ROCKWELL MEDICAL, INC.
Form 10-K
March 18, 2019
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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, 2018

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 every Interactive Data File required to be submitted 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 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	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, 2018 (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 $254,458,000.

Number of shares outstanding of the registrant's Common Stock, no par value, as of March 13, 2019: 57,098,327 shares.

Documents Incorporated by Reference

Portions of the Registrant's definitive Proxy Statement pertaining to the 2019 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.

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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,” “pre “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 retain major customers and distributors;
- 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;

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- 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;
- Ability to defend ourselves against securities litigation, which is costly and time-consuming to defend;
- Ability to continue as a going concern;
- Ability to remediate the identified material weaknesses in our internal control over financial reporting;
- Ability to obtain additional financing and raise capital as necessary to fund operations or pursue business opportunities; 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.

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PART I

Item 1. Business.

Overview

Rockwell Medical, Inc., together with its subsidiaries, (collectively, "we", "our", "us" or the "Company") is a specialty pharmaceutical company targeting end-stage renal disease ("ESRD") and chronic kidney disease with innovative therapies and products for the treatment of iron deficiency and hemodialysis (also referred to as "dialysis"). These products 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 outcomes. Our business strategy is to bring our pharmaceutical products to market ourselves in the United States and to utilize partners to develop and commercialize such products in international markets.

Triferic® (ferric pyrophosphate citrate) is the Company's proprietary iron therapy that replaces iron and maintains hemoglobin in dialysis patients without increasing iron stores. The Company has developed two presentations of Triferic that are added to the dialysate, or Dialysate Triferic, as the first and only FDA approved products indicated to replace iron and maintain hemoglobin concentration in adult hemodialysis patients. A liquid, single-patient presentation of Dialysate Triferic was approved by the FDA in 2015, and a powder packet, multiple-use formulation of Dialysate Triferic was approved in 2016. We are currently building a commercial organization for Triferic and expect to launch Dialysate Triferic in the U.S. during the second quarter of 2019. We have also developed an intravenous formulation of Triferic, or I.V. Triferic, a novel formulation of Triferic that would be used for the same indication, if approved. We expect to submit a new drug application ("NDA") for I.V. Triferic during the second quarter of 2019, with a potential FDA approval during the first half of 2020. We plan to leverage the commercial capabilities we are establishing in 2019 to support the potential launch of I.V. Triferic in 2020.

We are also an established manufacturer and leader in delivering high-quality hemodialysis concentrates and 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. As one of the two major suppliers in the United States, our dialysis concentrate products are used to maintain human life by removing toxins and replacing critical nutrients in the dialysis patient's bloodstream. In 2018, we supplied approximately 25% of the United States domestic market with dialysis concentrates, with the majority of our sales 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. To date, substantially all of our sales have been concentrate products and related ancillary items.

We are regulated by the United States Food and Drug Administration ("FDA") under the Federal Food, 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.

As of December 31, 2018, we had approximate balances of $22.7 million of cash and cash equivalents, $10.8 million of investments available-for-sale, working capital of $33.6 million and an accumulated deficit of $272.4 million. Net cash used in operating activities for the twelve months ended December 31, 2018 was approximately $20.4 million. We will require significant additional capital to sustain our operations and make the investments needed to execute our longer-term business plan. Our existing liquidity is not sufficient to fund our operations and anticipated capital expenditures within one year of the issuance of the accompanying consolidated financial statements. We intend to raise additional capital for our business through additional equity or debt financing and through international

partnership activities for Triferic; however, there are currently no commitments in place for further financing nor is there any assurance that such financing will be available to the Company on favorable terms, if at all.

Our recurring operating losses, net operating cash flow deficits, and an accumulated deficit, raise substantial doubt about our ability to continue as a going concern for one year from the issuance of the accompanying consolidated financial statements. The consolidated financial statements have been prepared assuming we will continue as a going concern. We have not made any adjustments to the accompanying consolidated financial statements related to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should we be unable to continue as a going concern.

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We were incorporated in the state of Michigan in 1996.

Our Market Opportunity – Hemodialysis

Hemodialysis is the primary treatment modality for ESRD employed in the United States with approximately 90% of all dialysis patients receiving in-center hemodialysis. We do 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 more than 7,000 Medicare-certified treatment clinics in the United States. The two largest national for-profit dialysis chains service approximately 73% of the domestic in-center hemodialysis market. According to the most recent statistics published by USRDS, there were approximately 511,000 dialysis patients in the United States as of the end of 2016, of which approximately 458,000 were receiving in-center hemodialysis.

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 6% annually. Data from USRDS and the European Renal Association indicates that there are more than two million patients undergoing hemodialysis globally. 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 we expect the United States dialysis population to grow approximately 3% annually over the next several years. The Asia-Pacific market is projected to experience rapid growth in both the incidence of kidney disease and total treatment in the ESRD population over the next decade. One common side-effect of dialysis treatments is iron deficiency anemia.

The great majority of hemodialysis patients receive dialysis treatment three times per week, or approximately 150 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 percentage of chronic patients receives 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 can exchange bicarbonate, sodium, 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 during 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, some of which we sell.

Triferic (Ferric Pyrophosphate Citrate)

Each hemodialysis treatment results in a small amount of blood loss due to trapping of red blood cells in the extracorporeal blood circuit and blood loss from vascular access. This blood loss, when combined with repeated blood draws, increased blood losses from the gastrointestinal ("GI") tract and stimulation of erythropoiesis by use of erythropoiesis stimulating agents ("ESAs"), frequently results in iron deficiency and anemia in hemodialysis patients. In total, hemodialysis-related and GI iron losses amount to about 1 g - 1.5 g of elemental iron annually, not taking into

consideration accidental blood losses from dialyzer clotting or bleeding from surgical procedures related to vascular access.

Triferic is the first and only FDA-approved iron replacement product indicated for the replacement of iron to maintain hemoglobin in adult patients with hemodialysis-dependent chronic kidney disease (HDD-CKD). We believe Triferic addresses an important unmet need in the treatment of ongoing iron losses and anemia in ESRD patients. Triferic's unique mode-of-action distinguishes it from conventional I.V. iron products because Triferic donates iron to transferrin, immediately, and completely, as soon as it enters the blood. The iron bound to transferrin is transported to the bone marrow to make hemoglobin. Triferic delivers approximately 5 – 7 mg of iron with every hemodialysis

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treatment to the bone marrow and maintains hemoglobin without increasing iron stores (ferritin). In addition to the unique mechanism of action of Triferic, our first formulation of the drug is delivered via the dialysate, which is an innovative mode of delivery that we believe adds a convenience factor for the dialysis units.

We developed Dialysate Triferic as the first and only FDA-approved product indicated to replace iron and maintain hemoglobin concentration in adult hemodialysis patients, and we are in the process of developing and seeking FDA approval for I.V. Triferic, a novel intravenous formulation of Triferic that would be used for the same indication, if approved. A description of Dialysate Triferic and I.V. Triferic is set forth below.

Dialysate Triferic

Dialysate Triferic received FDA approval in January 2015 and remains the only FDA-approved therapy indicated to replace iron and maintain hemoglobin in adult hemodialysis patients.

In 2013, we successfully completed two pivotal Phase 3 efficacy trials, called CRUISE-1 and CRUISE-2, for Dialysate Triferic. The CRUISE studies were identical single-blind, placebo controlled, parallel group, multi-center studies comparing Triferic delivered via hemodialysis bicarbonate concentrate to placebo group receiving standard hemodialysis solution, with approximately 600 subjects split evenly between the two studies and treatment arms. Oral or intravenous iron supplementation was prohibited, and ESA doses were held constant. Both CRUISE studies successfully met their primary endpoint, demonstrating a statistically significant mean change in hemoglobin from baseline to end-of-treatment. Triferic also met key secondary endpoints including maintenance of hemoglobin, maintenance of reticulocyte hemoglobin and increase in serum iron pre-to-post treatment without an increase in ferritin.

A supportive clinical trial, called the PRIME study, demonstrated that Triferic delivered via the hemodialysis concentrate significantly reduced the need for ESA and IV iron during dialysis compared to the placebo arm dialyzed using conventional dialysate. The PRIME study was a nine-month, prospective, randomized, placebo-controlled, double-blinded, multi-center study in the United States that randomized patients equally to dialysate containing Triferic versus conventional dialysate. A total of 103 patients received the blinded study drug (52 Triferic and 51 Placebo). A blinded central anemia management group facilitated ESA dose adjustments, and intravenous iron was administered according to the approved indication and product labeling when ferritin levels fell below 200 µg/L. Both groups successfully kept their hemoglobin concentrations within the target range. At the end of treatment, there was a significant 35% reduction in prescribed ESA dose in patients treated with Triferic compared with the placebo patients. In a subgroup of ESA hypo-responsive patients—those on more than 13,000 units of epoetin per week—patients needed 74% less ESA in the Triferic group compared to the placebo group at the end of treatment. According to data from Dialysis Outcomes and Practice Patterns Study (DOPPS), a study of hemodialysis practices in the U.S., hypo-responsive patients, as defined in the PRIME study, represent more than 20% of the dialysis population. Finally, patients treated with Triferic in this study used 51% less intravenous iron than the placebo patients.

In January 2014, we completed our long-term safety study for Triferic which was a prospective, randomized, double-blinded, placebo-controlled, crossover, multicenter, multinational, Phase 3 study with an enrollment of 718 hemodialysis patients in the United States and Canada. This large-scale long-term safety study, coupled with the successful Phase 3 CRUISE studies, dosed over 100,000 Triferic administrations and demonstrated a safety profile similar to placebo patients.

Dialysate Triferic received a reimbursement J-code on January 1, 2016 from the Centers for Medicare & Medicaid Services (“CMS”), providing that Dialysate Triferic would be reimbursed for administration to dialysis patients within

the existing fixed-price "bundle" of payments that CMS provides to dialysis providers. Because Dialysate Triferic reimbursement would be included in this bundled payment, we commenced efforts in early 2016 to seek so-called "add-on" or "separate" reimbursement for Dialysate Triferic, which is sometimes available for certain new, innovative therapies. Separate reimbursement, implemented by CMS through a program entitled Transitional Drug Add-on Payment Adjustment, or TDAPA, would allow dialysis clinics to more easily adopt Triferic because they would receive a payment over and above the bundled payment rate for Triferic, and would not need to consider the immediate financial impact of adopting the therapy. In the absence of separate reimbursement, adoption of Triferic could potentially be slowed due to the cost of conversion and the lack of an immediate financial incentive to adopt Triferic.

In June 2018, our Board of Directors determined, based on feedback provided from CMS's Innovation Center ("CMMI"), that Dialysate Triferic was unlikely to obtain add-on reimbursement in the near term. As a result, the Company

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changed its commercialization strategy to plan for the commercial launch of Dialysate Triferic with reimbursement within the bundle of payments to dialysis providers, while continuing to develop I.V. Triferic (discussed below). We currently expect to commercially launch Dialysate Triferic in the second quarter of 2019.

I.V. Triferic

We are also developing an intravenous formulation of Triferic, or I.V. Triferic, for use by hemodialysis patients in the United States as well as international markets. I.V. Triferic was developed pursuant to a Special Protocol Assessment ("SPA") with the FDA. As part of the SPA, the FDA agreed that an equivalence approach would be acceptable for I.V. Triferic. In other words, rather than conducting additional safety and efficacy trials, our NDA would be acceptable if we are able to show equivalence between I.V. Triferic and Dialysate Triferic by comparing pharmacokinetic ("PK") parameters of total iron and transferrin-bound iron of I.V. Triferic to Dialysate Triferic. The formal equivalence study was completed during 2018, and I.V. Triferic met bioequivalence criteria compared with Dialysate Triferic. Because I.V. Triferic is a new formulation and new method of administration, the FDA advised us that it requires a new 505(b)1 NDA. We held a pre-NDA meeting with the FDA in June 2018, during which the FDA agreed that the equivalence study was adequate for submission of an NDA. No other material issues were raised regarding our studies and a potential NDA filing. Based on the data from the equivalence study and feedback received during the pre-NDA meeting, we plan to submit our NDA to the FDA for approval during the second quarter of 2019, with an anticipated PDUFA date in the first half of 2020.

On November 1, 2018, CMS issued interpretive guidance on the availability of Medicare reimbursement for certain products indicated to treat renal disease (the "CMS Guidance"). As set forth in the CMS Guidance, Dialysate Triferic would not be eligible for add-on reimbursement under the CMS Transitional Drug Add On Pricing Adjustment ("TDAPA") program. However, based on the CMS Guidance, we believe that, if approved by the FDA on or after January 1, 2020, I.V. Triferic may be eligible for separate sole source payment with a separate J-Code for a two-year timeframe. In accordance with the current guidance, separate TDAPA payments would last for two years following launch, after which I.V. Triferic would be priced inside the bundle. We are working with outside experts to optimize our NDA filing and PDUFA action dates to realize the potential benefits of separate payment, and we are targeting a launch of I.V. Triferic in the first half of 2020, subject to receipt of FDA approval. Upon submission of the NDA, we will be required to pay a user fee to the FDA of approximately $1.3 million.

Limitations of Existing Therapies for Anemia in Hemodialysis Patients

The current standard of care for treating anemia in HDD-CKD patients includes injectable erythropoietin stimulating agents ("ESAs") and intravenous ("IV") iron products. ESAs and IV iron products are often used together to address the two primary causes of anemia in dialysis patients: low erythropoietin ("EPO") levels and iron deficiency. EPO is a hormone that is produced by the kidneys and stimulates red blood cell production in the bone marrow. In patients with CKD, the kidneys do not make enough EPO and as a result the bone marrow makes fewer red blood cells, causing anemia. ESAs are synthetic recombinant versions of human EPO that are administered to CKD patients to stimulate EPO production. Administration of ESAs creates a significant demand for iron in the bone marrow, since iron is a critical building block for hemoglobin that is contained in red blood cells. CKD patients often have deficient serum

iron levels, which can be caused by a number of factors including, but not limited to, blood lost during hemodialysis treatments and related lab testing, the limited diets of CKD patients, and iron sequestration that is caused by elevated levels of hepcidin, a hormone that regulates iron metabolism. Since iron is a critical component of hemoglobin production, reduced levels of iron can cause iron deficiency anemia. IV iron is used to support anemia management in dialysis patients to achieve or maintain an iron replete state prior to, during and following initiation of ESA therapy. IV iron products are macromolecular complexes which are taken up by macrophages where iron gets stored. Iron complexes are metabolized within the macrophages to release iron so that it can bind to transferrin in plasma - the iron carrier in the circulation. Transferrin carries the iron to the bone marrow for hemoglobin generation during red cell production. Due to the inflammation present in hemodialysis patients, hepcidin, the master molecule responsible for regulation of iron absorption from the GI tract and export of recycled iron from the macrophages is released, thereby blocking the release of iron from macrophages - referred to as iron sequestration. This reduces the efficiency of iron delivery to the bone marrow for erythropoiesis, leading to a state of functional iron deficiency. Since IV iron finds a depot in macrophages it can be administered in large doses and is therefore ideally suited as a replacement therapy in iron depleted patients. Consistent with this mechanism of action, IV iron products were approved as large dose injection/infusion to replenish and restore iron stores in iron-depleted patients (serum ferritin level < 200 ng/mL) with iron deficiency anemia. However, since IV iron has been the only therapy available for hemodialysis patients for over 30 years it has been

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commonly used off-label in hemodialysis patients in a proactive manner for maintaining iron balance and preventing the development of iron deficient state. When iron-carbohydrate complexes are administered IV to hemodialysis patients, a significant portion of the iron is sequestered and the dose needed to deliver sufficient iron to the bone marrow far exceeds the amount of iron lost, hence causing progressive and cumulative tissue iron overload with concomitant elevation of serum ferritin levels. In summary, we believe that cumulative tissue iron overload caused by IV iron over time is potentially hazardous to patients. The long term safety of IV iron remains to be established. Furthermore, the carbohydrate moiety in IV iron complexes is thought to be responsible for anaphylactic reactions seen in all IV iron complexes although rarely.

