2019 ANNUAL REPORT

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, 2019

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)

Delaware	**38-3317208**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
411 Hackensack Avenue, Suite 501, Hackensack, New Jersey	**07601**
(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:	**Trading Symbol(s):**	**Name of each exchange on which registered:**
Common Stock, par value $.0001	RMTI	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 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, 2019 (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 $152,509,967.

Number of shares outstanding of the registrant's Common Stock, par value $.0001, as of March 13, 2020: 69,049,102 shares.

Documents Incorporated by Reference

Portions of the Registrant's definitive Proxy Statement pertaining to the 2020 Annual Meeting of Stockholders, which the Registrant intends to file pursuant to Regulation 14A with the Securities and Exchange Commission not later than 120 days after the Registrant's fiscal year ended December 31, 2019, 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,” “predict”, “forecast”, “projected,” “intend” or similar expressions, or make statements regarding our intent, belief, or current expectations, we are making forward-looking statements. Our forward looking statements also include, without limitation:

- the acceptance of our products by doctors, patients or payors;
- the availability of adequate reimbursement for our products from insurance companies and the government;
- our ability to use existing inventory before shelf life expiration;
- the safety and efficacy of our products;
- our expectations regarding the timing of submissions to, and decisions made by, the U.S. Food and Drug Administration (the "FDA"), and other regulatory agencies, including foreign regulatory agencies;
- our ability to secure adequate protection for, and licensure of, our intellectual property;
- our estimates regarding the capacity of manufacturing and other facilities to support our products;
- our expectations regarding our ability to enter into marketing and other partnership agreements;
- our ability to successfully commercialize our products;
- the rate and degree of market acceptance and clinical utility of our products;
- our ability to obtain and/or retain major customers and distributors;
- our ability to compete against other companies and research institutions;
- our ability to attract and retain key personnel;
- our expectations for increases or decreases in expenses;
- our expectations for incurring capital expenditures to expand our research and development and manufacturing capabilities;
- our expectations for generating revenue or becoming profitable on a sustained basis;
- our expectations regarding the effect of changes in accounting guidance or standards on our operating results;
- the impact of healthcare reform laws and other government laws and regulations;
- the impact of potential shareholder activism;
- our ability to defend ourselves against securities litigation, which is costly and time-consuming to defend;
- our ability to continue as a going concern;
- our ability to remediate the identified material weaknesses in our internal control over financial reporting;

- our ability to obtain additional financing and raise capital as necessary to fund operations or pursue business opportunities;
- the duration over which our cash balances will fund our operations; and
- those risk factors identified in this Annual Report on Form 10-K under the heading "Risk Factors" and in other filings we periodically make with the SEC.

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 from the anticipated future results, performance or achievements expressed or implied by any forward-looking statements, including the factors described under the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." You should evaluate all forward-looking statements made in this Annual Report on Form 10-K, including the documents we incorporate by reference, in the context of these risks, uncertainties and other factors.

Other factors not currently anticipated may also materially and adversely affect our results of operations, cash flows, business, prospects and financial position. We do not undertake, and expressly disclaim, any obligation to update or alter any statements whether as a result of new information, future events or otherwise except as required by law.

PART I

Item 1. Business.

Overview

Rockwell Medical, Inc., together with its subsidiaries, (collectively, "we," "our," "us," the "Company" or "Rockwell") is a biopharmaceutical company dedicated to transforming anemia and improving outcomes for patients across the globe. We are initially 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"). 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. We believe Triferic is applicable to a wide variety of disease states in which iron deficiency is an issue, and we are initially targeting patients with ESRD. The Company has developed two formulations of Triferic: Dialysate Triferic, which adds Triferic to the dialysate, and I.V. Triferic, which delivers Triferic intravenously. Dialysate Triferic is the first and only FDA approved product indicated to replace iron and maintain hemoglobin concentration in adult hemodialysis patients. The Company has developed two presentations of Dialysate Triferic for ESRD patients. The first presentation is a liquid, single-patient presentation of Dialysate Triferic, which was approved by the FDA in 2015. The second presentation is a powder packet, multiple-use formulation of Dialysate Triferic, which was approved by the FDA in 2016. During 2019, we built a commercial organization for our Triferic products and launched Dialysate Triferic in the United States in May 2019. We have also developed an intravenous formulation of Triferic, hereinafter referred to as I.V. Triferic, which is a novel formulation of Triferic that would be used for the same indication as Dialysate Triferic, if approved. We submitted a new drug application ("NDA") for I.V. Triferic in May 2019, with a Prescription Drug User Fee Act ("PDUFA") action date of March 28, 2020. We plan to leverage the medical and commercial capabilities we established in 2019 to support the potential launch of I.V. Triferic.

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 2019, we estimate that we supplied approximately 25% of the United States domestic market with dialysis concentrates, with the majority of our sales being made in the United States. We also supply dialysis concentrates to distributors serving a number of foreign countries, primarily in the Americas and the Pacific Rim.

We believe that Triferic is an innovative treatment for iron replacement and has the potential to be developed in other disease states where iron replacement is required. We are actively evaluating additional indications for potential development. If we determine that a new indication demonstrates the potential for a sufficient return on investment, we will evaluate initiating clinical development of Triferic for such indication(s), provided we have the funding to do so.

We are regulated by the 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 for both drugs and medical devices.

As of December 31, 2019, we had approximate balances of $11.8 million of cash and cash equivalents, $14.3 million of investments available-for-sale, working capital of $24.5 million and an accumulated deficit of $306.5 million. Net cash used in operating activities for the twelve months ended December 31, 2019 was approximately $27.3 million. We will require significant additional capital to sustain our operations and make the investments needed to execute our longer-term business plan.

On February 4, 2020, we entered into an underwriting agreement (the "Underwriting Agreement") with Cantor Fitzgerald & Co., as underwriter (the "Underwriter"), pursuant to which we (i) agreed to issue and sell an aggregate of 3,191,489 shares of our common stock (the "Shares") to the Underwriter and (ii) granted the Underwriter an over-allotment option for 30 days to purchase up to an additional 478,723 shares that may be sold upon the exercise of such option by the Underwriter (the "Offering"). The Shares were purchased by the Underwriter from us at a price of $2.22 per share. The Offering was made pursuant to our effective Registration Statement on Form S-3 (File No. 333-227363), which was previously filed with the SEC under the Securities Act. The Offering closed on February 6, 2020. On February 19, 2020, the Underwriter exercised its over-allotment option in full and an additional 478,723 shares were sold to the Underwriter on February 21, 2020. We raised a total of $8.0 million, net of estimated issuance costs of $0.2 million, relating to the Offering.

On March 16, 2020, Rockwell Medical, Inc. and Rockwell Transportation, Inc., as Borrowers, entered into a Loan and Security Agreement (the "Loan Agreement") with Innovatus Life Sciences Lending Fund I, LP, as collateral agent, and the lenders party thereto to obtain term loans in an amount up to $35.0 million. $22.5 million was drawn under the Loan Agreement on the date of closing and the remaining $12.5 million will be available for subsequent draws based on our achievement of certain milestones. Net proceeds at closing were approximately $21 million after deducting estimated fees and expenses of $1.5 million. Interest on the loans will accrue either in cash or a combination of cash and in kind interest, at our election. Cash interest will accrue at a rate equal to the greater of (i) Prime Rate (as defined in the Loan Agreement) and (ii) 4.75% plus 4.00%, for an initial interest rate of 8.75% per annum. We have the option, under certain circumstances, to add 1.00% of such interest rate amount to the then outstanding principal balance in lieu of paying such amount in cash. We are entitled to make interest-only payments for thirty months, or up to thirty-six months if certain conditions are met. The Loan Agreement contains representations and warranties, affirmative and negative covenants, and events of default that are customary for credit facilities of this type. The term loans will mature on March 16, 2025.

