLC

Clinton Township, Michigan
March 15, 2018

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 15, 2018

/s/ Robert L. Chioini
Robert L. Chioini
Chairman, CEO and President

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 15, 2018

/s/ Thomas E. Klema
Thomas E. Klema
Vice President & Chief Financial Officer

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, 2017 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 15, 2018

/s/ Robert L. Chioini
Robert L. Chioini
Chief Executive Officer

Dated: March 15, 2018

/s/ Thomas E. Klema
Thomas E. Klema
Chief Financial Officer