Our Triferic Portfolio

Triferic is structurally and functionally different from IV iron and is specifically FDA-approved to treat the small amounts of iron losses that all dialysis patients experience. Triferic is unique in molecular structure, mode-of-action (bypassing the hepcidin induced block to iron release from the macrophages) and the FDA-approved clinical indication (to replace iron and maintain hemoglobin in adult hemodialysis patients). All components of Triferic are physiologic and present in all mammals. Triferic is used proactively in hemodialysis patients to maintain iron homeostasis such that the amount delivered to the patient and to the bone marrow for erythropoiesis closely approximates the amount lost. Consequently, tissue iron overload is avoided, unlike when iron-carbohydrate complexes are administered proactively. Triferic delivers iron and maintains hemoglobin without increasing iron stores (ferritin) and thus addresses an unmet need. Finally, Triferic has demonstrated an excellent safety profile in clinical trials and in the Company's sample demonstration program. No instances of anaphylaxis have been reported during > 600,000 doses administered and Triferic can be administered even to patients with history of allergic reactions to IV iron. Unlike IV iron, there are no contraindications to use of Triferic as per the FDA approved label.

The First and 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 physiologic nature that facilitates clinical and cost-saving benefits. Triferic is an innovative iron therapy that replaces the ongoing iron losses that routinely occur in the vast majority of hemodialysis patients. Effective January 1, 2016, Triferic received a CMS reimbursement code, commonly referred to as a J-Code.

Dialysate and Intravenous (I.V.) Formulations. We have two primary formulations of Triferic that we intend to commercialize. We expect to launch a formulation that is delivered through dialysate (Dialysate Triferic), including a liquid form and a power form, during the second quarter of 2019. We received FDA approval to market Dialysate Triferic in liquid form in 2015 and in powder form in 2016. We expect Dialysate Triferic will be reimbursed within the CMS bundled rate for dialysis providers. We have also developed an I.V. formulation of Triferic (I.V. Triferic), for which we expect to file an NDA during the second quarter of 2019. If approved, we believe the I.V. formulation could represent a significantly larger market opportunity in the United States for us given the potential for separate reimbursement pursuant to the CMS Guidance, as discussed in more detail below, and the fact that it provides for more flexible administration. Also, it can be delivered to patients who receive their treatment with dialysis machines using bicarbonate cartridges, which we believe is the predominant form of bicarbonate delivery in Europe and certain other non-US countries.

Separate Reimbursement. As set forth in the CMS Guidance, we believe that, if approved by the FDA on or after January 1, 2020, I.V. Triferic may be eligible for separate sole source reimbursement with a separate J-Code. In

accordance with the current guidance, separate TDAPA payments would last for two years following launch, after which I.V. Triferic would be priced inside the bundle. We believe that separate reimbursement for I.V. Triferic, if received, could result in more favorable pricing for I.V. Triferic.

International Opportunities. Our strategy for Triferic outside the United States is to license it to key partners for development and/or commercialization. To date, we have established partnerships in China, Canada, Peru and Chile. We are actively pursuing international licensing opportunities in a number of other countries and regions, with a focus on Europe, Japan and Latin America. Based on our discussions with market participants, we believe that many international markets disproportionately utilize dialysis machines that operate using dry bicarbonate cartridges or bags, whereas the significant majority of the U.S. market utilizes machines that operate using a liquid bicarbonate solution. As a result, we believe the international market opportunity for I.V. Triferic is greater than that of Dialysate Triferic due to the fact that Dialysate Triferic must be mixed with a liquid bicarbonate solution prior to administration. I.V. Triferic, on the other hand, can be infused regardless of the type of dialysis machines or hemodialysis solutions that are being

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utilized. We have recently received regulatory approval for Dialysate Triferic in Peru, and we expect to receive regulatory approval for Dialysate Triferic in Chile in 2019. We also expect to file for regulatory approval for Dialysate Triferic in China and I.V. Triferic in Canada during 2019, pending completion of any required clinical trials and discussions with local regulators. Pursuant to our license agreement with Wanbang Biopharmaceutical, Co., Ltd. ("Wanbang"), in China, we, at our sole discretion, may provide notice to Wanbang of any new formulation, presentation or indications for Triferic, and following such notice Wanbang shall have the right, but not the obligation, to develop and commercialize such product(s). In February 2019, we notified Wanbang of our development of I.V. Triferic, and we are negotiating a new license agreement for I.V. Triferic in China.

Develop Additional Clinical Indications and Product Presentations of Triferic. We are exploring additional 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 exploring other presentations of Triferic.

Dialysis Concentrate Products

We manufacture, sell, deliver and distribute hemodialysis concentrates, along with certain ancillary products. 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. We also supply dialysis concentrates to distributors serving a number of foreign countries, primarily in the Americas and the Pacific Rim. Nipro Medical Corporation distributes our dialysis concentrates in certain countries in Latin America that are not covered under the Baxter Distribution Agreement.

Dialysate concentrates accounted for approximately 96% of our 2018 revenue with ancillary products accounting for most of the remainder. Approximately 84% of our 2018 sales were to distributors and customers for use in the United States. All of our concentrate products are manufactured according to Association for the Advancement of Medical Instrumentation guidelines and current good manufacturing practices ("cGMP") established pursuant to Title 21 of the Code of Federal Regulations, Part 820 ("21 CFR 820"). Our concentrate products are diluted with purified 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 citric acid-based, and 100% acetate-free, in contrast to the acetate-based products used for many years. CitraPure does not promote inflammation associated with acetate-based products 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 acetic acid-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.

RenalPure Liquid Acid Concentrate

Our RenalPure Liquid Concentrate is our original acetic acid-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

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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 certain ancillary products to selected customers including cleaning agents, filtration salts and other supplies used by hemodialysis providers.

Decision on Calcitriol (Active Vitamin D) Injection

Calcitriol is an active Vitamin D injection for the management of hypocalcemia in patients undergoing chronic hemodialysis. Following a strategic review of this product, including pricing, commercial distribution and marketing, manufacturing efficiencies and capacity (including potential capital investment), we determined commercialization of Calcitriol in the U.S. would not be viable at this time. The decision was based, in part, on the fact that prevailing market prices for similar Vitamin D products are lower than our cost to produce Calcitriol on a dose-equivalent basis, and as a result it would be difficult for us to market Calcitriol profitably. As a result of this decision, we recorded an inventory reserve of $0.7 million for the fourth quarter of 2018, reflecting the remainder of our Calcitriol inventory. We are continuing to evaluate the potential commercialization of Calcitriol in China with our partner, Wanbang, including the market opportunity and regulatory pathway.

Our Growth Strategies

U.S. Commercialization of Triferic. The United States hemodialysis market is currently the largest market in the world for dialysis products. There are an estimated 458,000 hemodialysis patients in the United States, or approximately 71 million treatments annually.

Dialysate Triferic. Following the CMS Guidance described earlier, we announced that we intend to commercialize Dialysate Triferic in the second quarter of 2019 “within the bundle”. We believe that an attractive market opportunity exists for Dialysate Triferic within the bundle. Accordingly, we are building a sales, marketing, and medical

infrastructure to support the launch. We anticipate the launch will be supported by a combination of sales representatives, nurse educators and medical science liaisons. Our initial target customers will include selected medium and small sized dialysis chains and independent dialysis centers. We expect that the launch of Dialysate Triferic during 2019 will enable us to engage with key customers in the dialysis industry regarding the potential clinical and pharmacoeconomic benefits of Triferic and will provide us with valuable experience to support the potential launch of I.V. Triferic.

I.V. Triferic. We plan to submit an NDA for I.V. Triferic during the second quarter of 2019, with potential FDA approval in the first half of 2020. We expect to launch I.V. Triferic in the U.S. market in 2020, subject to FDA approval. We believe the market opportunity for I.V. Triferic in the U.S. is potentially larger than that of Dialysate Triferic due to the potential for separate reimbursement under TDAPA and more flexible administration.

Research to Support Triferic Value Proposition. To support the launch of Triferic in the U.S. and globally, we are evaluating potential clinical studies that we believe have the potential to support the value proposition for both Dialysate Triferic and I.V. Triferic. Such studies, if successful, have the potential to provide valuable clinical and pharmacoeconomic data that can be used by our medical teams to educate dialysis providers of the benefits of Triferic. As an example, we have reached an agreement with EMA on a Phase 3 clinical study design for I.V. Triferic in the E.U. that would include a primary endpoint related to ESA dosing. If successful, this trial will provide the data necessary to support a filing for regulatory approval in the E.U. and potentially provide additional data for our U.S. label. We also expect to initiate a clinical study in pediatric patients, as required under section 505B(a) of the Federal Food, Drug, and Cosmetic Act, during 2019.

International Commercialization of Triferic. We are working to commercialize Triferic in various markets across the globe. We are actively engaged in licensing negotiations for Triferic in a number of regions and countries.

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We believe that I.V. Triferic will be the preferred method of delivery in a number of countries and will support our out-licensing efforts for those territories. We intend to leverage the development, regulatory, commercial presence and expertise of potential business partners to accelerate sales of our products throughout the world. To date, our international licensing agreements for Triferic have been focused on Dialysate Triferic due to the fact that Dialysate Triferic is approved in the U.S., thereby simplifying the approval process in certain international countries. We expect that our international licensing activities in the future will be more focused on I.V. Triferic given the larger market opportunity for the product in certain major markets, including Europe, Japan and China.

In 2016, we licensed the commercialization rights for Dialysate Triferic for the Chinese market to Wanbang, a subsidiary of Shanghai Fosun Pharmaceutical (Group) Co., Ltd. (Fosun Pharma). People's Republic of China is expected to become the largest ESRD market in the world over the next several years. Commercial sales activity in this market will commence following regulatory or registration approval. We anticipate our Chinese partner will file for regulatory approval for Dialysate Triferic in 2019. In 2018 and early 2019, our partner commenced two clinical trials in China. Under the terms of the Wanbang Agreement, we received an upfront payment of $4 million, which we are recognizing as revenue 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, beginning with regulatory approval. We are also entitled to a transfer price on product sold to Wanbang that includes a double digit royalty, and Wanbang is responsible for the cost of the clinical trials and regulatory approval program in China. We retain manufacturing responsibilities for Triferic for China. Pursuant to the terms of our licensing agreement with Wanbang, we are negotiating a separate license agreement for I.V. Triferic with Wanbang, which license agreement will not include any additional development or sales milestones.

We have also executed a distribution agreement to market Triferic in Canada with RMC Health Care Inc. We expect to file for regulatory approval of I.V. Triferic in 2019, and if approved we are entitled to receive a transfer price based on our partner's sales price in Canada. Further, in 2017, we licensed the liquid formulation of Dialysate Triferic to Commercializadora Biorenal SpA in Chile and Quimica Europea in Peru. These distributors are responsible for obtaining regulatory approvals, and we are entitled to receive a fixed transfer price for sales of Dialysate Triferic in those markets. In January 2019, we received regulatory approval for Dialysate Triferic in Peru, representing the first approval of Triferic outside the United States, and we expect our partner to commercialize the product beginning in 2019.

Additional Potential Indications for Triferic. We are currently evaluating development of other clinical indications for Triferic. These clinical applications include peritoneal dialysis ("PD"), total parenteral nutrition ("TPN") and possibly treating cancer patients with functional iron deficiency.

Enhance Dialysis Concentrates Business: We are in the process of evaluating potential enhancements to our dialysis concentrates business in an effort to improve its profitability. Specifically, we are evaluating (i) price increases on selected products with certain customers, (ii) our ability to be more efficient in our manufacturing or transportation operations, and (iii) the expansion of our business to additional customers in the U.S. and other jurisdictions such as Latin America.

Clinical Development

Triferic is approved for commercial sale in the United States and Peru, and is not approved for sale in other major markets globally. We have received regulatory guidance from the European Medicines Agency ("EMA") regarding the

clinical studies that are needed to file for approval of I.V. Triferic in Europe. At the present time, we do not intend to commence these clinical studies, absent finding a development partner in Europe or raising additional capital. In conjunction with our licensee in the People's Republic of China, Wanbang Biopharmaceutical, two clinical pharmacology studies are ongoing, which we expect will be completed in 2019.

As a post-approval requirement under the Pediatric Research Equity Act, we are required to conduct a further clinical study of the effectiveness of Dialysate Triferic in a pediatric patient population. We have reached agreement with the FDA on the design of this study, which we intend to commence in 2019, assuming we have the liquidity and capital resources to do so. The study design has also been agreed with the EMA under a Pediatric Investigation Plan (PIP). The results of the pediatric study will support an EU marketing application if and when we are able to complete the other clinical trials that are required.

Additionally, we believe that Dialysate Triferic and I.V. Triferic have potential to be developed for use in other iron deficiency anemia indications, as well as other product presentations and other clinical applications, as described above.

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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 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 (i) 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, (ii) a change of control of the Company occurs and 270 days' notice is provided, or (iii) 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.

Pursuant to the Distribution Agreement, we received an upfront fee of $20 million. If a "Refund Trigger Event" occurs, we would be obligated to repay a portion of the upfront fee and any paid portion of the facility fee. A "Refund Trigger Event" means any of the following: (i) a change of control of the Company involving any of certain specified companies; (ii) a termination by Baxter due to the Company's bankruptcy or breach, or due to price increases that exceed the stated thresholds; (iii) a termination by either party due to a force majeure; (iv) 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 (v) any regulatory action or ruling relating to a covered product that materially

and adversely affects Baxter's commercialization of the product. In the event of a Refund Trigger Event occurring from January 1, 2019 to December 31, 2021, Baxter would be eligible for a 25% benefit of the Agreement's Upfront Payment. 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 eligible for a partial refund of $6.6 million. 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.

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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. We expect that our drug products will generally be delivered to our customers by our third-party logistics provider in the United States.