Based on the capital raise and debt financing noted above, management believes the Company currently has sufficient funds to meet its operating requirements for at least the next twelve months from the date of the filing of this report.

The Company will require additional capital to sustain its operations and make the investments it needs to execute upon its longer-term business plan, including the commercialization of Dialysate Triferic and I.V. Triferic, if approved, and executing plans for enhancing its medical capabilities and generating additional data for Triferic. If the Company is unable to generate sufficient revenue from its existing long-term business plan, the Company will need to obtain additional equity or debt financing. If the Company attempts to obtain additional debt or equity financing, the Company cannot assume that such financing will be available on favorable terms, if at all.

Our Initial 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 approximately 7,300 Medicare-certified hemodialysis 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 523,000 dialysis patients in the United States as of the end of 2017, of which approximately 468,000 were receiving 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” dialysis 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 in-center 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)

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"). 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 possible blood losses from dialyzer clotting or bleeding from surgical procedures related to vascular access.

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, providing bioavailable iron to the body. 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 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. We developed I.V. Triferic, a novel intravenous ("IV") formulation of Triferic that would be used for the same indication, if approved, and we have a PDUFA date of March 28, 2020. Descriptions of Dialysate Triferic and I.V. Triferic are 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 May 2019, we commenced commercial sales of Dialysate Triferic in the United States.

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 IV 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 Dialysate Triferic 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 IV 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, a study of hemodialysis practices in the United States, 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 IV iron than the placebo.

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.

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. On April 26, 2019, pursuant to a request we submitted earlier in 2019, we were notified of a preliminary recommendation by CMS to grant our powder packet formulation of Dialysate Triferic a separate J-Code, which became effective on July 1, 2019.

In June 2018, the Company 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 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 commercially launched Dialysate Triferic in May 2019.

I.V. Triferic

We are also developing I.V. Triferic, an intravenous formulation of 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, the FDA agreed that 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 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, on May 28, 2019, we submitted a NDA seeking FDA approval to market I.V. Triferic in the United States for the clinical indication of replacing iron and maintain hemoglobin in adult dialysis patients. We have a PDUFA date of March 28, 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 believed that, if approved by the FDA on or after January 1, 2020, I.V. Triferic would be eligible for separate sole source payment with a separate J-Code for a two-year timeframe. However, on October 31, 2019, CMS finalized revised guidance regarding the TDAPA program that significantly limited the eligibility of new products for TDAPA to only certain NDA types, as classified by the FDA. Pursuant to the revised guidance, I.V. Triferic will not be eligible for TDAPA.

Limitations of Existing Therapies for Anemia in Hemodialysis Patients

The current standard of care for treating anemia in HDD-CKD patients includes injectable ESAs and 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 and reduced absorption of dietary iron which are 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, which is 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 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 reported instances of anaphylaxis have been received during more than 1,000,000 doses administered and Triferic can be administered even to patients with history of allergic reactions to IV iron.

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 that Triferic, due to its unique mechanism of action, facilitates potential 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, for the liquid presentation of Dialysate Triferic. An additional J-code for the Triferic powder packet presentation of Dialysate Triferic was received effective July 1, 2019.

Dialysate and I.V. Formulations. We have two primary formulations of Triferic for commercialization: Dialysate Triferic and I.V. Triferic. We launched Dialysate Triferic, a formulation that is delivered through dialysate, including a liquid form and a powder form, in May 2019. We received FDA approval to market Dialysate Triferic in liquid form in 2015 and in powder form in 2016. Dialysate Triferic is reimbursed within the CMS bundled rate for dialysis providers. We have also developed I.V. Triferic, an I.V. formulation of Triferic, for which we submitted an NDA in May 2019. Importantly, I.V. Triferic 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-U.S. countries.

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, India, Canada, Peru and Chile. We are actively pursuing international licensing opportunities in 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 majority of the United States 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 utilized. We have received regulatory approval for Dialysate Triferic in Peru, and we expect to receive regulatory approval for Dialysate Triferic in Chile in 2020. We also have a license agreement (the "Wanbang Agreement") with Wanbang Biopharmaceutical, Co., Ltd. ("Wanbang"), for the development and commercialization of Triferic in China, which grants to Wanbang rights to both Dialysate Triferic and I.V. Triferic in China.

Develop Additional Product Presentations and Clinical Programs for Triferic in ESRD. We are also continuing to evaluate, research, and explore other presentations of Triferic for potential application in ESRD patients. In addition, we believe that Triferic represents an innovative development within ESRD and we will be initiating preclinical studies that will evaluate the compatibility of Triferic with the new prolyl hydroxylase inhibitors versus IV iron.

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 (collectively, the “Distribution Agreement”). In June 2017, we entered into the First Amendment to Exclusive Distribution Agreement with Baxter which, among other things, enabled us to negotiate directly with DaVita, Inc. ("DaVita") on a long-term contract for the supply of our concentrate products. In August 2019, we signed a new Products Purchase Agreement with DaVita (the "Products Purchase Agreement"). The Products Purchase Agreement provides for an increase in the product sale prices relative to the prices charged for products under the previous agreement with DaVita. 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 2019 revenue. Approximately 89% of our 2019 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 our Dry Acid Concentrate products realize numerous advantages, including lower cost per treatment, reduced storage space requirements, reduced number of deliveries and more flexibility in scheduling deliveries, while enabling us 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.

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 468,000 hemodialysis patients in the United States, or approximately 73 million treatments annually, approximately 98% of which are conducted in hemodialysis centers.

Dialysate Triferic. During 2019, we built a sales, marketing, and medical infrastructure to support the launch of Dialysate Triferic. The launch is being supported by a combination of sales representatives, nurse educators and medical science liaisons. Our initial target customers include selected medium and small sized dialysis chains and independent dialysis centers. The launch of Dialysate Triferic has enabled us to engage with key customers in the dialysis industry regarding the potential clinical and pharmacoeconomic benefits of Triferic and is providing us with valuable experience to support our future commercial and medical initiatives, as well as the potential launch of I.V. Triferic.

I.V. Triferic. We submitted an NDA for I.V. Triferic in May 2019, with a PDUFA date of March 28, 2020. We expect to launch I.V. Triferic in the U.S. market in the fourth quarter of 2020, subject to FDA approval.

Research to Support Triferic Value Proposition. To support the launch of our Triferic products in the United States and globally, we are evaluating potential clinical studies and real-world data initiatives that we believe have the potential to support the value proposition for both Dialysate Triferic and I.V. Triferic. Such initiatives, 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 European Union 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 are also collecting data from sites that are purchasing Dialysate Triferic in the United States so that we can assess the impact of Dialysate Triferic on various clinical and pharmacoeconomic measures.

International Commercialization of Triferic. We are working to commercialize Triferic and our Triferic products in various markets across the globe. We are actively engaged in licensing negotiations for Triferic in a number of regions and countries. We believe that I.V. Triferic is a more relevant 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 primarily on Dialysate Triferic due to the fact that Dialysate Triferic is approved in the United States, 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"). The 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. 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 Dialysate Triferic for China. In March 2019, we entered into an amendment to the Wanbang Agreement that provided Wanbang with rights to I.V. Triferic in China.

On January 14, 2020, we entered into license and supply agreements with a wholly-owned subsidiary of Sun Pharmaceutical Industries Ltd. (together, "Sun Pharma"), for the rights to commercialize Dialysate Triferic (ferric pyrophosphate citrate) in India. Under the terms of the agreements, Sun Pharma will be the exclusive development and commercialization partner for Dialysate Triferic in India and we will supply the product to Sun Pharma. In consideration for the license, we received an upfront fee of $100,000, and will be eligible for milestone payments and royalties on net sales. A Joint Alliance Committee, comprised of members from the Company and Sun Pharma, will guide the development and execution for Dialysate Triferic in India. Sun Pharma will be responsible for all clinical, regulatory and commercialization activities.

We have also executed a distribution agreement to market our Triferic products in Canada with RMC Health Care Inc. We expect to file for regulatory approval of I.V. Triferic in 2020, 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 a Triferic product outside the United States, and we expect our partner to commercialize the product beginning in 2020.

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

Enhance Dialysis Concentrates Business: During 2019, we identified certain potential enhancements to our dialysis concentrates business in an effort to improve its profitability. Specifically, we: (i) implemented price increases on selected products with certain customers, including DaVita; (ii) evaluated our ability to be more efficient in our manufacturing or transportation operations, and established a plan to implement certain measures during 2020 to improve our efficiency in these areas; and (iii) evaluated the expansion of our business to include additional products for sale to customers in the United States and other jurisdictions such as Latin America.

Clinical Development

Dialysate 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, we completed two clinical pharmacology studies in 2019, which demonstrated no ethnic difference in Triferic PK in Chinese subjects compared to U.S. subjects. In December 2019, we and Wanbang met with the National Medical Products Administration ("NMPA"), China's equivalent of the FDA, to discuss the results of the PK studies and whether they would be sufficient to support a regulatory submission for Dialysate Triferic in China. During the meeting, we and Wanbang received guidance from NMPA that an additional clinical study would be required to support a regulatory submission, and accordingly we are working with Wanbang to determine the scope and timing of such clinical study. Under our agreement with Wanbang, Wanbang is responsible for all clinical development costs required to support the approval of Triferic in China.

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, and in 2019 we entered into a contract with a Contract Research Organization (CRO) and initiated start-up work for the conduct of the study. We expect to begin enrollment in the study during 2020. 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.

We believe that Triferic has the potential to be developed for use in other indications in which iron replacement is required. We have engaged a third-party consultant to assist in evaluating the medical and commercial viability of Triferic in potential new indications. If this research demonstrates that a new indication has the potential for a sufficient return on investment, and if funding is available, we would look to potentially initiate clinical programs in such new indications. In addition, we are assessing potential investment in clinical programs to evaluate additional product presentations of Triferic within ESRD.

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 provided incentives 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% refund of the Distribution Agreement's upfront fee.

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

Distribution and Delivery Operations

The majority of our domestic dialysis concentrate products are delivered through our subsidiary, Rockwell Transportation, Inc., which operates a fleet of trucks used to deliver products to our customers. Rockwell distribution and delivery will continue to operate under the Distribution Agreement on behalf of Baxter for domestic business. We perform delivery services that are generally not available from common carriers or our competitors, such as stock rotation, non-loading-dock delivery and drum pump-off service. As a result, we believe we offer a higher level of service than other providers. Dialysate Triferic is generally delivered to our customers by our third-party logistics provider in the United States.

Sales and Marketing

The top ten dialysis providers treat approximately 426,000 hemodialysis patients in their centers according to an article published by Nephrology News in 2019. We believe this constitutes approximately 91% of the in-center hemodialysis patients in the United States as of 2019. We market and sell Dialysate Triferic, and intend to market and sell 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 and throughout 2019, we assembled sales and marketing leadership and a field-based sales team to support the commercialization of Dialysate Triferic in the United States. The team consists of sales and marketing leaders who have extensive experience selling and marketing products within the ESRD marketplace. This leadership is supported by experienced sales representatives responsible for effectively promoting the product within the United States and clinical nurse educators responsible for supporting the integration of Triferic into United States dialysis clinics. We believe this sales force is appropriately sized for marketing Triferic to the nephrology community within the United States This infrastructure will be leveraged for the launch of I.V. Triferic, if approved.

Our dialysis concentrate products are sold to customers in the United States through Baxter and DaVita in accordance with the Distribution Agreement and the Product Purchase Agreement, respectively. Our dialysis concentrate products are sold to international customers through independent sales agents, distributors and direct.

Medical Affairs

We believe that Triferic represents innovation for iron replacement within ESRD. We believe that medical education will play an integral role in helping to further the awareness and understanding of how Triferic can address the replacement of ongoing iron losses and maintenance of hemoglobin in ESRD patients. Accordingly, we have invested in our Medical Affairs capabilities by hiring a Chief Medical Officer in November 2019, who will also lead any clinical investigations of Triferic in such new indications for the product that we identify as feasible and commercially attractive, and hiring a team of Medical Science Liaisons. In addition, we have enhanced our Medical Advisory Board with preeminent key opinion leaders in the anemia management space. We anticipate applying this medical expertise in ESRD to educate dialysis clinicians through disease state presentations, 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 anticipate targeting our 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.

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 2,600 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 profile.

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 Vifor Pharma Management Ltd. ("Vifor"). Vifor 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 inhibitors ("PHIs"), or HIF-PHIs, that are in development for a variety of indications, including the treatment of anemia for patients with chronic kidney disease. HIF-PHIs are designed to stimulate erythropoiesis and manage iron utilization and can be administered orally. Certain HIF-PHI compounds, including roxadustat and vadadustat, have reached or completed Phase 3 development in the United States, and a NDA for roxadustat was submitted in the United States in December 2019. If successfully developed and approved, HIF-PHIs 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 as disclosed in the recent roxadustat phase III dialysis study results, where approximately half of the patients on roxadustat were administered IV iron.

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.

Quality Assurance and Control

We have established a Quality Management System ("QMS") which defines systems and procedures used to assure quality in the design, manufacture, and delivery of our finished device and pharmaceutical products. Our quality system activities are planned and executed to ensure compliance to the requirements of 21 CFR Parts 820, 210, and 211.

Dialysis Concentrate Solutions Business

We operate under FDA guidelines and place significant emphasis on providing quality products and services to our customers. We have established an organizational structure and quality system procedures to ensure our device products are designed and produced to meet product quality requirements and FDA guidelines. Dialysis products are manufactured and tested using validated equipment and defined process controls to ensure rigid conformance to specifications. To assure quality and consistency of our dialysis concentrates, analytical testing is performed using validated instrument methods to verify that the chemical and microbial properties of each product lot complies with the specifications required by industry standards. Our concentrates are labeled per FDA Unique Device Identifier ("UDI") code requirements to ensure traceability of distributed products. Our quality program activities 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.

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 ensure our contract manufactures have established robust quality systems and employ validated processes to ensure the quality and compliance of our drug products to their 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. Most Class I devices (general controls) and some Class II devices (general and special controls) are exempt from the premarket notification (i.e., 510(k) clearance) requirements. Class III devices generally require "premarket approval" ("PMA") from the FDA as described in further detail below. FDA grants 510(k) clearance 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.