Sales and Marketing

The top ten dialysis providers treat approximately 417,000 hemodialysis patients in their centers according to an article published by Nephrology News in 2018. We believe this constitutes approximately 86% of the hemodialysis patients in the United States as of 2018. We intend to market and sell Dialysate Triferic and I.V. Triferic directly to these customers and independent clinics in the United States. Our global strategy is to partner with and license these products to established companies in other regions of the world to assist in the further development (primarily clinical trials and regulatory activities), if necessary, and commercialize in those regions. We continue to pursue international licensing opportunities in a number of countries and specific regions.

During the fourth quarter of 2018, we began to assemble a sales and marketing leadership team to support the commercialization of Triferic in the U.S. As of December 31, 2018, the team includes a Vice President of Sales and Strategic Accounts, who will be responsible for promoting Triferic to large and mid-sized dialysis chains, a Director of Sales, who will be responsible for managing a targeted sales team to promote Triferic to small and mid-sized dialysis chains and clinics. Additionally, our team includes a Vice President of Marketing, who has responsibility for managing the integrity of the Triferic brand worldwide. During 2019, we expect to expand our team to include (i) sales representatives who will promote Triferic to nephrologists and dialysis clinics; and (ii) nurse educators who will work closely with dialysis center nurses and technical staff to support the use of Triferic with appropriate dialysis patients.

We expect to market and educate through trade publications, journals, product literature, medical industry trade conferences and congresses, and other channels including digital, social and healthcare related mediums, and web-based applications. We will target our commercial and medical education 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 and DaVita 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 (“Fresenius”), 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, through its Fresenius Kidney Care division, operates approximately 2,500 clinics and treats approximately 37% of the in-center hemodialysis patients in the United States. Fresenius also manufactures and sells a full range of renal products, including dialysis machines, dialyzers, 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 expect to differentiate Triferic for iron maintenance therapy for hemodialysis patients based on its unique mode of action, clinical benefits, ability to lower treatment cost for providers, ease of administration and excellent safety

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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 during every dialysis treatment and IV iron is administered when there is excessive blood loss in a patient. Accordingly, as Triferic gains market share, we expect IV iron use will decline.

We are also aware of a class of drugs, known as hypoxia-inducible factor (HIF) prolyl hydroxylases (PH) inhibitors, or HIF-PH inhibitors, that are in development for a variety of indications, including the treatment of anemia for patients with chronic kidney disease. HIF-PHs are designed to stimulate erythropoiesis and manage iron utilization and can be administered orally. Certain HIF-PH compounds, including roxadustat and vadadustat, have reached Phase 3 development in the United States. If successfully developed and approved, HIF-PHs could potentially offer a more convenient, more effective and/or safer alternative to injectable ESAs for treatment of anemia in CKD patients while potentially increasing iron availability for hemoglobin synthesis. However, we believe iron replacement therapies, such as Triferic, will continue to be required to address ongoing iron losses in hemodialysis patients.

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.

Quality Assurance and Control

Dialysis Concentrate Solutions Business

We operate under FDA 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 and microbial properties of the concentrates comply with the specifications required by industry standards. Each product is assigned a lot number for tracking purposes.

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Drug Manufacturing

We utilize Contract Manufacturing Organizations ("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. We have also developed a quality system for our drug products to ensure the products comply with required specifications prior to distribution.

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 and drugs. 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 are developing and commercializing selected drug candidates, such as Triferic. 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, as opposed to Class III devices, which require "premarket approval" (PMA) from the FDA as described in further detail below. 510(k) 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. 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 (acid and 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 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. 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

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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, including 21 CFR 820, 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. 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"); and (v) review and approval of the NDA 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.

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

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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 for approval. If an application is submitted, there can be no assurance that the FDA will review and approve the NDA in a timely manner. The FDA may refuse to file an NDA if it is not sufficiently complete to permit substantive review. The FDA may deny an NDA by way of a complete response letter 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 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.

Once an NDA is approved, a product is subject to certain post-approval requirements. The FDA regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

Pediatric Requirements

Under the Pediatric Research Equity Act, or PREA, NDAs or supplements to NDAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA does not apply to any drug for an indication where orphan designation has been granted.

The Best Pharmaceuticals for Children Act, or BPCA, provides NDA holders a six-month extension of any exclusivity—patent or non-patent—for a drug if certain conditions are met. Conditions for exclusivity include the FDA’s determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the FDA making a written request for pediatric clinical trials, and the applicant agreeing to perform, and reporting on, the requested clinical trials within the statutory timeframe. Applications under the BPCA

are treated as priority applications, with all of the benefits that designation confers.

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

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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. We do not expect that compliance with these regulations, including environmental laws, will have a material adverse impact on our financial condition.

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. On October 7, 2018, we entered into a Master Services and IP Agreement (the “Charak MSA”) with Charak, LLC and Dr. Ajay Gupta (collectively, “Charak”), who serves as Executive Vice President and Chief Scientific Officer of the Company. Pursuant to the Charak MSA, the parties entered into three additional agreements described below related to the license of certain soluble ferric pyrophosphate (“SFP”) intellectual property owned by Charak, as well as the Employment Agreement (defined below). The Charak MSA provides for a payment of $1,000,000 to Dr. Gupta, payable in four quarterly installments of $250,000 each on October 15, 2018, January 15, 2019, April 15, 2019 and July 15, 2019, and reimbursement for certain legal fees incurred in connection with the Charak MSA. The first two installments due under the Charak MSA were paid when due.

Pursuant to the Charak MSA, the aforementioned parties entered into an Amendment, dated as of October 7, 2018 (the “Charak Amendment”), to the Licensing Agreement between the Company and Charak, dated January 7, 2002, as amended (the “2002 Agreement”), under which Charak granted the Company an exclusive, worldwide, non-transferable license to commercialize SFP for the treatment of patients with renal failure. The Charak Amendment amends the royalty payments due to Charak under the 2002 Agreement such that the Company is liable to pay Charak royalties on net sales by the Company of products developed under the license, which includes the Company’s Triferic product, at a specified rate until December 31, 2021 and thereafter at a reduced rate from January 1, 2022 until February 1, 2034. Additionally, the Company shall pay Charak a percentage of any sublicense income during the term of the agreement, which amount shall not be less than a minimum specified percentage of net sales of the licensed products by the sublicensee in jurisdictions where there exists a valid claim, on a country-by-country basis, and no be less than a lower rate of the net sales of the licensed products by the sublicensee in jurisdictions where there exists no valid claim, on a country-by-country basis.

Also pursuant to the Charak MSA, the Company and Charak entered into a Commercialization and Technology License Agreement I.V. Triferic, dated as of October 7, 2018 (the "IV Agreement"), under which Charak granted the Company an exclusive, sublicensable, royalty-bearing license to SFP for the purpose of commercializing certain intravenous-delivered products incorporating SFP for the treatment of iron disorders worldwide for a term that expires on the later of February 1, 2034 or upon the expiration or termination of a valid claim of a licensed patent. The Company is liable to pay Charak royalties on net sales by the Company of products developed under the license at a specified rate until December 31, 2021. From January 1, 2022 until February 1, 2034, the Company is liable to pay Charak a base royalty at a reduced rate on net sales and an additional royalty on net sales while there exists a valid claim of a licensed patent, on a country-by-country basis. The Company shall also pay to Charak a percentage of any sublicense income received during the term of the IV Agreement, which amount shall not be less than a minimum specified percentage of net sales of the licensed products by the sublicensee in jurisdictions where there exists a valid claim, on a country-by-country basis, and no be less than a lower rate of the net sales of the licensed products by the sublicensee in jurisdictions where there exists no valid claim, on a country-by-country basis.

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Also pursuant to the Charak MSA, the Company and Charak entered into a Technology License Agreement TPN Triferic, dated as of October 7, 2018 (the "TPN Agreement"), pursuant to which Charak granted the Company an exclusive, sublicensable, royalty-bearing license to SFP for the purpose of commercializing worldwide certain parenteral nutritional ("TPN") products incorporating SFP. The license grant under the TPN Agreement continues for a term that expires on the later of February 1, 2034 or upon the expiration or termination of a valid claim of a licensed patent. During the term of the TPN Agreement, the Company is liable to pay Charak a base royalty on net sales and an additional royalty on net sales while there exists a valid claim of a licensed patent, on a country-by-country basis. The Company shall also pay to Charak a percentage of any sublicense income received during the term of the TPN Agreement, which amount shall not be less than a minimum royalty on net sales of the licensed products by the sublicensee in jurisdictions where there exists a valid claim, on a country-by-country basis, and no be less than a lower rate of the net sales of the licensed products by the sublicensee in jurisdictions where there exists no valid claim, on a country-by-country basis.

The foregoing summary does not purport to be a complete description of the terms of the MSA, the Amendment, the IV Agreement and the TPN Agreement and each is qualified in their entirety by reference to the full text of such documents.

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 registration of such marks in the United States and several foreign countries. Most such applications have resulted in registration of such trademarks and service marks.

As of December 31, 2018, we owned or had the rights to 19 issued patents (4 U.S. and 15 foreign) and 102 pending applications (4 U.S. and 98 foreign). Patents and patent applications owned or licensed by us include claims to I.V. and Dialysate Triferic compositions, formulations and methods of making, as well as other patent claims, including Erythropoietin Stimulation Agent (ESA) sparing methods using Triferic, and parenteral nutritional compositions including Triferic.

	United States			Foreign		
Description	Issued	Expiration	Pending	Issued	Expiration	Pending
Triferic (I.V. and Dialysate)	1	2029(1)	1	3(2)	2028(1)	56
Triferic (ESA Sparing)	—	2034	2	2(3)	2034	37
Triferic (Nutritional)	1	2026		9(4)	2026	1
Other	2	—	1	1	—	4

Total	4	4	15	98

(1)Expiration date in U.S. and foreign (Europe, Japan and Canada) for the synthesis and formulation of our pharmaceutical grade formulation of our Triferic product. In the United States, this patent is listed in Orange Book.

(2)European patent validated in 32 European states.

(3) European patent validated in 4 European states.

(4)European patent validated in 12 European states.

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

Suppliers

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. The raw materials for our concentrates products consist primarily of chemical ingredients and packaging components, all of which meet or exceed the requirements of United States Pharmacopeia (“USP”). Key raw materials for our hemodialysis concentrates include citric acid USP, calcium chloride USP, dextrose USP, glacial acetic acid USP, magnesium chloride USP, potassium chloride USP, sodium bicarbonate hemodialysis grade USP and sodium chloride USP, as well as key packaging components such as bottles, caps, bags, boxes and labels. There are multiple potential suppliers for each of these raw materials. We generally negotiate pricing and approximate material quantities for our

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chemicals on an annual basis and utilize blanket purchase orders with monthly release schedules to meet our needs for production.

We have engaged CMOs for the manufacture and packaging of Triferic. We have two suppliers for the active pharmaceutical ingredient ("API") utilized in Triferic, two packagers for the powder formulation of Dialysate Triferic and one fill and finish vendor for the liquid formulation of Dialysate Triferic and I.V. Triferic. New production is generally initiated via purchase orders, though we will evaluate the need for supply agreements based on our forecasted product needs. The lead time to qualify and obtain regulatory approval for an additional CMO could be lengthy. The loss of any significant drug product supplier could have a material adverse effect on our business, financial condition and results of operations.

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

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 2018 and 2017, our direct sales to Baxter aggregated approximately 26% and 27% of sales, respectively, and we had a receivable from Baxter of $2,824,051 and $1,863,412 as of December 31, 2018 and 2017, respectively.

One customer, DaVita Healthcare Partners, Inc. ("DaVita"), accounted for 46% of our sales in 2018 and 50% of our sales in 2017. Our accounts receivable from this customer were $2,538,503 and $2,411,367 as of December 31, 2018 and 2017, respectively. Our contract with DaVita was recently extended and is scheduled to expire on June 30, 2019. While we are confident that we will be able to negotiate a new agreement with DaVita, we can provide no assurance that we will be able to reach such agreement on terms that are acceptable to us.

Another customer, Nipro Medical Corporation, accounted for 10% and 7% of our sales in 2018 and 2017, respectively.

DaVita, Baxter, the accounts administered by Baxter, and Nipro 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 two years were sales to domestic distributors that were resold to end users outside the United States. Our total international sales, including sales made through domestic distributors for resale outside the United States, aggregated 14% and 12%, of our overall sales in 2018 and 2017, respectively.

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

Employees

As of December 31, 2018, we had approximately 269 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

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We have invested heavily in the testing and development of Triferic. We have engaged outside service providers, contract research organizations, consultants and legal counsel to assist us with clinical trials, product development and obtaining regulatory approval. 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 and presentations, including the IV formulation, a proof of concept clinical study in peritoneal dialysis patients, and a pediatric study of Triferic. We have incurred product development and research costs aggregating approximately $5,642,000 and $6,321,000 in 2018 and 2017, respectively, with such costs primarily related to Triferic. Such costs also include effort to address manufacturing issues in an effort to achieve FDA approval of Calcitriol (refer to "Decision on Calcitriol").

We expect research and product development spending in 2019 and 2020 will focus on the Triferic platform, with projects that may include the pediatric study to satisfy FDA and EMA requirements, a Phase 3 study in Europe to support registration for approval, and post-marketing studies to further demonstrate the pharmacoeconomics and patient outcomes of Triferic. Additional studies of Triferic in new indications, including peritoneal dialysis and total parenteral nutrition, are being considered.

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

Our near-term success depends substantially on our launch of Dialysate Triferic and receipt of regulatory approval for I.V. Triferic. Although Triferic has been approved by the FDA, we may not be able to commercialize it successfully.

Although we are in the process of starting the commercial launch of Dialysate Triferic, it is possible that we will not be successful in the launch of this drug. Based on feedback from CMS, Dialysate Triferic will be reimbursed "within

the bundle," which means that dialysis providers will not receive any additional amount of reimbursement from Medicare or Medicaid to compensate them for the cost of purchasing and administering Dialysate Triferic. This reimbursement status may result in a slower rate of commercial adoption, as we must work to show dialysis providers that improved patient outcomes, the reduction of utilization in other therapies and the resulting savings offset the costs associated with Dialysate Triferic. Additionally, Dialysate Triferic competes against current anemia therapies (including intravenous iron and the ESA class of drugs) and possibly other future products. Additionally, it may be difficult to gain

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market acceptance from dialysis chains, anemia managers and nephrologists and such acceptance may be slower than expected, if at all.

Market acceptance will depend on a number of factors, such as demonstration of Triferic's safety and efficacy, cost-effectiveness, and advantages over existing products. Other factors that may impact the commercial success and ultimate profitability of Dialysate Triferic include:

- the rate of adoption of Dialysate Triferic relative to the shelf life of the existing inventory that we have on hand and whether we can sell our existing inventory before it expires;
- the effectiveness of our marketing, sales and distribution strategies and operations for development and commercialization;
- the impact of Triferic on established customer protocols and formularies;
- reimbursement of Dialysate Triferic by government and commercial payors;
- our ability to execute our marketing strategy without significant additional expenditures;
- our competitors' activities, including aggressive marketing and pricing practices and other tactics to retain their market share;
- our ability to successfully assert our patents against potential competitors who may seek to introduce generic versions of Dialysate Triferic;
- our ability to comply with ongoing regulatory requirements applicable to Dialysate Triferic and the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping applicable to Dialysate Triferic;
- the impact of certain royalties related to our sale of Dialysate Triferic granted by us on the profitability of Dialysate Triferic;
- our ability to avoid third party patent interference or patent infringement claims;
- our ability to maintain a continued acceptable safety profile of Dialysate Triferic; and
- the 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 Dialysate Triferic. We cannot assure you that we will be able to generate meaningful and sustained revenues through the sale of Dialysate Triferic. If we are not successful in commercializing Dialysate Triferic, or are significantly delayed in doing so, our entire investment in Dialysate 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 Dialysate Triferic, due to the highly concentrated nature of the market, our continued success may depend on adoption of Dialysate Triferic by the limited number of existing dialysis providers. Further, we believe that the market opportunity for Dialysate Triferic is more limited than for I.V. Triferic, which is not approved for commercialization. In order to realize the full potential value for our Triferic franchise, we will need to successfully commercialize Dialysate Triferic, obtain regulatory approval for I.V. Triferic, and then successfully commercialize I.V. Triferic. Our inability to do so could significantly harm our long-term prospects.

If we are unable to develop and maintain sales, marketing and distribution capabilities to sell and market Dialysate Triferic or any other products we may develop, our product sales may be hindered.

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We are in the process of establishing an internal sales organization for the sale, marketing and distribution of Dialysate Triferic, as well as I.V. Triferic (if approved). In order to successfully commercialize Dialysate Triferic, I.V. Triferic and any other product we may develop, we must establish and/or increase our sales, marketing, distribution and other non-technical capabilities. The development of a sales organization to market Dialysate Triferic, I.V. Triferic, or any other product we may develop, is expensive and time-consuming, and we cannot be certain that we will be able to successfully develop this capacity or that this function will execute as expected. If we are unable to establish adequate sales, marketing and distribution capabilities, we may not be able to generate product revenue and our business and results of operations will suffer.

If we are unable to use our Dialysate 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.

Given that we have not yet commenced commercialization of Dialysate Triferic, we cannot predict the rate of future sales and usage of the drug. As of December 31, 2018, we had a gross inventory balance for Triferic of $8.0 million, including approximately $4.1 million in Triferic's active pharmaceutical ingredient and $3.9 million in finished goods inventory. Of this amount, we had reserved $5.8 million related to our Triferic finished goods and active pharmaceutical ingredient inventory. As a result of this reserve, our total Triferic inventory had a net book value of $2.2 million as of December 31, 2018. The Dialysate Triferic inventory has an initial shelf life ranging from one to three years. If we are unable to utilize some or all of our Dialysate Triferic inventory before its shelf life expires, some or all of our investment in Dialysate Triferic inventory may not be saleable. This would reduce the inventory we have available for sale and require us to reserve for the reduction in value, which would likely require 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, financial position and cash flows.

Expansion of Triferic franchise requires regulatory approval of I.V. Triferic. Although we believe that we currently have sufficient data to support the approval of I.V. Triferic in the United States, there is no guarantee of success.

Expansion of our Triferic franchise will depend on approval of I.V. Triferic by the FDA, as well as foreign regulators, such as the EMA. Although we believe that we have sufficient data to support the approval of I.V. Triferic, it is possible that the FDA could request additional data regarding the drug or the manufacturing process. Accordingly, there is no guarantee the FDA or the EMA will approve I.V. Triferic. In reviewing our planned NDA submission for I.V. Triferic, 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. Furthermore, at the time of FDA approval of our NDA for Dialysate Triferic, we agreed to perform a post-approval clinical study of Dialysate Triferic in a pediatric population. If we do not timely satisfy our post-approval study requirements, it is possible that the FDA could decline to act on future Triferic filings, which could include I.V. Triferic. If approval is not granted for I.V. Triferic on the timeframe we expect, or if it is not approved at all, the value of our Triferic franchise would be severely limited.

Although we believe that I.V. Triferic (if approved) should be eligible for add-on reimbursement status, it is possible that it will not receive this reimbursement status, which would limit the commercial opportunity.

In November 2018, CMS issued guidance regarding the eligibility of certain new drugs approved after January 1, 2020 for a transitional period of add-on reimbursement status under the so-called "TDAPA" program. To be eligible for this transitional add-on reimbursement status, I.V. Triferic must be approved no earlier than January 1, 2020 and must be considered to be a new drug. If I.V. Triferic is approved prior to January 1, 2020 or if it not considered by CMS to

qualify as a new drug (i.e., in light of the prior approval of Dialysate Triferic), then we may be deemed ineligible to participate in the TDAPA program, in which case I.V. Triferic may also be required to be sold within the bundled payment for dialysis treatment. This could significantly limit the overall commercial opportunity in the United States for I.V. Triferic.

Our ability to market Dialysate Triferic is limited by the FDA to those specific indications and conditions for which clinical safety and efficacy have been demonstrated.

The FDA must approve any new indication for an approved product. Dialysate Triferic is approved by the FDA for use in adult patients receiving hemodialysis treatments and has not yet been approved for other indications or for

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other claims for which we may seek approval, such as ESA-sparing. We are not able to promote Dialysate Triferic or encourage our customers to use Dialysate Triferic for purposes other than the indications of use that have been specifically approved by the FDA as safe and effective. If we are not able to obtain FDA approval for additional indications for Dialysate Triferic or secure an expanded product label, our ability to fully market Dialysate Triferic on the basis of cost savings or improved patient outcomes may be limited, which would limit our ability to take full advantage of Dialysate Triferic's market opportunity.

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 drug products and processes in the U.S. and in other important markets remains uncertain and is dependent upon the scope of protection afforded to us by the patent offices, courts, administrative bodies and lawmakers in the relevant jurisdictions. We can provide no assurance that we will successfully obtain or preserve patent protection for the technologies incorporated into our drug 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.

While we have an issued patent in the United States and certain other major markets, including Europe and Japan, that covers IV and Dialysate formulations of Triferic, these patents expire in 2029. The previously issued foundational composition-of-matters patents for Triferic expired in 2016. In light of the current patent protection that we have for Triferic, it is possible that a competitor could seek to manufacture a generic version of Triferic using product specifications and manufacturing methods that do not infringe our issued patent. Further, it is possible that a competitor could seek to invalidate our issued Triferic patent.

We also rely on regulatory exclusivity for protection of our drug products, which includes regulatory data protection and market protection. Implementation and enforcement of regulatory exclusivity varies widely from country to country. Failure to qualify for regulatory exclusivity, or failure to obtain or maintain the necessary extent or duration of such protections for our drug products could affect our revenues, our decision on whether to market our drug products in a particular country and could otherwise have an adverse impact on our results of operations. In the United States, our regulatory exclusivity for Dialysate Triferic as a new chemical entity started with FDA approval of the product. Because of the delay between approval and the commercial launch of Triferic, our regulatory exclusivity has expired and we must rely on patent protection for the long-term protection of our Triferic franchise.

Litigation, interferences, oppositions, inter partes reviews, administrative challenges or other similar types of proceedings are, have been and may in the future be necessary to determine the validity and scope of certain of our proprietary rights. Such proceedings may also be necessary 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 drug products. We may also face challenges to our patent and regulatory protections covering our drug products by third parties, including manufacturers of generics that may choose 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 drug 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 drug products. Furthermore, payments under any licenses that we are able to obtain would reduce our profits derived from the covered products and services.

We depend on third parties to manufacture Triferic. 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 business will be harmed.

We rely on contract manufacturing organizations ("CMOs") to manufacture Triferic. If a CMO is unable to manufacture Triferic in sufficient quantities and on a consistent basis, or if it becomes unwilling to produce Triferic for us, we may not be able to supply our customers in a timely manner. For I.V. Triferic and our liquid formulation of

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Dialysate Triferic, we have a single-source finished goods supplier and do not have a long-term supply contract. If we were to experience a supply disruption, it could take an extended period of time to find and qualify an alternate supplier. The manufacturing facilities and processes used by our CMOs must be approved by the FDA and foreign regulators, where applicable, before the drug products manufactured by such CMOs can be sold. After approval, CMOs must meet certain ongoing regulatory requirements for product testing and stability of our commercially marketed products. We do not control the manufacturing processes of our CMOs and depend on them to comply with current good manufacturing practices ("cGMP"), and obtain and maintain regulatory approval. If approval for a CMO is not received or ongoing testing does not continue to meet approved standards and approval is withdrawn, the CMO's production would be delayed or suspended, which could adversely affect our Triferic commercialization efforts. If that was to happen, we may be forced to find another capable CMO 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 with our drug products 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 the raw materials or packaging components we need, or the price of such materials or components may rise significantly, for a variety of reasons, including but not limited to:

- a business interruption, including 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
- failure of a supplier to comply with cGMP standards, which could result 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 are 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 packaging components and are not able to establish alternative supply sources, or if the prices for such items increase substantially, our CMOs may not be able to produce the desired quantities of our drug products and our expected gross profit margins may be materially adversely affected.

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 Triferic or other drug products outside of the United States. Even if we, or our partners, are successful in obtaining the required regulatory approvals, we may not be effective at marketing our drug products in certain markets or at all.

The regulatory procedures for obtaining marketing approval of drug products, including Triferic, outside the United States vary from country to country and such approvals can be difficult to obtain. Regulatory approval in foreign countries may require additional clinical testing, such is the case with Triferic and our ability to file for regulatory

approval in Europe. These tests may be expensive and time consuming and there can be no assurance as to our ability to achieve a positive result, even if we have had positive clinical trial results in the past. 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.

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Even if we obtain the necessary foreign approval in a particular market, we do not have expertise selling and marketing on an international level and, therefore, may not be successful in realizing commercial value from our drug products. Thus, our strategy is to out-license the rights to our drug products in markets outside the United States to partners who we believe will have the necessary resources and expertise to obtain regulatory approval and ultimately commercialize our out-licensed drug products. However, we may not be successful in finding new partners who will be willing to invest in our drug products outside the United States. 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 regulatory approval ourselves, it may take longer than expected to obtain such approval and to market and manufacture our drugs. As a result, 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 develop and commercialize our drug products in foreign markets, we will be dependent upon their effectiveness in selling and marketing our drug 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 drug products, any of which could reduce the market potential for our drug products and our success in those markets.

If Triferic or other drug candidates 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 Triferic or other drug candidates 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;
- anti-corruption laws, including the Foreign Corrupt Practices Act, or the FCPA
- 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. We may not be able to identify such products. If we do, 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.

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

Medicare and Medicaid fund the majority of dialysis costs in the United States. 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. Changes to health insurance and reimbursement by Congress may have a negative impact on Medicare and Medicaid funding and on reimbursement protocols. If Medicare and Medicaid funding were to be materially decreased, dialysis 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 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. Such legislation includes potential changes to or the repeal of Medicaid expansion, coverage for pre-existing conditions and insurance coverage minimum benefits. The likelihood of passage and the impact of this legislation is uncertain. However, it could potentially impact reimbursement by Medicare and Medicaid programs for our drug products and dialysis and could negatively affect 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.

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.

We have in-licensed rights to certain patents that cover our products. If we fail to remain in compliance with these license agreements, we could forfeit the rights to these patents, which could negatively impact our ability to commercialize our products.

We have acquired rights to certain patents under license agreements, including with an affiliate of Ajay Gupta, our Chief Scientific Officer. These in-licensed patent rights cover I.V. Triferic and have other claims that could cover Triferic and other products. If we fail to remain in compliance with the terms of these license agreements, including due diligence obligations relating to our efforts to develop and commercialize licensed products in certain markets, we could be found to be in breach of these license agreements. If this was to happen, the licensor could terminate the license agreement in certain circumstances, causing us to forfeit our rights to the licensed patents. This could cause us to lose the ability to sell certain products, including I.V. Triferic, and could potentially subject us to expensive and protracted litigation. Any of these occurrences could significantly harm our results of operations and future prospects.

The dialysis market is highly concentrated in the United States, with two organizations (DaVita and Fresenius) accounting for approximately 73% of the total number of hemodialysis patients. Given this concentrated market power, our success in commercializing Triferic will depend in part on the willingness of DaVita and Fresenius to adopt Triferic.

DaVita Inc. and Fresenius North America own or manage a large number of the outpatient dialysis facilities located in the United States and account for a substantial majority of Triferic's addressable market opportunity in the free-standing dialysis clinic setting. Due to this concentration, these entities have substantial purchasing leverage, which may put pressure on our pricing by their potential ability to extract price discounts on our products, correspondingly negatively impacting our bargaining position and profit margins. Additionally, if one or both of these entities elect to not adopt Triferic, that decision would have a significant impact on our ability to successfully penetrate a large portion of the total addressable market in the United States.

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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.

Upon the occurrence of a "Refund Trigger Event" under the Distribution Agreement with Baxter, we may be required to repay to Baxter $5.0 million of the $20 million upfront fee and a portion of the facility fee. A Refund Trigger Event includes, among other things, termination due to an uncured material breach by us. 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 2019, Baxter would be entitled to a refund of up to $6.6 million. If we are required to make any such payment to Baxter, 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 medical device 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 as an 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.

We face competition in the concentrate market and have a large competitor with substantial resources.

The primary competitor in the market for our concentrate products is Fresenius Medical Care NA, or Fresenius, a large diversified company which has financial, technical, manufacturing, marketing, research and management resources substantially greater than ours. We and our distributor, Baxter, may not be able to successfully compete with Fresenius. Fresenius has historically used product bundling and low pricing as a competitive strategy to capture market share of concentrate products. We and Baxter may be at a disadvantage in competing against these strategies to sell concentrate products. Furthermore, Fresenius is vertically integrated and is the largest provider of dialysis services in the United States, treating approximately 37% of all U.S. in-center hemodialysis patients through its clinics. Fresenius has routinely acquired our customers, and it may acquire more of our customers in the future.

We may be affected materially and adversely by increases in raw material and shipping 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 the Distribution Agreement with Baxter, such cost inflation may result in increases in the prices we charge Baxter. If these increases exceed levels specified 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. Additionally, we have

been adversely affected by a general shortage in commercial truckers in the United States. This has negatively impacted our profit margins as we pay higher costs to ship products to our customers. Continued increases in shipping costs, or the costs of raw materials, could negatively impact our profit margins, as we may be limited in our ability to pass these costs along to our customers.

RISKS RELATED TO OUR BUSINESS AS A WHOLE

We have substantial doubt as to our ability to continue as a going concern.

We have substantial doubt as to our ability to continue as a going concern. We expect to incur further losses in the development of our business, all of which casts substantial doubt about our ability to continue as a going concern. Our

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ability to continue as a going concern is dependent upon our ability to generate future profitable operations and/or to obtain the necessary financing to meet our obligations and repay our liabilities arising from normal business operations, including research and development, when they come due. Our auditors report for the year ended December 31, 2018 included an explanatory paragraph that raises substantial doubt about the Company's ability to continue as a going concern. Management anticipates that we will need to obtain additional funding. There are no current arrangements in place for future funding. If we cannot generate sufficient revenues from our services or seek additional funding we may have to delay the implementation of our business plan.