Class III devices typically are devices that sustain or support life, prevent impairment of human health or present a potential unreasonable risk of illness or injury. 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. Our hemodialysis concentrate products and other ancillary devices are subject the FDA 510(k) requirements. 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.

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

Any devices manufactured or distributed by us pursuant to FDA clearances or approvals are subject to continuing regulation by the FDA and certain state agencies. As a manufacturer of medical devices for marketing in the United States, we are required to adhere to regulations, including 21 CFR 820, which is commonly referred to as the Quality System Regulation, 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 an 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 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, such as cGMP requirements, 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 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. As an NDA applicant, we are required to submit to FDA information about any adverse event associated with the use of our approved drug, whether or not the adverse event is considered drug related. If our marketed drug is found to be potentially harmful or does not comply with applicable requirements, we also may recall the product. 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. Major changes and some moderate changes to an approved drug, or to the conditions established in the approved NDA, may require the submission and approval of a new NDA or NDA supplement before the change can be implemented. Other changes may be made at the time of FDA's receipt of the NDA supplement or may be described in our next annual report for the approved NDA.

Pediatric Requirements

Under the Pediatric Research Equity Act ("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 ("BPCA") provides NDA holders a six-month extension of the marketing exclusivity or patent protection 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 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 generally do not require additional testing for products that have received FDA approval.

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

Product License Agreements

We are party to a Licensing Agreement between the Company and Charak, LLC ("Charak") dated January 7, 2002 (the "2002 Agreement") that grants the Company exclusive worldwide rights to certain patents and information related to our Triferic products. On October 7, 2018, we entered into a Master Services and IP Agreement (the "Charak MSA") with Charak and Dr. Ajay Gupta, 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 provided 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. As of December 31, 2019, all payments under the Charak MSA were paid.

Pursuant to the Charak MSA, the aforementioned parties entered into an Amendment, dated as of October 7, 2018 (the "Charak Amendment"), to 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.

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 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, which are filed as exhibits to this Annual Report on Form 10-K.

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, 2019, we owned or had the rights to 25 issued patents (5 U.S. and 20 foreign) and 64 pending applications (5 U.S. and 59 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)	2	2029 (1)	1	3 (2)	2028 (1)	30
Triferic (ESA Sparing)	—	2034	2	7 (3)	2034	28
Triferic (TPN)	1	2026	—	9 (4)	2026	1
Other	2	—	2	1	—	0
Total	5		5	20		59

(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 (not included in total).
(3) European patent validated in 3 European states (not included in total).

(4) European patent validated in 12 European states (not included in total).

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 concentrate 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 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. Any material dispute, lack of quality of the product, or 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.

One customer, DaVita, accounted for 49% of our sales in 2019 and 46% of our sales in 2018. Our accounts receivable from this customer were $1.2 million and $2.5 million as of December 31, 2019 and 2018, respectively. In August 2019, we signed a new Products Purchase Agreement with DaVita, with an initial term expiring on December 31, 2023.

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 2019 and 2018, our direct sales to Baxter aggregated approximately 27% and 26% of sales, respectively, and we had a receivable from Baxter of $2.0 million and $2.8 million as of December 31, 2019 and 2018, respectively.

Another customer, Nipro Medical Corporation, accounted for 9% and 10% of our sales in 2019 and 2018, respectively.

DaVita, Baxter, the accounts administered by Baxter, and Nipro Medical Corporation 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 11% and 14%, of our overall sales in 2019 and 2018, respectively.

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

Employees

As of December 31, 2019, we had 299 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

We have invested heavily in the testing and development of Triferic and our Triferic products. 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 Dialysate Triferic to the FDA in 2014. We received FDA approval for Dialysate Triferic in January 2015.

Since the approval of Dialysate 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 $6.9 million and $5.6 million in 2019 and 2018, respectively, with such costs primarily related to Triferic. Such costs also included efforts to address manufacturing issues in an effort to achieve FDA approval of Calcitriol, which we have since discontinued.

We expect that research and product development spending in 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, post-marketing studies to further demonstrate the pharmacoeconomics and patient outcomes of Triferic and additional studies of Triferic in new indications.

Corporate Information

We were originally incorporated in the state of Michigan in 1996, and re-domesticated to the state of Delaware in 2019. Our executive offices are located at 411 Hackensack Avenue, Suite 501, Hackensack, New Jersey 07601. Our telephone number is (248) 960-9009 and our website is *http://www.rockwellmed.com*.

Our website 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 are advised to read this Annual Report on Form 10-K in conjunction with other reports and documents that we file from time to time with the SEC. In particular, please read our definitive proxy statement, which will be filed with the SEC in connection with our 2020 annual meeting of stockholders, our quarterly reports on Form 10-Q and any current reports on Form 8-K that we may file from time to time. You can access free of charge on our website copies of these reports 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

We may not be successful in commercializing Dialysate Triferic, which will impede our development and growth and may limit our long-term prospects.

In June 2018, we announced plans to commence initial steps to prepare for the commercial launch of Dialysate Triferic without waiting to receive separate reimbursement status. While we have commenced commercialization of Dialysate Triferic as of the date of the report, we will need to add to our sales and marketing infrastructure in order to successfully commercialize Dialysate Triferic. We do not know whether we will be able to successfully implement our commercialization strategy for Dialysate Triferic or whether our new business strategy will ultimately be successful. We may not be able to convince potential customers

that the safety, efficacy, clinical utility of Dialysate Triferic are compelling enough to effectuate a change in their clinical practice, including potential operational changes required to adopt Dialysate Triferic. Additionally, the initial demand for the product will impact our ability to utilize existing product inventory prior to expiration. If we commercialize Dialysate Triferic slower than currently anticipated, we may need to write off additional inventory reserves, which could result in material accounting charges in future periods. Additionally, the expiration of existing product inventory could limit the total inventory available for commercial sales while we ramp-up commercial production and attempt to manage production in light of anticipated demand.

In assessing our ability to meet these challenges, a potential investor should take into account our recent management turnover, limited cash position, limited sales and marketing personnel and their limited commercialization experience, the competitive conditions existing in our industry and general economic conditions. Our future success is largely dependent on our ability to successfully implement our Dialysate Triferic commercialization business strategy. Our revenues may be adversely affected if we fail to implement our Dialysate Triferic commercialization business strategy.

Our near-term success depends substantially on the commercialization of Dialysate Triferic and, if approved, I.V. Triferic. Although Dialysate Triferic has been approved by the FDA, and the FDA may approve I.V. Triferic, we may not be able to commercialize either product successfully.

Dialysate Triferic launched commercially in the United States in May 2019 and I.V. Triferic has a PDUFA date of March 28, 2020; however, it is possible that either version of Triferic will not gain market acceptance and that we will not be successful in the commercialization of these products. We do not know whether we will be able to successfully implement our commercialization strategy for Dialysate Triferic and I.V. Triferic, if approved, or whether our new business strategy will ultimately be successful.