Our existing capital resources may not be adequate to finance our operating cash requirements for the length of time that we have estimated and additional capital that we may need to operate or expand our business may not be available.

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:

- the timing and expenditures associated with the commercialization of Triferic and the timing and magnitude of cash received from product sales;
- the timing and expenditures associated with the build-up of inventory;
- the timing, design and conduct of, and results from, clinical trials that we may conduct; and
- 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 newly issued securities may have rights, preferences or privileges senior to those of holders of our common stock.

Debt financing, if available, may involve significant cash payment obligations and covenants that restrict our ability to operate as a business. Additionally, we may have difficulty borrowing money through a term loan or debt facility given the covenants in our distribution agreement with Baxter which prohibit us from entering into a contract encumbering the assets used in our concentrate business. These assets 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.

Regardless of whether we seek to raise additional working capital through the sale of equity securities or the incurrence of indebtedness, if we do not have sufficient funds available to launch Triferic, conduct planned clinical studies and pursue business opportunities, our business, results of operations, financial position and cash flows could be materially adversely affected.

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. After a product is approved, regulatory authorities may impose significant restrictions on a product's indicated uses or marketing or requirements for potentially costly post-marketing studies. Our drug 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. 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 our partners must continue to expend time, money and effort in all areas to achieve and maintain

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regulatory compliance. We are also required to report certain adverse reactions and production problems, if any, to applicable regulatory authorities and to comply with requirements concerning advertising and promotion for our drug products.

If non-compliant inventory is sold or if a regulatory agency determines that we are not compliant with any applicable regulatory requirements, we may be subject to warnings from, or enforcement action by, state and federal government authorities, which 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 FDA on our intended marketing or the use of our drug products.

Our failure to comply with applicable regulations could also result in product liability litigation against us. In addition, our failure to comply with applicable regulations 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, which resulted in the negotiation of changes to the Board and substantial costs were incurred. 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. 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.

We replaced our senior management team in 2018. Our inability to successfully manage the transition and integration into our Company of these key executives may have a material adverse impact on our business, results of operations and financial condition.

We hired a new Chief Executive Officer and Chief Financial Officer in 2018 and have hired additional executive-level employees who are leading the commercial launch of Dialysate Triferic. This leadership transition may be difficult to manage and may cause operational and administrative inefficiencies, added costs, decreased productivity among our employees, and loss of personnel with deep institutional knowledge, which could result in significant disruptions to our operations. In addition, we must successfully integrate our new management team members within our organization in order to achieve our operating objectives, and these changes in key management positions may temporarily affect our financial performance and results of operations as our new management becomes familiar with our businesses. These changes could also increase the volatility of our stock price. If we are unable to mitigate these or other similar risks, our businesses, results of operations, and financial condition may be adversely affected.

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We could be found to be infringing intellectual property rights of third parties, which could prevent us from selling products and could require us to pay significant damages and compel us to defend against litigation.

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 drug 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 drug products. 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 drug 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 and proprietary information related to our business, our customers and our business partners, on our information technology systems. Despite the implementation of security measures, these systems are vulnerable to damage from computer viruses, unauthorized access, cyber-attacks, 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,

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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, including protected health information or personal data of employees or former employees, 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.

We are and may become the target of additional securities litigation, which is costly and time-consuming to defend.

In addition to the purported shareholder class action lawsuits filed against us as described in Note 14 "Commitments and Contingencies" in the accompanying consolidated financial statements for the year ended December 31, 2018, it is possible that other class action securities litigation and derivative lawsuits could be brought against us in the future. The results of complex legal proceedings are difficult to predict. These lawsuits assert types of claims that, if resolved against us, could give rise to substantial damages, and an unfavorable outcome or settlement of these lawsuits, or any future lawsuits, could have a material adverse effect on our business, financial condition, results of operations and/or stock price. Even if any future lawsuits are not resolved against us, the costs of defending such lawsuits may be material to our business and our operations. Moreover, these lawsuits may divert our Board and our management's attention from the operation of our business. For more information on our legal proceedings, see Note 14 "Commitments and Contingencies – Litigation" in the accompanying consolidated financial statements for the year ended December 31, 2018.

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

We received letters in 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. In

2018, we received additional requests (including a subpoena) from the SEC asking for certain records and information relating to the termination of our prior Chief Executive Officer and Chief Financial Officer, as well as the facts and circumstances leading up to the resignation of our prior audit firm. 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 have provided all of the requested information and documents to the SEC from the 2017 requests and are substantially complete in providing the requested information and documents from the 2018 subpoena. We intend to continue to fully cooperate with the SEC investigation. At this stage, we are unable to predict when the SEC's inquiry will conclude or what the consequences may be. Furthermore, any continuation of the SEC inquiry may cause a diversion of

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management's time and attention, which could have a material adverse effect on our business, results of operations, financial position and cash flows.

We may be subject to future disputes with respect to the Settlement Agreement.

On August 7, 2018, we entered into a confidential settlement agreement and mutual release, or Settlement Agreement, with our former CEO, former CFO and a former and then-current director. We may be subject to disputes, claims or other disagreements with such parties with respect to the Settlement Agreement that may require us to incur legal fees and divert management's time and attention.

RISKS RELATED TO OUR COMMON STOCK

The restatement of our previously issued financial statements contained in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2018 may lead to additional risks and uncertainties, including regulatory, shareholder or other actions, loss of investor confidence and negative impacts on our stock price.

Our Audit Committee, after consultation with management and discussing with outside counsel, external auditors and third-party consultants, concluded on August 12, 2018 that our previously issued consolidated financial statements for the quarter ended March 31, 2018 should be restated for the reasons described in "Explanatory Note" preceding Part I, Item 1 and Note 3 - Restatement of Unaudited Condensed Consolidated Financial Statements of the Notes to Consolidated Financial Statements in Part I, Item 1 of the amended Form 10-Q for the quarter ended March 31, 2018. Our amended Form 10-Q for the quarter ended March 31, 2018 includes restated unaudited financial statements and selected financial data (and related disclosures). Financial information included in our previously filed Form 10-Q for the quarter ended March 31, 2018, and all earnings press release and similar communications issued by us, for the period, should not be relied upon and are superseded in their entirety by our amended Form 10-Q for the quarter ended March 31, 2018. The amended Form 10-Q for the quarter ended March 31, 2018 amends and restates, in its entirety, our Form 10-Q for the quarter ended March 31, 2018.

As a result of this restatement and associated non-reliance on previously issued financial information, we have become subject to a number of additional costs and risks, including unanticipated costs for accounting and legal fees in connection with or related to the restatement and the remediation of our ineffective disclosure controls and procedures and material weaknesses in internal control over financial reporting. Likewise, the attention of our Board and our management team has been diverted by these efforts. In addition, we could also be subject to additional shareholder, governmental, regulatory or other actions or demands in connection with the restatement or other matters. Any such proceedings will, regardless of the outcome, consume a significant amount of the Board's and management's time and attention and may result in additional legal, accounting, insurance and other costs. If we do not prevail in any such proceedings, we could be required to pay damages or settlement costs. In addition, the restatement and related matters could impair our reputation or could cause our customers, shareholders, or other counterparties to lose confidence in us. Any of these occurrences could have a material adverse effect on our business, results of operations, financial condition and stock price.

Our plan to remediate the identified material weaknesses in our internal control over financial reporting and the restatement of our previously issued financial statements contained in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2018 may not be sufficient to correct all material weaknesses and deficiencies.

On June 22, 2018, we announced the resignation of our registered independent public accounting firm, Plante & Moran, PLLC ("Plante"). Plante's report on the Company's financial statements for the year December 31, 2017 did not contain an adverse opinion or a disclaimer of opinion, nor were they qualified or modified as to uncertainty, audit scope, or accounting principles and during the year ended December 31, 2017 and through June 22, 2018 (the date of

Plante's resignation), the Company had no disagreements with Plante on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreements, if not resolved to Plante's satisfaction, would have caused it to make reference to the subject matter of the disagreements in connection with its reports.

In connection with the restatement of our financial statements for the quarter ended March 31, 2018, Plante and our management team identified a material weaknesses in our internal control over financial reporting with respect to the quarter ended March 31, 2018. Accordingly, the Board and management have concluded that management's reports

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related to the effectiveness of internal and disclosure controls for the quarter ended March 31, 2018 may not have been correct and we identified material weaknesses in our controls over financial reporting, including, insufficient segregation of duties, ineffective controls related to the accuracy and completeness of compensatory amounts and deficiencies in the computation of our inventory reserves.

As of December 31, 2018, we identified an additional weakness in our in our controls over financial reporting relating to improper evaluation of information technology. We identified deficiencies related to the Information Technology General Controls ("ITGC") relating to the upgrade of our enterprise resource planning system. We had not performed a proper evaluation of our information technology environment and the related disclosure controls and procedures and internal control over financial reporting.

A material weakness is a deficiency, or combination of deficiencies, in internal controls over financial reporting that results in a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. Although our Audit Committee and management are implementing improvements to our internal controls to remediate the identified material weaknesses, these improvements may not be effective to fully remediate such material weakness or prevent a material misstatement of our annual or interim financial statements in the future. Our material weaknesses are fully described in Item 9(a) "Control and Procedures" for Form 10-K.

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, 2018, there were 6,470,500 shares issuable upon the exercise of the then-outstanding and exercisable stock options and 1,774,105 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

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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.

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 2021. We also lease two other manufacturing facilities, a 51,000 square foot facility in Grapevine, Texas under a lease expiring in December 2020, and a 57,000 square foot facility in Greer, South Carolina under a lease expiring in February 2020. In addition, we executed a lease for 4,100 square feet of office space in Hackensack, New Jersey with a lease term beginning on April 1, 2019 and expiring on July 1, 2024.

We 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 use the office space in Wixom, Michigan as our principal administrative office and the office space in Hackensack, New Jersey for senior executives and other local administrative staff. 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.

The Company, and its subsidiaries, are subject at times to various claims, lawsuits and governmental proceedings relating to the Company's business and transactions arising in the ordinary course of business. We cannot predict the final outcome of such proceedings. Where appropriate, the Company vigorously defends such claims, lawsuits and proceedings. Some of these claims, lawsuits and proceedings seek damages, including, consequential, exemplary or punitive damages, in amounts that could, if awarded, be significant. Certain of the claims, lawsuits and proceedings arising in ordinary course of business are covered by the Company's insurance program. The Company maintains property, automobile and various types of liability insurance in an effort to protect the Company from such claims. In terms of any matters where there is

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no insurance coverage available to the Company, or where coverage is available and the we maintain a retention or deductible associated with such insurance, the Company may establish an accrual for such loss, retention or deductible based on current available information. In accordance with accounting guidance, if it is probable that an asset has been impaired or a liability has been incurred as of the date of the financial statements, and the amount of loss is reasonably estimable, then an accrual for the cost to resolve or settle these claims is recorded by the Company in the accompanying consolidated balance sheets. If it is reasonably possible that an asset may be impaired as of the date of the financial statement, then the Company discloses the range of possible loss. Paid expenses related to the defense of such claims are recorded by the Company as incurred and paid and included in the accompanying consolidated statements of operations. Management, with the assistance of outside counsel, may from time to time adjust such accruals according to new developments in the matter, court rulings, or changes in the strategy affecting the Company's defense of such matters. On the basis of current information, the Company does not believe there is a reasonable possibility that, other than with regard to the Class Action described below, any material loss, if any, will result from any claims, lawsuits and proceedings to which the Company is subject to either individually, or in the aggregate.

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").

Our complaint alleged various violations of the Securities and Exchange Act of 1933 (the "Exchange Act") by the Richmond/Ravich Defendants.

Richmond/Ravich Settlement

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.

Termination of our CEO and CFO

The Company terminated its CEO and CFO, which resulted in the following litigation involving the Company.

Circuit Court for Oakland County, Michigan

Following the Board's termination of the Company's former CEO on May 22, 2018, and in response to his continued assertion that he remained the duly appointed Chief Executive Officer of the Company, on May 23, 2018, the Company filed a complaint in the Oakland County Circuit Court in Michigan ("State Court") seeking declaratory relief and a temporary restraining order. On May 24, 2018, the Board terminated its then-serving CFO. On July 11, 2018, the

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State Court entered a stipulated order permitting the Company to withdraw its complaint and allowing the parties to litigate in the Federal Court action described below. On July 17, 2018, the lawsuit in the State Court action was dismissed and closed.

United States District Court for the Eastern District of Michigan

On June 13, 2018, the Company's former CEO and CFO filed a complaint in the United States District Court for the Eastern District of Michigan ("Federal Court") against the Company and certain directors (collectively, the "Defendants"). The complaint requested that the Federal Court reinstate the former CEO to his former position of Chief Executive Officer, reinstate the former CFO to his former position of Chief Financial Officer and order the Defendants to pay all costs associated with the matter. The complaint alleged that the Defendants possibly violated their duties of loyalty and care to the Company; rules under Regulation Fair Disclosure; and various federal securities laws, including Section 10(b) of the Exchange Act and SEC Rule 10b-5. On July 2, 2018, the Company filed an answer and counterclaim against the Company's former CEO, former CFO, a former director and a then-serving director. On August 7, 2018, the parties entered into the Settlement Agreement by which the parties agreed to dismiss the Federal Court action with prejudice.

Settlement Agreement and Dismissal of State and Federal Court Actions

On August 7, 2018, the parties entered into a Settlement Agreement by which the parties agreed to dismiss the federal court action with prejudice. The court dismissed and closed the action on August 15, 2018.

On August 7, 2018, the Company, the Company's former CEO, former CFO, a former director and a then-serving director and the Defendants, entered into the Settlement Agreement, pursuant to which the parties agreed to dismiss the Federal Court action with prejudice and to enter into a broad mutual release of claims. The Company agreed to: (i) pay the Company's former CEO, former CFO, a former director and a then-serving director a total of $1,500,000, one-half of which was paid at execution and the remainder of which will be paid in nine equal monthly installments of $83,333, (ii) pay $30,000 to the then-serving director (who then agreed to resign as a director); (iii) accelerate the vesting of options held by the Company's former CEO and former CFO as of the date of their terminations; and (iv) grant an extended option exercise period for vested options. The Company's former CEO, former CFO, a former director and the resigning director agreed to certain standstill covenants for a period of approximately five years and agreed to forfeit a total of 333,200 unvested shares of restricted common stock.

SEC Investigation

As a follow up to its prior inquiry letters, the Company received a subpoena from the SEC during the Company's third quarter requesting, among other things, certain information and documents relating to the status of the Company's

request to CMS for separate reimbursement status for Dialysate Triferic, the Company's reserving methodology for expiring Triferic inventory, and the basis for the Board's termination of the former CEO and CFO. The Company is cooperating with the SEC and is responding to the SEC's requests for documents and information.