Both formulations of 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 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 Triferic. Additionally, 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 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 Dialysate Triferic's safety and efficacy, cost-effectiveness, and advantages over existing products. Other factors that may impact the commercial success and ultimate profitability of Triferic include:

- the rate of adoption of Dialysate Triferic and I.V. 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;
- our ability to manage inventory available for commercial sale;
- the effectiveness of our marketing, sales and distribution strategies and operations for development and commercialization;
- the impact of Dialysate Triferic and I.V. Triferic on established customer protocols, formularies and operational practices;
- reimbursement of either formulation of 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 either formulation of Triferic;
- our ability to comply with ongoing regulatory requirements applicable to either formulation of Triferic and the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping applicable to Triferic;

- the impact of certain royalties related to our sale of either formulation of Triferic paid by us based on the profitability of either formulation of Triferic;
- our ability to avoid third party patent interference or patent infringement claims;
- our ability to maintain a continued acceptable safety profile of either formulation of Triferic;
- the discovery of previously unknown problems with either formulation of Triferic or with any third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements;
- the ability to successfully manufacture commercial product to enable a launch of I.V. Triferic in 2020; and
- the ability to successfully complete our I.V. Triferic commercialization planning thereby enabling a launch of Triferic I.V. in 2020.

An adverse development with respect to any of the foregoing may have a material adverse effect on our ability to manufacture and market either formulation of Triferic. We cannot assure you that we will be able to generate meaningful and sustained revenues through the sale of either formulation of Triferic. If we are not successful in commercializing either formulation of Triferic, or are significantly delayed in doing so, our entire investment in Triferic may be of no value, our inventory of finished product may expire or become obsolete (resulting in write-offs of such inventory), our licensing rights could be materially adversely affected and the price of our common stock could substantially decline. Even if we are successful in commercializing either formulation of Triferic, since the market is highly concentrated with two significant suppliers, our continued success may depend on adoption of Dialysate Triferic by the limited number of existing dialysis providers.

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.

We are still 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 future product candidates, 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 future product candidate, 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 recently commenced commercialization of Dialysate Triferic, we cannot predict the rate of future sales and usage of the drug. As of December 31, 2019, we had a gross inventory balance for Dialysate Triferic of $3.5 million, including approximately $2.9 million in Dialysate Triferic's active pharmaceutical ingredient and $0.6 million in finished goods inventory. Of this amount, we had reserved $2.8 million related to our Dialysate Triferic finished goods and active pharmaceutical ingredient inventory. As a result of this reserve, our total Dialysate Triferic inventory had a net book value of $0.7 million as of December 31, 2019. 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 salable. 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.

In order to realize the full potential value for our Triferic franchise, we will need to obtain 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.

In order to expand and realize the full potential value of our Triferic franchise, we will need to obtain approval of I.V. Triferic by the FDA, as well as foreign regulators, such as the EMA. We believe that the market opportunity for I.V. Triferic is greater than for Dialysate Triferic. 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 product or the manufacturing process. Accordingly, there is no guarantee the FDA or any other foreign regulator 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 Dialysate Triferic or I.V. Triferic filings. 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.

I.V. Triferic, if approved, is ineligible for add-on reimbursement status, the commercial opportunity for the drug product in the United States could be limited.

On October 31, 2019, CMS issued a final rule to update payment policies and rates under the ESRD Prospective Payment System for renal dialysis services to beneficiaries on or after January 1, 2020. ("2020 Final Rule"). The 2020 Final Rule included certain revisions to the eligibility requirements for the CMS TDAPA program. Under the revised TDAPA rules, ESRD drugs approved by the FDA under NDA Type 3 (or certain combination types) are ineligible for TDAPA effective as of January 1, 2020. As previously disclosed, we have filed an NDA for I.V. Triferic. The FDA has informed us that the NDA for I.V. Triferic will be classified as a Type 3 NDA. As a result, the Company believes that I.V Triferic will not be eligible for TDAPA. This could significantly limit the overall commercial opportunity in the United States for I.V. Triferic should the FDA approve the drug.

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 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.

Because we may be unable to complete our development, manufacturing and commercialization of our products, we could face significant harm to our business plans, prospects, results of operations, financial condition and liquidity.

Commercializing Dialysate Triferic depends on a number of factors, including but not limited to:

- further product and manufacturing process development;
- completion, refinement and management of our supply chain and distribution channels;
- meeting regulatory requirements for clinical information;
- differentiation of our products from competitive products, including those in development by other companies;
- demonstration of efficiencies that will make our products attractively priced; and
- development of an adequate sales force and sales channels necessary to distribute our products and achieve our desired revenue goals.

We cannot commercialize I.V. Triferic unless and until we receive FDA approval of our NDA for this product candidate, which was submitted in May 2019. Even if the FDA approves I.V. Triferic for commercialization, under the 2020 Final Rule published by CMS in October 2019, it appears that I.V. Triferic is not be eligible for add-on reimbursement, meaning I.V. Triferic would 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.

We cannot assure investors that the strategies we intend to employ will enable us to support the manufacture, distribution and selling of Dialysate Triferic or I.V. Triferic (if approved). If we are unable to implement the necessary steps of our business plan, our prospects, results of operations and financial condition will suffer.

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 product candidates. The degree of patent protection that will be afforded to our drug products and processes in the United States 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 the I.V. 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 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 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 or disagreement over the terms and conditions 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.

An epidemic of the coronavirus disease is ongoing in China and other parts of the world and may result in significant disruptions to our and our partners' clinical trials, supply chain and product demand, any of which could have a material adverse effect on our business.

An epidemic of the coronavirus disease is ongoing in China and other parts of the world. As the outbreak is still evolving, much of its impact remains unknown. As of this filing, it is impossible to predict the effect and potential spread of the coronavirus disease in China and globally.

Wanbang is our commercialization partner for both Dialysate Triferic and I.V. Triferic in China. We currently expect Wanbang to initiate additional clinical studies during 2020 that are necessary to support a submission for regulatory approval in China. We also expect to begin enrollment in a pediatric clinical study in 2020. However, the coronavirus disease may result in significant delays or disruptions for such clinical trials, which could affect the regulatory approval process. If the patients involved with these clinical trials become infected with the coronavirus disease, we may have more adverse events and deaths in our clinical trials as a result. We may also face difficulties enrolling patients in our clinical trials if the patient populations that are eligible for our clinical trials are impacted by the coronavirus disease.

Additionally, if our clinical trial patients are unable to travel to our clinical trial sites as a result of quarantines or other restrictions resulting from the coronavirus disease, we may experience higher drop-out rates or delays in our clinical trials. We may also face decreased demand if our dialysis patients are unable to travel to dialysis clinics.

The severity of the coronavirus disease could also make access to our existing supply chain difficult or impossible and could materially impact our business. Any one or a combination of these events could have an adverse effect on our business.

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 Dialysate Triferic, I.V. Triferic or any other drug product candidates 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 and product candidates, including Dialysate Triferic and I.V. 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.

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 and even if we are able to find new partners, they may not be able to obtain the necessary foreign regulatory approvals. If we are not successful in out-licensing our drug products 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 products. 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 Dialysate Triferic, I.V. Triferic or any other drug product 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 Dialysate Triferic, I.V. Triferic or any other drug product 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 (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 disease outbreaks, including the recent coronavirus disease epidemic, 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 or product candidates that we believe are a complementary fit with our current product portfolio, as well as other product or product candidates that we believe have substantial development potential. We may not be able to identify such products or product candidates. 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 or product candidates effectively.

In addition, the market potential for new drug products or product candidates 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.

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 ("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 Dr. 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.

The dialysis market is highly concentrated in the United States. DaVita and Fresenius own or manage a large number of the outpatient dialysis facilities located in the United States, which account for 73% of the total number of hemodialysis patients in the United States. This represents 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.

New classes of drugs, such as HIF-PHIs, may limit the need for iron to be administered to ESRD patients.