Shareholder Class Action Lawsuits

On July 27, 2018, Plaintiff Ah Kit Too filed a putative class action lawsuit in the United States District Court in the Eastern District of New York against the Company and former officers, Robert Chioini and Thomas Klema. The complaint is a federal securities class action purportedly brought on behalf of a class consisting of all persons and entities, other than Defendants, who purchased or otherwise acquired the publicly traded securities of the Company between March 16, 2018 and June 26, 2018. The Complaint alleges that the Company and Messrs. Chioini and Klema violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"). Specifically, the Complaint alleges that defendants filed reports with the Securities and Exchange Commission that contained purported inaccurate and misleading statements regarding the potential for the Company's drug, Triferic, to quality for separate reimbursement status by the Centers for Medicare and Medicaid Services.

On September 4, 2018, Plaintiff Robert Spock filed a similar putative class action lawsuit in the United States District Court in the Eastern District of New York against the Company and Messrs. Chioini and Klema. The Spock complaint is a federal securities class action purportedly brought on behalf of a class consisting of persons who purchased the Company's securities between November 8, 2017 and June 26, 2018. This complaint alleges that the Company and Messrs. Chioini and Klema violated the Exchange Act in that the Company was aware the Centers for Medicare and

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Medicaid Services would not pursue the Company's proposal for separate reimbursement for Triferic; misstated reserves in the Company's quarterly report for the first quarter of 2018; had a material weakness its internal controls over financial reporting, which rendered those controls ineffective; Mr. Chioini withheld material information regarding Triferic from the Company's auditor, corporate counsel, and independent directors of the Board; and, as a result of these alleged issues, statements about the Company's business were materially false and misleading.

On September 25, 2018, four Company stockholders filed motions to appoint lead plaintiffs, lead counsel, and to consolidate the Ah Kit Too v. Rockwell securities class action with the Spock v. Rockwell securities class action. On October 10, 2018, the court issued an order consolidating the two actions, appointing co-lead plaintiffs and co-lead counsel. On December 10, 2018, lead Plaintiffs filed a consolidated amended complaint, which included the same allegations as the initial complaints and asserted claims on behalf of a putative class consisting of person who purchased the Company's securities between November 8, 2017 and June 26, 2018. On February 18, 2019, the Company answered the consolidated amended complaint. The lawsuits seek damages allegedly sustained by the class and an award of plaintiffs' costs and attorney fees. The case is at an early stage with no significant pre-trial proceedings (such as substantive motions, discovery, etc.) having occurred. The Company believes it has defenses to the claims of liability and damages and is responding accordingly.

The Company has tendered the class action to its D&O insurance carrier(s) for defense and indemnity under its applicable insurance policies. The Company maintains a $1.0 million self-insured retention under the applicable insurance policies, which can be exhausted by payment of expenses or indemnity.

Item 4. Mine Safety Disclosures.

Not applicable.

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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 2018 and 2017.

	Price Range	
	High	Low
2018		
Fourth Quarter	$ 4.54	$ 2.19
Third Quarter	5.07	3.85
Second Quarter	6.55	3.62
First Quarter	6.92	4.84
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

As of February 28, 2019, there were 26 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.

Unregistered Sales of Equity Securities

There were no unregistered sales of equity securities which have not been previously disclosed in a quarterly report on Form 10-Q or a current report on Form 8-K during the year ended December 31, 2018.

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.

Stock Performance Graph

Not applicable.

Item 6. Selected Financial Data.

Not applicable.

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

Overview and Recent Developments

We are a specialty pharmaceutical company targeting end-stage renal disease and chronic kidney disease with products for the treatment of iron deficiency and hemodialysis. We are also a manufacturer of hemodialysis concentrates/dialysates to dialysis providers and distributors in the United States and abroad. We supply approximately 25% of the United States domestic market with dialysis concentrates and we also supply dialysis concentrates to distributors serving a number of foreign countries, primarily in the Americas and the Pacific Rim. To date, substantially all of our sales have been 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 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

Triferic is the Company's proprietary iron therapy that replaces iron and maintains hemoglobin in dialysis patients without increasing iron stores. The Company has developed Dialysate Triferic (Ferric Pyrophosphate Citrate) as the only FDA approved product indicated to replace iron and maintain hemoglobin concentration in adult HDD-CKD hemodialysis patients, and is in the process of developing and seeking FDA approval for I.V. Triferic, a novel intravenous formulation of Triferic that would be used for the same indication, if approved. A description of Dialysate Triferic and I.V. Triferic is set forth below.

Dialysate Triferic

Our dialysate formulation of Triferic ("Dialysate Triferic") received FDA approval in 2015 and remains the only FDA-approved therapy indicated to replace iron and maintain hemoglobin in adult hemodialysis patients. Dialysate Triferic received a Centers for Medicare & Medicaid Services ("CMS") reimbursement J-code on January 1, 2016, providing that Dialysate Triferic would be reimbursed for administration to dialysis patients within the existing fixed-price "bundle" of payments that CMS provides to dialysis providers. Because Dialysate Triferic reimbursement would be included in this bundled payment, we commenced efforts in early 2016 to seek so-called "add-on" or "separate" reimbursement for Dialysate Triferic, which is sometimes available for certain new, innovative therapies.

Following receipt of the reimbursement J-code in early 2016 until June 2018, the Company's commercialization strategy for Dialysate Triferic was primarily focused on obtaining add-on reimbursement status from CMS for Dialysate Triferic, at which point the Company planned to commence commercializing the drug.

In June 2018, our Board of Directors determined, based on feedback from CMS's Innovation Center ("CMMI"), that Dialysate Triferic was unlikely to obtain add-on reimbursement in the near term. As a result, the Company changed its commercialization strategy to plan for the commercial launch of Dialysate Triferic with initial reimbursement within the bundle of payments to dialysis providers, while continuing to pursue add-on reimbursement, if possible, and while continuing to develop I.V. Triferic (discussed below). We expect to commercially launch Dialysate Triferic in the second quarter of 2019.

While the Company was pursuing the earlier strategy of delaying commercialization until receipt of add-on reimbursement approval, we built up significant inventory of Active Pharmaceutical ingredient ("API") and Dialysate Triferic finished goods. However, due to the delays in launching and feedback received from CMMI in March 2018

regarding near-term approval, our inventory reserves for Triferic increased by a total of $8.1 million during 2018 from $3.5 million as of December 31, 2017 to $11.6 million as of December 31, 2018. Net of inventory destroyed or used for samples during 2018 of $5.8 million, we had a total inventory reserve of $5.8 million as of December 31, 2018. As of December 31, 2018, we had $3.9 million of Dialysate Triferic finished goods inventory that could expire within the next 12 months and against which we have reserved $3.4 million. As of December 31, 2018, we also had approximately $4.1 million of API against which we have reserved $2.4 million and classified $1.6 million of API as non-current inventory. Depending on the timing and success of our commercial launch of Dialysate Triferic in 2019, additional amounts or all of our current investment in Dialysate Triferic finished goods inventory and some or all of our API inventory will likely need

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to be written off. Additional inventory write-offs will not have a material negative impact on our cash flow, but would have a material adverse impact on our reported results of operations and financial position.

I.V. Triferic

We are also developing an intravenous injection of Triferic ("I.V. Triferic") for use by hemodialysis patients in the United States as well as international markets. A clinical equivalence study of I.V. Triferic infusion presentation has been completed and, on the basis of the clinical and non-clinical data prepared by the Company, we intend to submit a New Drug Application ("NDA") seeking FDA approval to market I.V. Triferic in the United States for the clinical indication of replacing iron and maintaining hemoglobin in adult hemodialysis patients in the second quarter of 2019.

The November 2018 CMS Guidance provided interpretative guidance regarding the CMS Transitional Drug Add On Pricing Adjustment ("TDAPA") program and its potential application to I.V. Triferic. Based on the CMS Guidance, the Company believes that, if approved by the FDA on or after January 1, 2020, I.V. Triferic may be eligible for separate sole source payment with a separate J-Code for a two-year timeframe. In accordance with the current guidance, separate TDAPA payments would last for two years following launch, after which I.V. Triferic would be priced inside the bundle. Upon filing of the NDA, we will be required to pay a filing fee to the FDA of approximately $1.3 million.

While we intend to market and sell Dialysate Triferic and I.V. Triferic directly in the United States, our international strategy is to partner with and license these products to established companies in other regions of the world to assist in the further development (primarily clinical trials and regulatory activities), if necessary, and commercialize in those regions. We continue to pursue international licensing opportunities in a number of countries and specific regions.

Dialysis Concentrates

We manufacture, sell, deliver and distribute hemodialysis concentrates, along with a line of ancillary dialysis products abroad. We use Baxter as our exclusive marketer and distributor in the United States and in select foreign markets. Dialysate concentrates accounted for approximately 96% of our revenues for the year ended December 31, 2018, with ancillary products accounting for most of the remainder. We receive a pre-defined gross profit margin on our concentrate products sold pursuant to the Baxter Agreement, subject to an annual true-up of costs.

Calcitriol (Active Vitamin D) Injection

Calcitriol, an active Vitamin D injection for the management of hypocalcemia in patients undergoing chronic hemodialysis, is FDA approved under an Abbreviated New Drug Application. To date, we have not commercially

launched Calcitriol. Following a strategic review of this product, including pricing, commercial distribution and marketing, manufacturing efficiencies and capacity (including potential capital investment), we have determined commercialization of Calcitriol in the U.S. would not be viable at this time. The decision was based, in part, on the fact that prevailing market prices for similar Vitamin D products are lower than our cost to produce Calcitriol on a dose-equivalent basis, and as a result it would be difficult for us to market Calcitriol profitably. As a result of this decision, we recorded an inventory reserve of $665,000 for the fourth quarter of 2018, reflecting the remainder of our Calcitriol inventory.

Clinical Development

Although Triferic is approved for commercial sale in the United States, it is not approved for sale in other major markets globally. We have received regulatory guidance from the European Medicines Agency ("EMA") regarding the clinical studies that are needed to file for approval of I.V. Triferic in Europe. At the present time, we do not intend to commence these clinical studies, absent finding a development partner in Europe or raising additional capital. In conjunction with our licensee in the People's Republic of China, Wanbang Biopharmaceutical, two clinical pharmacology studies have been initiated and are expected to be completed during 2019.

As a post-approval requirement under the Pediatric Research Equity Act, we are required to conduct a further clinical study of the effectiveness of Triferic in a pediatric patient population. We have reached agreement with the FDA on the design of this study, which we intend to commence in 2019, assuming we have the liquidity and capital resources to do so. We expect that the data from this study could be used as part of the overall clinical data package to support approval by the EMA, if and when we are able to complete the other clinical trials needed to support making such a filing.

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Additionally, we believe that Dialysate Triferic and I.V. Triferic have potential to be developed for use in other iron deficiency anemia indications, as well as other product presentations and other clinical applications, including peritoneal dialysis and total parenteral nutrition.

Results of Operations

For the years ended December 31, 2018 and December 31, 2017

Sales

During the year ended December 31, 2018, our sales were $63.4 million compared to sales of $57.3 million during the year ended December 31, 2017. The increase of $6.1 million was primarily due to higher domestic dialysis concentrate sales primarily due to increased pass through delivery costs billed to Baxter. Our international sales increased by approximately $2.1 million, or 31% compared to the year ended December 31, 2017, primarily due to increased purchases from our largest international customers. Revenue recognized from licensing fees was $2.4 million and $ 2.3 million for years ended December 31, 2018 and 2017, respectively.

Gross Profit

Cost of sales during the year ended December 31, 2018 was $65.0 million, resulting in a gross loss of $1.6 million in 2018, compared to cost of sales of a $53.6 million and gross profit of $3.7 million during the year ended December 31, 2017. Gross profit declined by $5.3 million in 2018 compared to 2017, due primarily to an increase in inventory reserves and write-offs of our Triferic inventory of $4.6 million and a gross profit decrease of $0.6 million in our dialysis concentrates products. The decrease in gross profit for our dialysis concentrates products was primarily attributable to increased distribution costs and lower pricing under our distribution agreement with Baxter, partially offset by increased unit volume growth. Recently implemented government regulation in the trucking industry has further negatively impacted a nationwide driver shortage resulting in increased costs for both incoming materials and shipments within the United States. We expect this trend to continue to increase shipping costs for our dialysis concentrate products in the near term.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $23.1 million during the year ended December 31, 2018 compared with $23.3 million during the year ended December 31, 2017. The $0.2 million decrease was due to reduced salaries and stock compensation, offset by increases to legal, insurance and outside consulting expenses. While we expect some of these fees to decrease in future periods, overall selling, general and administrative expenses are expected to increase in 2019 as the Company prepares for the U.S. commercial launch of Dialysate Triferic and I.V. Triferic, if approved, and invests in the necessary infrastructure to support these commercial plans.

Settlement Expenses

During the year ended December 31, 2018, the Company recorded settlement fees of $1.0 million related to our confidential settlement agreement with our former CEO, former CFO and a former and then current director. The $1.0 million settlement fee is net of a $0.5 million insurance reimbursement, which was collected in the fourth quarter of 2018.

Research and Development (including licenses acquired)

Research and product development expenses were $6.7 million for the year ended December 31, 2018 compared with $6.3 million of expenses incurred during the year ended December 31, 2017. We incurred research and product development costs due to our investment in future product development, intellectual property and regulatory activities primarily for Dialysate and I.V. Triferic and Calcitriol. Research and development expenses for the year ended December 31, 2018 included clinical trials and other product development expenses of $2.5 million for Triferic and $1.5 million for Calcitriol, compared to $3.7 million and $1.4 million, respectively, during the year ended December 31, 2017. During the year ended December 31, 2018, $1.1 million was expensed related to our product license agreement for exclusive worldwide rights to certain patents and information related to our Triferic product. For the year ended December 31, 2018, research and development expenses included an inventory reserve of $0.7 million for Calcitriol, as well as medical, scientific and technical staffing costs and consulting expenses. We expect our research and product development expenses

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to increase in the future due to additional clinical development of Dialysate and I.V. Triferic, including the conduct of the pediatric clinical trial described above, assuming we have the liquidity and capital resources to do so.

Other Income, Net

Other income for the year ended December 31, 2018 was $0.3 million, consisting of interest income of $0.5 million, offset by $0.2 million of realized losses. Other income for the year ended December 31, 2017 was a nominal amount, consisting of $0.7 million of interest income, offset by a realized loss of $0.8 million related to our available-for-sale securities.

Liquidity and Capital Resources

As of December 31, 2018, we had approximately $33.5 million of cash, cash equivalents and investments available-for-sale, and working capital of $33.6 million. Net cash used in operating activities for the year ended December 31, 2018 was approximately $20.4 million. In October 2018, the Company raised $21.9 million, net of issuance costs, in capital from the offering and sale of 5,541,562 shares of common stock at a price of $3.97 per share, along with warrants to purchase up to an additional 2,770,781 shares of common stock at a price of $4.96 per share.