A new class of drugs, known as HIF-PHIs, is currently in development for a variety of indications, including the treatment of anemia for patients with chronic kidney disease. HIF-PHIs are designed to stimulate erythropoiesis and manage iron utilization and can be administered orally. Certain HIF-PHI compounds, including roxadustat and vadadustat, have reached or completed Phase 3 development in the United States, and an NDA for roxadustat was submitted in the United States in December 2019. If successfully developed and approved, HIF-PHIs 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. It is possible that HIF-PHIs may significant limit or potentially eliminate the need for parenteral iron to be administered to patients on dialysis.

Historically, iron has been provided to patients within the dialysis setting via an intravenous push as this has been viewed as a more effective way to provide iron than oral iron products. However, it is possible that clinicians may start to provide patients with oral iron agents, instead of IV iron or Triferic. Significant utilization of oral agents would diminish the commercial opportunity of Triferic within ESRD dialysis patients receiving hemodialysis.

Part of the growth strategy of the Triferic portfolio is to evaluate and potentially initiate clinical programs for new indications. We are currently conducting research as to the medical and economic viability of Triferic in new indications and it is possible that the research may determine that Triferic is not either medically or economically viable in new indications.

A potential growth driver for the Triferic portfolio is the potential utility of Triferic in disease states outside of ESRD where iron replacement is required. We are currently performing an evaluation of the potential utility of Triferic in certain other disease states. It is possible that the results of this project may show that Triferic and/or its potential presentations may not be medically viable within these new disease states. It is also possible that the results of this project may demonstrate that even if Triferic were medically viable in new disease states, it would not be economically viable or we may not have the funds to conduct required clinical trials. To launch a product in a new disease state, we would likely need to substantially conclude that Triferic could supplement and/or compete with the current standard of care, and raise the funds needed for the development of such new indications.

Even if we were to determine that Triferic is medically and economically viable in new indications, and even if we were able to obtain additional funding to conduct the necessary clinical trials, clinical trials for our products are expensive, may take several years to complete, and their outcomes are uncertain.

Assuming that our research identifies new clinical indications for Triferic that would be both economically and medically feasible, and assuming that we were able to obtain the necessary funding to conduct clinical trials, conducting clinical trials is a lengthy, time-consuming and expensive process. We would incur substantial expense for both pre-clinical testing and clinical trials with no guarantee that these efforts would either be completed in a timely manner or that they would result in a positive outcome. Completion of clinical trials may take several years or more. The length of time can vary substantially with the type, complexity, novelty and intended use of the product. Factors that can influence and affect the rate of completion of clinical trials include: the potential delay by a partner in beginning a clinical trial; the failure of third-party contract research organizations ("CROs") and other third-party service providers and independent clinical investigators to manage and conduct the trials, to perform their oversight of the trials or to meet expected deadlines; the inability to recruit clinical trial participants at the expected rate; the inability to follow patients adequately after treatment; unforeseen safety issues; and unforeseen governmental or regulatory issues or concerns, including those of the FDA, DEA and other regulatory agencies.

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 $20.0 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 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, 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 transportation 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 (as a Refund Trigger Event) 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 FINANCIAL POSITION

We have limited capital resources and will likely need additional funding before we are able to achieve profitability. If we are unable to raise additional capital on attractive terms, or at all, we may be unable to sustain our operations.

We have limited capital resources, a cumulative deficit of approximately $306.5 million since inception and we expect to incur further losses for the foreseeable future. As of December 31, 2019, we had approximately $26.0 million of cash, cash equivalents and investments available-for-sale, and working capital of $24.5 million. Net cash used in operating activities for the year ended December 31, 2019 was approximately $27.3 million.

On March 22, 2019, we entered into a sales agreement with Cantor Fitzgerald & Co. (the "Agent"), pursuant to which we may offer and sell from time to time up to $40,000,000 of shares of common stock through the Agent. We are not required to sell any shares at any time during the term of the sales agreement. Our ability to sell common stock under the sales agreement may be limited by several factors, including, among other things, the trading volume of our common stock and certain black-out periods that we may impose upon the sales agreement, among other things.

On June 20, 2019, we closed a public offering of 5,833,334 shares of common stock at a price of $3.00 per share. On July 9, 2019, the underwriters of the public offering partially exercised their over-allotment option to purchase an additional 425,800 shares of common stock at a price of $3.00 per share, which closed on July 11, 2019.

On February 6, 2020, we closed a public offering of 3,191,489 shares of common stock at a price of $2.22 per share. On February 19, 2020, the underwriter of the public offering exercised its over-allotment option to purchase an additional 478,723 shares of common stock at a price of $2.22 per share in full, which closed on February 21, 2020.

On March 16, 2020, Rockwell Medical, Inc. and Rockwell Transportation, Inc., as Borrowers, entered into a Loan and Security Agreement (the "Loan Agreement") with Innovatus Life Sciences Lending Fund I, LP, as collateral agent and the lenders party thereto to obtain term loans in an amount up to $35.0 million. $22.5 million was drawn under the Loan Agreement on the date of closing, and the remaining $12.5 million will be available for subsequent draws based on our achievement of certain milestones. Net proceeds at closing were approximately $21 million after deducting estimated fees and expenses of $1.5 million. Interest on the loans will accrue either in cash or a combination of cash and in kind interest, at our election. Cash interest will accrue at a rate equal to the greater of (i) Prime Rate (as defined in the Loan Agreement) and (ii) 4.75% plus 4.00%, for an initial interest rate of 8.75% per annum. We have the option, under certain circumstances, to add 1.00% of such interest rate amount to the then outstanding principal balance in lieu of paying such amount in cash. We are entitled to make interest-only payments for thirty months, or up to thirty-six months if certain conditions are met. The Loan Agreement contains representations and warranties, affirmative and negative covenants, and events of default that are customary for credit facilities of this type. The term loans will mature on March 16, 2025.

Based on the capital raise and debt financing noted above, management believes the Company currently has sufficient funds to meet its operating requirements for at least the next twelve months from the date of the filing of this report.

The Company will require additional capital to sustain its operations and make the investments it needs to execute upon its longer-term business plan, including the commercialization of Dialysate Triferic and I.V. Triferic, if approved, and executing plans for enhancing its medical capabilities and generating additional data for Triferic. If the Company is unable to generate sufficient revenue from its existing long-term business plan, the Company will need to obtain additional equity or debt financing. If the Company attempts to obtain additional debt or equity financing, the Company cannot assume that such financing will be available on favorable terms, if at all.

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 Dialysate 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 and product candidate 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 successfully commercialize Dialysate 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 drug product candidates 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 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 or product candidates.

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. 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.

Our future success depends on our ability to retain executives and key employees and to attract, retain and motivate qualified personnel in the future.

We are highly dependent on the product development, clinical and business development expertise of the principal members of our management, scientific and clinical team. Although we have entered into employment agreements with our

executives and key employees, each of them may terminate their employment with us at any time. We do not maintain "key person" insurance for any of our executives or other employees.

Recruiting and retaining qualified scientific, clinical, manufacturing, sales and marketing personnel is critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of, and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel.

We hired a new Chief Executive Officer and Chief Financial Officer in 2018 and have hired additional executive-level employees who are leading the commercialization 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.

We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating drug product, nonclinical development, clinical development, regulatory strategy, and commercial strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to provide services to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited. If we are unable to mitigate these or other similar risks, our businesses, results of operations, and financial condition may be adversely affected.