The Company will require significant additional capital to sustain its operations and make the investments it needs to execute its longer-term business plan. The Company’s existing liquidity is not sufficient to fund its operations and anticipated capital expenditures within the next 12 months. The Company intends to seek additional equity or debt financing; however, there are currently no commitments in place for further financing nor is there any assurance that such financing will be available to the Company on favorable terms, if at all.

The Company’s recurring operating losses, net operating cash flow deficits, and an accumulated deficit, raise substantial doubt about the Company’s ability to continue as a going concern for one year from the issuance of the accompanying consolidated financial statements. The consolidated financial statements have been prepared assuming the Company will continue as a going concern. The Company has not made any adjustments to the accompanying consolidated financial statements related to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

General

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 expenses and revenue associated with the commercial launch of Dialysate Triferic and I.V. Triferic, if approved, in the United States; the timing and magnitude of cash received from drug product sales; and the timing and expenditures associated with the development of Triferic for international markets; and the costs associated with

ongoing litigation and investigatory matters.

We may elect to raise capital in the future through one or more of the following: (i) equity and debt raises through the equity and capital markets, though there can be no assurance that we will be able to secure additional capital or funding on acceptable terms, of if at all; and (ii) strategic transactions, including potential alliances and collaborations focused on markets outside the U.S., as well as potential combinations (including by merger or acquisition) or other corporate transactions. In particular, our Baxter Agreement prohibits us from entering into a contract that would encumber 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, or we may find it difficult, to obtain secured debt financing without the consent of Baxter.

We believe that our ability to fund our activities in the long term will be highly dependent upon our ability to successfully launch Dialysate Triferic and to obtain regulatory approval for, and successfully launch, I.V. Triferic. Our commercialization of Dialysate Triferic and I.V. Triferic (if approved) is subject to significant risks and uncertainties, such that there can be no assurance that we will be successful in completing the commercialization in accordance with our plans, or at all. If our commercialization of Dialysate Triferic and/or I.V. Triferic should be delayed for any reason, we may be forced to implement cost-saving measures that may potentially have a negative impact on our activities and potentially the results of our research and development programs. Even if we begin commercialization of Dialysate Triferic as planned, if the results are unsuccessful, we may be unable to secure the additional capital that we will require to continue our research and development activities and operations, which could have a material adverse effect on our business If we are

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unable to raise the required capital, we may be forced to curtail all of our activities and, ultimately, cease operations. Even if we are able to raise sufficient capital, such financings may only be available on unattractive terms, or result in significant dilution of shareholders' interests and, in such event, the market price of our common stock may decline.

Cash Used in Operating Activities

Net cash used in operating activities was $20.4 million for the year ended December 31, 2018. The net loss for this period was higher than net cash used in operating activities by $11.7 million, which was primarily attributable to non-cash expenses of $15.1 million, consisting of, $8.8 million of inventory reserves, $4.4 million of stock-based compensation, $1.1 million of research and development licenses acquired, $0.7 million of depreciation and amortization, and $0.2 million of realized losses on sale of investments available-for-sale, primarily offset by an increase of $0.8 million in inventory, a decrease of $2.4 million in deferred revenue related to the recognition of revenue from our licensing agreements, an increase of $0.6 million in accounts receivable related to increases in revenues related to our international sales and an increase of $0.4 million in settlement fees related to the Settlement Agreement between the Company and its former directors and officers.

Net cash used in operating activities was $21.1 million for the year ended December 31, 2017. The decrease in cash is primarily due to $6.3 million of research and development expenses, as well as substantial amounts for legal and professional fees related to litigation, the settlement with Baxter and the contested 2017 director election.

Cash Provided by Investing Activities

Net cash provided by investing activities was $12.7 million during the year ended December 31, 2018. The net cash provided was primarily due to the sale of our available-for-sale investments of $33.9 million, offset by $20.2 million used for the purchase of investments available-for-sale, $0.7 million for the purchase of equipment and $0.3 million for the purchase of research and development licenses acquired.

Net cash provided by investing activities was $14.5 million during the year ended December 31, 2017. The net cash provided was primarily due to the sale of our available-for-sale investments of $51.9 million, offset by $35.7 million used for the purchase of investments available-for-sale and $1.7 million for the purchase of equipment.

Cash Used in Financing Activities

Net cash provided by financing activities was $22.0 million during the year ended December 31, 2018. The net cash provided was primarily due to the proceeds received from the issuance of the Company's common stock of $21.9 million, net of issuance costs, and proceeds received from the exercise of employee stock options of $0.1 million.

Net cash used in financing activities was $2.2 million during the year ended December 31, 2017. The net cash used was related to $2.3 million of restricted stock retained in satisfaction of tax liabilities offset by $0.1 million of proceeds from the issuance of common shares.

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 ("U.S. GAAP"). 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 could 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.

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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 3 to our Consolidated Financial Statements.

Revenue recognition

The Company recognizes revenue under Accounting Standards Codification ("ASC") 606, Revenue from Contracts with Customers. The core principle of the new revenue standard is that a company should recognize revenue to depict the transfer of 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 following five steps are applied to achieve that core principle:

- Step 1: Identify the contract with the customer
- Step 2: Identify the performance obligations in the contract
- Step 3: Determine the transaction price
- Step 4: Allocate the transaction price to the performance obligations in the contract
- Step 5: Recognize revenue when the company satisfies a performance obligation

Taxes assessed by a governmental authority that are both imposed on and concurrent with a specific revenue-producing transaction, that are collected by us from a customer, are excluded from revenue.

Shipping and handling costs associated with outbound freight related to contracts with customers are accounted for as a fulfillment cost and are included in cost of sales when control of the goods transfers to the customer.

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 and are depreciated using the straight line method over the useful lives of the assets, which range from three to ten years. Expenditures for routine maintenance and repairs are expense as incurred. Leasehold improvements are amortized using the straight line method over the shorter of the useful lives or the related lease term.

Impairment of Long-lived Assets

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amounts may not be recoverable. Impairment losses on long-lived assets, such as real estate and equipment, are recognized when events or changes in circumstances indicate that the undiscounted cash flows estimated to be generated by such assets are less than their carrying value and, accordingly, all or a portion of such carrying value may not be

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recoverable. Impairment losses are then measured by comparing the fair value of assets to their carrying amounts. For the years ended December 31, 2018 and 2017, there were no impairments of long-lived assets.

Goodwill and Intangible Assets

Goodwill is the excess of purchase price over the fair value of identified net assets of businesses acquired. Intangible assets with indefinite useful lives are measured at their respective fair values as of the acquisition date. We do not amortize goodwill and intangible assets with indefinite useful lives.

We review goodwill and indefinite-lived intangible assets at least annually for possible impairment. Goodwill and indefinite-lived intangible assets are reviewed for possible impairment between annual tests if an event occurs or circumstances change that would more likely than not reduce the fair value of the reporting unit or the indefinite-lived intangible assets below their carrying values.

Intangible assets with definite lives are amortized 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.

Definite-lived intangible assets consist of our 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.

Deferred Revenue

In October of 2014, the Company entered into a 10-year distribution agreement with Baxter and received an upfront fee of $20 million. The upfront fee was recorded as deferred revenue and is being recognized based on the proportion of product shipments to Baxter in each period, compared with total expected sales volume over the term of the Distribution Agreement. The Company recognized revenue of approximately $2.1 million related to the Baxter agreement during each of the years ended December 31, 2018 and 2017, respectively.

During the year ended December 31, 2016, the Company entered into a distribution agreement with Wanbang and received an upfront fee of $4.0 million. The upfront fee was recorded as deferred revenue and is being recognized as revenue based on the agreement term. The Company recognized revenue of approximately $0.3 million during the years ended December 31, 2018 and 2017, respectively. Deferred revenue related to the Wanbang agreement totaled $3.2 million and $3.5 million as of December 31, 2018 and 2017, respectively

Stock-Based Compensation

The Company expenses stock-based compensation to employees over the requisite service period based on the estimated grant-date fair value of the awards. For stock-based compensation awards to non-employees, the Company re-measures the fair value of the non-employee awards at each reporting period prior to vesting and finally at the vesting date of the award. Changes in the estimated fair value of these non-employee awards are recognized as compensation expense in the period of change. The Company estimates the fair value of stock option grants using the Black-Scholes option pricing model, and the assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgement. For the years ended December 31 2018 and 2017, the Company recorded stock-based compensation expense on its options granted under the Company's equity compensation plans to its directors and officers, and its employees

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

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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 3, "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.

Not Applicable.

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 33 and incorporated herein by reference.

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

On June 22, 2018, our independent accountant, Plante & Moran, PLLC ("Plante"), resigned as our independent registered public accounting firm, effective immediately.

Plante's report on the Company's financial statements for the year ended December 31, 2017 did not contain an adverse opinion or a disclaimer of opinion, nor were they qualified or modified as to uncertainty, audit scope, or accounting principles. Plante's report on the Company's internal control over financial reporting for the year ended December 31, 2017 contained an unqualified opinion without modification.

During the year ended December 31, 2017 and through June 22, 2018 (the date of Plante's resignation), we had no disagreements with Plante on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreements, if not resolved to Plante's satisfaction, would have caused it to make reference to the subject matter of the disagreements in connection with its reports.

In its letter to the Audit Committee dated June 22, 2018, issued by Plante in conjunction with its resignation letter, Plante identified certain reportable events, as described in Item 304(a)(1)(v) of Regulation S-K, relating to the Company's financial statements and disclosures contained in the Company's Quarterly Report on Form 10-Q for the period ended March 31, 2018. Plante resigned for the reasons set forth in the Company's Current Report on Form 8-K,

as filed with the SEC on June 27, 2018.

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

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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.

Under the supervision of and with the participation of our management, including the Company's Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31, 2018. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, because of the material weaknesses in our internal controls over financial reporting described below, our disclosure controls and procedures were not effective for the reasons described below. Notwithstanding the material weaknesses described below, the Company's management, including the Chief Executive Officer and Chief Financial Officer, has concluded that the consolidated financial statements included in this Annual Report are fairly stated, in all material respects, in accordance with generally accepting accounting principles in the United States for each of the periods presented herein.

During the year ended December 31, 2018, we, together with our independent registered public accounting firm, identified material weaknesses in our internal control over financial reporting, as described below. A "material weakness" is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis.

As of December 31, 2018, our material weaknesses in internal control over financial reporting are:

a. Insufficient segregation of duties, oversight of work performed and lack of compensating controls in our finance and accounting functions due to limited personnel;

b. Control deficiencies related to Information Technology General Controls ("ITGC") in connection with the upgrade of our enterprise resource planning ("ERP") system in May 2018. We had not performed a proper evaluation of our information technology environment and the related disclosure controls and procedures and internal control over financial reporting. Specifically, we were unable to obtain satisfactory documentation regarding the internal controls of the company that hosted our ERP system following the upgrade, insufficient user acceptance testing was completed prior to the migration to the upgraded system, EDI transactions were not performed as expected following the upgrade, and insufficient access controls were implemented for the new system. The Company's ITGC user access security, change management, operations and third-party management controls to the ERP system were not designed effectively to provide an adequate audit trail for system change management and for the periodic review and testing of user access rights and permissions.

c.

Management did not design and maintain effective controls related to developing an appropriate methodology to record discretionary bonuses and stock-based compensation, including an on-going review of the assumptions within the methodology to determine the completeness and accuracy of such compensatory amounts; and

d. We concluded that errors occurred in establishing our inventory reserves as of March 31, 2018 due to a design deficiency in our controls over the computation and recording of such reserves. Our method of calculating inventory reserves resulted in the misapplication of U.S. GAAP, which caused us to restate our March 31, 2018 condensed consolidated financial statements in August 2018. Specifically, due to the lack of communication amongst certain former employees, we concluded our controls were not adequately designed to ensure that we were accurately calculating inventory reserves based on the consideration of overall demand assumptions for our inventory.

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These ITGC material weaknesses in our ERP, combined with inadequate compensating financial close and review controls, had a pervasive impact to the various activity level cycles and accounts, including financial reporting, distribution, revenue and accounts receivable, inventory and cost of goods, expenditures and accounts payable, treasury and payroll, and creates a reasonable possibility that a material misstatement to the consolidated financial statements will not be prevented or detected on a timely basis and represent a material weakness in the Company's internal control over financial reporting. The Company's management, including the Chief Executive Officer and Chief Financial Officer, has concluded that the consolidated financial statements included in this Annual Report are fairly stated, in all material respects, in accordance with generally accepting accounting principles in the United States for each of the periods presented herein.

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, 2018. 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, and due to the material weaknesses described above, we concluded that we did not maintain effective control over financial reporting at a reasonable assurance level as of December 31, 2018.

In connection with the material weaknesses noted above, management has taken a number of steps with the intention of remediating the control deficiencies. We formed a Disclosure Committee comprised of Company officers and other important employees and advisors who would be in possession of material information with respect to our operations and financial statements ("Key Persons"). Each Key Person is required to participate in the preparation and review, and to certify that he or she has provided all material information to the Chief Executive and Chief Financial Officer in connection with the preparation, review and filing, of our periodic SEC reports, registration statements and related financial statements. The Disclosure Committee is chaired by our external General Counsel, with dual-reporting responsibility to both our Chief Executive Officer and the Board as a whole. In November 2018, we hired a new Chief Financial Officer and a new accounting manager, and prior to December 31, 2018 we implemented new procedures designed to add compensating controls in our finance and accounting functions. As it relates to the ITGC deficiencies in connection with our ERP upgrade, in March 2019 we migrated the hosting of our ERP system and performed rigorous testing of the system prior to completion of the migration. As it relates to deficiencies in controls over discretionary bonuses and stock-based compensation, we have implemented new programs and policies to provide better controls over these activities. Finally, we have upgraded the process for computing and reviewing work related to our inventory reserve calculations.

The remediation of the material weaknesses described above is among our highest priorities. Our Audit Committee will continually assess the progress and sufficiency of these initiatives and make adjustments as and when necessary. As of the date of this report, our management believes that our efforts, when completed, will remediate the material weaknesses in internal control over financial reporting as described above.

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Attestation Report of Independent Registered Public Accounting Firm

Marcum LLP, 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, 2018. Marcum's report, which expresses an adverse opinion on the effectiveness of our internal control over financial reporting due to material weaknesses, is included herein.

The attestation report required under this Item 9A can be found on page F-4 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

As described above, during the year ended December 31, 2018, our management identified material weaknesses in our internal control over financial reporting and is taking action intended to remediate such material weaknesses.

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.

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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, 2018:

Plan Category	Number of securities to be issued upon exercise of outstanding options and restricted stock units (a)	Weighted average exercise price of outstanding options (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 (1)	7,735,022	$ 7.50	1,888,646
Equity compensation plans not approved by security holders (2)	2,070,000	$ 4.70	—
Total	9,805,022	$ 7.24	1,888,646

(1) Consists of 7,468,355 stock options with a weighted average exercise price of $7.50 and 266,667 restricted stock units.
(2) Consists of 776,250 stock options with a weighted average exercise price of $4.70 and 1,293,750 restricted stock units.

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.

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(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).
4.1	Form of Common Stock Warrant, dated October 17, 2018 (Company's Form 8-K filed October 19, 2018).
10.1	Licensing Agreement, dated January 7, 2002, by and among the Company, Charak LLC and Dr. Ajay Gupta (with certain portions of the exhibit redacted pursuant to a confidential treatment order) (Company's Form 10 KSB filed April 1, 2002).
10.2	Amending Agreement, dated January 16, 2006, by and among the Company, Charak LLC and Dr. Ajay Gupta (Company's Form 10 KSB filed March 21, 2006).
10.3	First Amended and Restated Products Purchase Agreement, dated May 8, 2013, by and between the Company and DaVita Healthcare Partners, Inc. (with certain portions redacted pursuant to a confidential treatment order) (Company's Form 10 Q filed August 1, 2013).
10.4	Exclusive Distribution Agreement, dated October 2, 2014, by and 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).
10.5	Investment Agreement, dated October 2, 2014, by and between the Company and Baxter Healthcare Corporation (Company's Form 10 K filed March 3, 2015).
*10.6	Amendment to October 1, 2014 Stock Option Agreement with Robert L. Chioini (Company's Form 10 K filed March 3, 2015).
*10.7	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).
10.8	Rockwell Medical, Inc. 2018 Long Term Incentive Plan (Company's Proxy Statement for the 2018 Annual Meeting of Shareholders filed on April 30, 2018).
*10.9	Form of Nonqualified Stock Option Agreement (2007 Long Term Incentive Plan) (Director Version) (Company's Form 8 K filed December 20, 2007).
*10.10	Form of Nonqualified Stock Option Agreement (2007 Long Term Incentive Plan) (Employee Version) (Company's Form 8-K filed December 20, 2007).
*10.11	Form of Restricted Stock Award Agreement (2007 Long Term Incentive Plan) (Director Version) (Company's Form 10 K filed February 29, 2016).
*10.12	Form of Restricted Stock Award Agreement (2007 Long Term Incentive Plan) (Executive Version) (Company's Form 10 Q filed May 12, 2014).
*10.13	Form of Performance Share Award Agreement March 2017 (Executive Version) (Company's Form 10-Q filed May 9, 2017).
*10.14	Form of Performance Share Award Agreement March 2017 (Director Version) (Company's Form 10-Q filed May 9, 2017).
*10.15	Form of Director and Officer Indemnification Agreement September 2017 (Company's Form 10-Q filed November 8, 2017).

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	Form of Stock Option Agreement (2018 Long Term Incentive Plan) (Employee Version).
*10.16	
*10.17	Form of Contingent Option Agreement for Directors (2018 Long Term Incentive Plan) (Company's Form 8-K filed March 21, 2018).
*10.18	Amendment to October 2, 2015 Stock Option Agreement with Robert L. Chioini (Company's Form 10 K filed February 29, 2016).
10.19	First Amendment to Exclusive Distribution Agreement, dated 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).
10.20	First Amendment to Investment Agreement, dated June 23, 2017, by and between the Company and Baxter Healthcare Corporation (Company's form 10-Q filed August 9, 2017).
*10.21	Form of Director and Officer Indemnification Agreement (Company's Form 10-Q filed November 8, 2017).
10.22	Stock Appreciation Right Agreement, dated September 5, 2017, by and between the Company and John G. Cooper (Company's Form 10-Q filed November 8, 2017).
10.23	Settlement and Standstill Agreement, dated November 22, 2017, by and among the Company, Richmond Brothers, Inc., Mark H. Ravich, and other persons collectively referred to as the "Shareholder Group" (Company's Form 8-K filed November 29, 2017).
10.24	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).
*10.25	Executive Employment Agreement, dated March 7, 2018, between the Company and Robert L. Chioini (Company's Form 8-K filed on March 13, 2018).
*10.26	Executive Employment Agreement, dated March 7, 2018, between the Company and Thomas E. Klema (Company's Form 8-K filed on March 13, 2018).
*10.27	Approval of Independent Director Compensation (Company's Form 8-K filed March 21, 2018).
10.28	Amendment No. 1 to Letter Agreement, dated April 17, 2018, by and among the Company, Richmond Brothers, Inc. and David S. Richmond (Company's Form 8-K filed April 19, 2018).
10.29	Term Sheet, dated June 20, 2018 (Company's Form 8-K filed June 21, 2018).
*10.30	Ajay Gupta Employment Agreement, dated October 7, 2018 (Company's Form 8-K filed October 12, 2018).
10.31	Registration Rights Agreement, dated October 17, 2018 (Company's Form 8-K filed October 19, 2018).
*10.32	Angus Smith Employment Agreement, dated October 26, 2018 (Company's Form 8-K filed November 2, 2018).
+10.33	Confidential Settlement Agreement and Release, dated August 7, 2018, by and among the Company, Robert Chioini, Thomas Klema, Patrick Bagley and Ronald Boyd (Company's Form 10-Q filed November 9, 2018).
10.34	Master Services and IP Agreement, dated October 7, 2018, by and among the Company, Charak, LLC and Dr. Ajay Gupta.
10.35	Amendment to License Agreement, dated October 7, 2018, by and among the Company, Charak, LLC and Dr. Ajay Gupta.
10.36	Commercialization and Technology License Agreement IV Triferic, dated October 7, 2018, by and among the Company, Charak, LLC and Dr. Ajay Gupta.

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10.37	Technology License Agreement TPN Triferic, dated October 7, 2018, by and among the Company, Charak, LLC and Dr. Ajay Gupta.
10.38	First Amendment to the First Amended and Restated Products Purchase Agreement, dated December 7, 2018, by and between the Company and DaVita Inc. (fka DaVita Healthcare Partners Inc.).
10.39	Second Amendment to the First Amended and Restated Products Purchase Agreement, dated March 1, 2019, by and between the Company and DaVita Inc. (fka DaVita Healthcare Partners Inc.).
21.1	List of Subsidiaries.
23.1	Consent of Marcum LLP.
23.2	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

*Indicates management contracts or compensatory plans or arrangements.

+Confidential treatment has been granted with respect to certain portions (indicated by asterisks) of this exhibit. Omitted portions have been filed separately with the SEC.

Item 16. Form 10-K Summary.

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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/ Stuart Paul
Stuart Paul
President and Chief Executive Officer

Date: March 15, 2019

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/ Stuart Paul Stuart Paul	President, Chief Executive Officer and Director (Principal Executive Officer)	March 15, 2019
/s/ Angus Smith Angus Smith	Chief Financial Officer (Principal Financial Officer)	March 15, 2019
/s/ David Kull David Kull	Principal Accounting Officer	March 15, 2019
/s/ Benjamin Wolin Benjamin Wolin	Director	March 15, 2019
/s/ Lisa Colleran Lisa Colleran	Director	March 15, 2019
/s/ JOHN G. COOPER John G. Cooper	Director	March 15, 2019
/s/ Robin L. Smith Robin L. Smith	Director	March 15, 2019

/s/ MARK H. RAVICH Mark H. Ravich	Director	March 15, 2019

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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 consolidated balance sheet of Rockwell Medical Inc. and Subsidiaries (the "Company") as of December 31, 2018, the related consolidated statements of operations, comprehensive loss, changes in shareholders' equity and cash flows for the year then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018, and the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the Company's internal control over financial reporting as of December 31, 2018, based on the criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in 2013 and our report dated March 15, 2019, expressed an adverse opinion on the effectiveness of the Company's internal control over financial reporting because of the existence of material weaknesses.

Explanatory Paragraph – Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 2, the Company has incurred a significant net loss of $32.1 million and operating cash flow deficit of $20.4 million during the year ended December 31, 2018, has an accumulated deficit of $272.4 million as of December 31, 2018 and needs to raise additional funds to meet its obligations, sustain its operations and execute on its longer term business plan. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements 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 the financial statements are free of material misstatement, whether due to error or fraud. Our audit 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 audit 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 audit provides a reasonable basis for our opinion.

/s/ Marcum llp

Marcum llp

We have served as the Company’s auditor since 2018.

Chicago, IL
March 15, 2019

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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 sheet of Rockwell Medical, Inc. and Subsidiaries (the “Company”) as of December 31, 2017 and the related statements of operations, comprehensive loss, changes in shareholders’ equity, and cash flows for the year then ended, and the related notes (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 the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

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 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 the financial statements are free of material misstatement, whether due to error or fraud. Our audit 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 audit 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 audit provides a reasonable basis for our opinion.

We began serving as the Company’s auditor in 1998. Our tenure as the Company’s auditor ended in 2018.

/s/ Plante & Moran, PLLC

Clinton Township, Michigan

March 15, 2018

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM ON INTERNAL CONTROL OVER FINANCIAL REPORTING

To the Shareholders and Board of Directors of

Rockwell Medical, Inc. and Subsidiaries

Adverse Opinion on Internal Control over Financial Reporting

We have audited Rockwell Medical Inc. and Subsidiaries' (the “Company”) internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. In our opinion, because of the effect of the material weaknesses described in the following paragraph on the achievement of the objectives of the control criteria, the Company has not maintained effective internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission.

A material weakness is a control deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. The following material weaknesses have been identified and included in “Management's Annual Report on Internal Control Over Financial Reporting:”

a. The Company identified insufficient segregation of duties, oversight of work performed and lack of compensating controls in the Company’s finance and accounting functions due to limited personnel;

a. The Company identified control deficiencies related to Information Technology General Controls (“ITGC”) in connection with the upgrade of the Company’s enterprise resource planning (“ERP”) system in May 2018. The Company had not performed a proper evaluation of its information technology environment and the related disclosure controls and procedures and internal control over financial reporting. Specifically, the Company was unable to obtain satisfactory documentation regarding the internal controls of the company that hosted the Company’s ERP system following the upgrade, insufficient user acceptance testing was completed prior to the migration to the upgraded system, EDI transactions were not performed as expected following the upgrade, and insufficient access controls were implemented for the new system. The Company’s ITGC user access security, change management, operations and third-party management controls to the ERP system were not designed effectively to provide an adequate audit trail for system change management and for the periodic review and testing of user access rights and permissions.

a. The Company did not design and maintain effective controls related to developing an appropriate methodology to record discretionary bonuses and stock-based compensation, including an on-going review of the assumptions within the methodology to determine the completeness and accuracy of such compensatory amounts; and

a. The Company concluded that errors occurred in establishing the Company's inventory reserves as of March 31, 2018 due to a design deficiency in the Company's controls over the computation and recording of such reserves. The Company's method of calculating inventory reserves resulted in the misapplication of U.S. GAAP, which caused the Company to restate its March 31, 2018 condensed consolidated financial statements in August 2018. Management concluded that the Company's controls were not adequately designed to ensure that the Company was accurately calculating inventory reserves based on the consideration of overall demand assumptions for the Company's inventory.

These ITGC material weaknesses, combined with inadequate compensating financial close and review controls, had a pervasive impact to the various activity level cycles and accounts, including financial reporting, revenue, distribution and accounts receivable, inventory and cost of goods, expenditures and accounts payable, treasury and payroll, and creates a reasonable possibility that a material misstatement to the consolidated financial statements will not be prevented or

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detected on a timely basis and represent a material weakness in the Company's internal control over financial reporting.

These material weaknesses were considered in determining the nature, timing and extent of audit tests applied in our audit of the fiscal December 31, 2018 consolidated financial statements, and this report does not affect our report dated March 15, 2019, on those consolidated financial statements.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the consolidated balance sheet as of December 31, 2018 and the related consolidated statements of operations, comprehensive loss, changes in shareholders' equity, and cash flows for the year then ended of the Company and our report dated March 15, 2019 expressed an unqualified opinion on those consolidated financial statements and which report included an explanatory paragraph that raises substantial doubt about the Company's ability to continue as a going concern.

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 Annual 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 the 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 degree of compliance with the policies or procedures may deteriorate.

/s/ Marcum LLP

Marcum LLP

Chicago, IL

March 15, 2019

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ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

	December 31, 2018	December 31, 2017
ASSETS		
Cash and Cash Equivalents	$ 22,713,980	$ 8,406,917
Investments Available-for -Sale	10,818,059	24,648,459
Accounts Receivable, net of a reserve of $2,104 in 2018 and $11,000 in 2017	6,979,514	6,355,566
Insurance Receivable	371,217	—
Inventory	4,038,778	7,637,384
Prepaid and Other Current Assets	1,903,682	1,779,992
Total Current Assets	46,825,230	48,828,318
Property and Equipment, net	2,638,293	2,548,978
Inventory, Non-Current	1,637,000	5,986,752
Goodwill	920,745	920,745
Other Non-current Assets	536,516	494,847
Total Assets	$ 52,557,784	$ 58,779,640
LIABILITIES AND SHAREHOLDERS' EQUITY		
Accounts Payable	$ 4,492,071	$ 4,222,159
Accrued Liabilities	5,129,761	4,715,712
Settlement Payable	416,668	—
Deferred License Revenue	2,252,868	—
Customer Deposits	63,143	205,303
Other Current Liability - Related Party	850,000	—
Total Current Liabilities	13,204,511	9,143,174
Deferred License Revenue	12,076,399	16,723,318
Total Liabilities	25,280,910	25,866,492
Commitments and Contingencies (See Note 14)		
Shareholders' Equity:		
Preferred Shares, no par value, 2,000,000 shares authorized, no shares issued and outstanding at December 31, 2018 and 2017	—	—
Common Shares, no par value, 57,034,154 and 51,768,424 shares issued and outstanding at December 31, 2018 and 2017, respectively	299,601,960	273,210,907
Accumulated Deficit	(272,388,234)	(240,262,376)
Accumulated Other Comprehensive Income (Loss)	63,148	(35,383)
Total Shareholders' Equity	27,276,874	32,913,148
Total Liabilities And Shareholders' Equity	$ 52,557,784	$ 58,779,640

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

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ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

For The Years Ended December 31, 2018 and 2017

	2018	2017
Net Sales	$ 63,388,617	$ 57,300,281
Cost of Sales	64,973,157	53,598,390
Gross Profit (Loss)	(1,584,540)	3,701,891
Selling, General and Administrative	23,082,304	23,303,409
Settlement Expense, net of Reimbursement	1,030,000	—
Research and Product Development	5,642,317	6,321,400
Research and Development - Licenses Acquired (Related Party)	1,100,000	—
Operating Loss	(32,439,161)	(25,922,918)
Other Income (Expense)		
Realized Gain (Loss) on Investments	(222,338)	(792,207)
Interest Income	535,328	790,226
Other Income	313	2,873
Foreign Currency Gain	—	742
Total Other Income (Expense)	313,303	1,634
Net Loss	$ (32,125,858)	$ (25,921,284)
Basic and Diluted Net Loss per Share	$ (0.61)	$ (0.51)
Basic and Diluted Weighted Average Shares Outstanding	52,824,486	51,067,412

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

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ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

For The Years Ended December 31, 2018 and 2017

	2018	2017
Net Loss	$ (32,125,858)	$ (25,921,284)
Unrealized Gain on Available-for-Sale Investments	109,293	866,031
Foreign Currency Translation Adjustments	(10,762)	1,134