We expect to continue to expand our sales and marketing function, as well as our corporate operations, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

During the fourth quarter of 2018 and throughout 2019, we assembled sales and marketing leadership and a field-based sales team to support the commercialization of Dialysate Triferic in the United States. To manage this growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

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 or product candidates 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.

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 and product candidates. Many of these consultants were previously employed at, may have previously been, or are currently providing consulting services to, other biotechnology or pharmaceutical companies, including our competitors or potential competitors. As such, the Company advises consultants not to disclose, or use trade secrets, or proprietary information of their former employers or their former or current customers. Although no claims against us are currently pending, we may be subject to claims that these consultants or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers or their former or current customers. Litigation may be necessary to

defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management and day-to-day business operations.

Our drug products and product candidates 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 product candidate as a result of undesirable side effects identified during clinical testing, the FDA may decline to approve the product candidate 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 product candidate. Following FDA approval, if we or others later identify previously unknown undesirable side effects caused by our product candidate 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.

We may be subject to claims that our employees or directors have wrongfully used or disclosed alleged trade secrets of their former employers.

Many of our employees and certain of our directors were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees and directors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees or directors have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's or director's former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

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, electrical and other system failures due to employee error, malfeasance or other disruptions. We could experience a business interruption, intentional theft of confidential information or reputational damage, including damage to key customer and partner relationships, from system failures, espionage attacks, malware, ransomware or other cyber-attacks. Such cyber-security breaches may compromise our system infrastructure or lead to data leakage, either internally or at our contractors or consultants. In particular, system failures or cyber-security breaches could result in the loss of nonclinical or clinical trial data from completed, ongoing or planned trials, which could cause delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. The risk of a security breach or disruption, particularly through cyber-attacks, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased.

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 laws and regulations governing the protection of health and other personally identifiable information and related 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 and shareholder litigation, which is costly and time-consuming to defend.

In addition to the purported class action, shareholder derivative action and SEC investigation filed against us as described in Note 15 "Commitments and Contingencies" in the accompanying consolidated financial statements for the year ended December 31, 2019, it is possible that other legal proceedings 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 15 "Commitments and Contingencies – Litigation" in the accompanying consolidated financial statements for the year ended December 31, 2019.

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

Unfavorable weather or global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general weather conditions, as well as conditions in the global economy and in the global financial markets. A severe storm in our locations or those of our suppliers, or prolonged economic downturn, such as the recent global financial crisis, could result in a variety of risks to our business, including our ability to raise additional capital when needed on acceptable terms, if at all. This is particularly true in Europe, where the Brexit has created additional economic uncertainty. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

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, stockholders, 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 may not be sufficient to correct all material weaknesses and deficiencies.

AS of December 31, 2019, we had 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. Specifically, management identified control deficiencies related to Information Technology General Controls ("ITGC") in connection with change management, user access controls and segregation of duties as it relates to user access controls. 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. The ITGC material weakness in our ERP 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 represents a material weakness in the Company's internal control over financial reporting. 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.

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

Any future sales by us of substantial amounts of our common stock, or the possibility of such sales, could adversely affect the market price of our common stock 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 stock may have an adverse effect on the market price of our common stock and may dilute the economic value and voting rights of existing stockholders.

In addition, as of December 31, 2019, there were 6,481,095 shares issuable upon the exercise of the then-outstanding and exercisable stock options and 1,728,929 shares issuable upon the exercise of then-outstanding stock options that were not yet exercisable. The market price of the common stock 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. Some of the factors that may cause the market price of our common stock to fluctuate include:

- our ability to obtain regulatory approvals for our product candidates, and delays or failures to obtain such approvals;
- failure of any of our drug products or product candidates, if approved, to achieve commercial success;
- issues in manufacturing our drug products or product candidates;
- the results of our current and any future clinical trials of our product candidates;
- the entry into, or termination of, key agreements, including key commercial partner agreements;
- the initiation of, material developments in, or conclusion of litigation to enforce or defend any of our intellectual property rights or defend against the intellectual property rights of others;
- announcements by commercial partners or competitors of new commercial products, clinical progress or the lack thereof, significant contracts, commercial relationships or capital commitments;
- the introduction of technological innovations or new therapies that compete with our products;
- the loss of key employees;
- changes in estimates or recommendations by securities analysts, if any, who cover our common stock;
- general and industry-specific economic conditions that may affect our research and development expenditures;
- changes in the structure of healthcare payment systems; and
- the reporting of sales, operating results and cash resources.

In addition, third parties may engage in trading strategies that result in intentional volatility to and control over our stock price. Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock.

In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our profitability and reputation.

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

We do not anticipate paying dividends in the foreseeable future.

Since inception, we have not paid any cash dividend on our common stock 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.

If securities analysts do not publish research or reports about our business, or if they publish negative evaluations, the price of our common stock could decline.

The trading market for our common stock may be impacted by the availability or lack of research and reports that third-party industry or financial analysts publish about the Company. There are many large, publicly traded companies active in the biopharmaceutical industry, which may mean it will be less likely that we receive widespread analyst coverage. Furthermore, if one or more of the analysts who do cover the Company downgrade our stock, our stock price would likely decline. If we do not receive adequate coverage by reputable analysts that have an understanding of our business and industry, we could fail to achieve visibility in the market, which in turn could cause our stock price to decline.

Our certificate of incorporation, bylaws and Delaware law could prevent a third party from acquiring us (even if an acquisition would benefit our stockholders), may limit the ability of our stockholders to replace our management and limit the price that investors might be willing to pay for shares of our common stock.

Our certificate of incorporation and bylaws could have the effect of making it more difficult for a third party to acquire, or of discouraging a third party from attempting to acquire, control of us. These provisions could delay or prevent a change in control of the company and could limit the price that investors might be willing to pay in the future for shares of our common stock. These provisions, among other things:

- establish a staggered board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- authorize our board of directors to issue new series of preferred stock without stockholder approval and create, subject to applicable law, a series of preferred stock with preferential rights to dividends or our assets upon liquidation, or with superior voting rights to our existing common stock;
- disallow our stockholders to fill vacancies on our board of directors;
- establish advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon by stockholders at our annual stockholder meetings;
- permit our board of directors to establish the number of directors between three and fifteen;
- provide that stockholders can remove directors only for cause and only upon the approval of not less than a majority of all outstanding shares of our voting stock;
- require the approval of not less than a majority of all outstanding shares of our voting stock to amend our bylaws and specific provisions of our certificate of incorporation; and
- limit the jurisdictions in which certain stockholder litigation may be brought.

We are not subject to the provisions of Section 203 of the Delaware General Corporation Law, which could negatively affect your investment.

We elected in our certificate of incorporation to not be subject to the provisions of Section 203 of the Delaware General Corporation Law ("Section 203"). In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. A "business combination" includes a merger, asset sale or other transaction resulting in a financial benefit to the interested stockholder. An "interested stockholder" is a person who, together with affiliates and associates, owns (or, in certain cases, within three years prior, did own) 15% or more of the corporation's voting stock. This may make us more vulnerable to takeovers that are completed without the approval of our Board of Directors and/or without giving us the ability to prohibit or delay such takeovers as effectively.

Our certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our certificate of incorporation provides that the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another state court or a federal court located within the State of Delaware) is the exclusive forum for any claims that are based upon a violation of a duty by a current or former director, officer, employee or stockholder in such capacity, or as to which the Delaware General Corporation Law confers jurisdiction upon the Court of Chancery. This provision would not apply to claims brought to enforce a duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. This choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees. If a court were to find the choice of forum provision contained in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business.

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 2023. 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.

Information pertaining to legal proceedings is provided under the heading "Litigation" in Note 15, Commitments and Contingencies, to the consolidated financial statements and is incorporated by reference herein.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Our common stock trades on The Nasdaq Global Market under the trading symbol "RMTI".

As of February 28, 2020, there were 26 holders of record of our common stock.

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 stock 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, 2019.

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.

Per §229.301 of Regulation S-K, the Company, designated a Smaller Reporting Company as defined in §229.10(f)(1) of Regulation S-K, is not required to provide the disclosure required by this Item.

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

Overview and Recent Developments

We are a biopharmaceutical company dedicated to transforming anemia and improving outcomes for patients with anemia across the globe, with an initial focus on ESRD. We are also a manufacturer of hemodialysis concentrates for dialysis providers and distributors in the United States and abroad. We supply the 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. Substantially, all of our sales have been concentrate products and ancillary items, though we initiated commercial sales of our proprietary therapeutic, Dialysate Triferic, during the second quarter of 2019.

Our mission is to transform anemia management in a wide variety of disease states across the globe while improving patients' lives. Accordingly, we are building the foundation to become a leading medical and commercial organization in the field of dialysis.

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. Descriptions of Dialysate Triferic and I.V. Triferic are set forth below.

Dialysate Triferic

Dialysate Triferic, our dialysate formulation of 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 reimbursement J-code on January 1, 2016 from the 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. On April 26, 2019, pursuant to a request we submitted earlier in 2019, we were notified of a preliminary recommendation by CMS to grant our powder packet formulation of Dialysate Triferic a separate J-Code, which became effective on July 1, 2019.

In June 2018, the Company determined, based on feedback provided from 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 reimbursement within the bundle of payments to dialysis providers, while continuing to develop I.V. Triferic (discussed below). We commercially launched Dialysate Triferic in the May 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 to $11.6 million as of December 31, 2018. We had a total inventory reserve of $5.8 million as of December 31, 2018, net of inventory destroyed or used for samples during 2018 was $5.8 million.

As of December 31, 2019, we had $0.6 million of Dialysate Triferic finished goods inventory that could expire within the next 12 months and against which we have reserved $0.4 million. As of December 31, 2019, we also had approximately $2.9 million of API against which we have reserved $2.4 million and classified $0.4 million of API as non-current inventory. Depending on the success of our commercialization of Dialysate Triferic, additional amounts or all of our current investment in Dialysate Triferic finished goods inventory and some or all of our API inventory may need to be written off. Additional inventory write-offs will not have a material negative impact on our cash flow, but could have a material adverse impact on our reported results of operations and financial position.

I.V. Triferic

We are also developing I.V. Triferic, an intravenous injection of Triferic, for use by hemodialysis clinics in the United States as well as international markets. Based on the data from a clinical equivalence study and feedback received during the pre-NDA meeting, on May 28, 2019, we submitted a NDA seeking FDA approval to market I.V. Triferic in the United States for the clinical indication of replacing iron and maintain hemoglobin in adult dialysis patients. We have a PDUFA date of March 28, 2020.

On November 1, 2018, CMS issued interpretive guidance on the availability of Medicare reimbursement for certain products indicated to treat renal disease. As set forth in the CMS guidance, Dialysate Triferic would not be eligible for add-on reimbursement under the CMS TDAPA program. However, based on the CMS guidance, we believed that, if approved by the FDA on or after January 1, 2020, I.V. Triferic would be eligible for separate sole source payment with a separate J-Code for a two-year timeframe. However, on October 31, 2019, CMS finalized revised guidance regarding the TDAPA program that significantly limited the eligibility of new products for TDAPA to only certain NDA types, as classified by the FDA. Pursuant to the revised guidance, I.V. Triferic will not be eligible for TDAPA.

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, 2019, with ancillary products and Triferic 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 a full inventory reserve in 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 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, we completed two clinical pharmacology studies in China during 2019. We expect Wanbang to initiate additional clinical studies during 2020 that are necessary to support a submission for regulatory approval in China.

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 and we expect to initiate enrollment in the study during 2020, 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.

Additionally, we believe that Triferic has the potential to be developed for use in other indications in which iron replacement is required. In addition, we are assessing investing in potential clinical programs to evaluate other product presentations of Triferic within ESRD.

Results of Operations

The following table summarizes our operating results for the periods presented below (dollars in thousands):

	For the Year Ended December 31,				
	2019	**% of Revenue**	**2018**	**% of Revenue**	**% Change**
Net Sales	**$ 61,303**		**$ 63,389**		**(3.3)%**
Cost of Sales	58,464	95.4 %	64,973	102.5 %	(10.0)
Gross Profit (Loss)	2,839	4.6	(1,584)	(2.5)	DM
Selling and Marketing	9,050	14.8	1,005	1.6	800.5
General and Administrative	20,998	34.3	22,078	34.8	(4.9)
Settlement Expense, net of Reimbursement	430	0.7	1,030	1.6	(58.3)
Research and Product Development	6,886	11.2	5,642	8.9	22.0
Research and Development - Licenses Acquired (Related Party)	—	—	1,100	1.7	(100.0)
Operating Loss	**$ (34,525)**	**(56.3)%**	**$ (32,439)**	**(51.2)%**	**6.4 %**

Net Sales

During the year ended December 31, 2019, our net sales were $61.3 million compared to net sales of $63.4 million during the year ended December 31, 2018. Net sales of hemodialysis concentrates to dialysis providers and distributors in the United States and abroad were $60.8 million for the year ended December 31, 2019 compared to $63.1 million for the year ended December 31, 2018. The decrease of $2.3 million was primarily due to decreased sales to international customers offset by an increase in

sales pursuant to the Company's contract with DaVita. Net sales of Triferic were approximately $0.5 million for the year ended December 31, 2019 compared to $0.3 million for the year ended December 31, 2018. For each year ended December 31, 2019 and 2018, Triferic net sales included approximately $0.3 million of deferred revenue recognized under the Company's license in the People's Republic of China with Wanbang. Dialysate Triferic net sales for the year ended December 31, 2019 also included approximately $0.3 million of Dialysate Triferic product sales to United States customers.

Cost of Sales and Gross Profit (Loss)

Cost of sales during the year ended December 31, 2019 was $58.5 million, resulting in gross profit of $2.8 million during the year ended December 31, 2019, compared to cost of sales of $65.0 million and a gross loss of $1.6 million during the year ended December 31, 2018. Gross profit increased by $4.4 million during the year ended December 31, 2019 compared to the year ended December 31, 2018, due primarily to a reduction in non-cash charges taken for inventory reserves of $7.6 million, partially offset by a gross profit decrease of $1.2 million in our dialysis concentrates products. The decrease in gross profit for our dialysis concentrates products was primarily attributable to increased labor, materials and overhead costs.

Selling and Marketing Expense

Selling and marketing expenses were $9.1 million during the year ended December 31, 2019 compared with $1.0 million during the year ended December 31, 2018. The increase of $8.1 million was due to the investments the Company made in developing a commercial platform to support the commercial launch of Dialysate Triferic, which included $4.4 million in marketing costs and $4.7 million in costs associated with hiring, training and educating new employees for the year ended December 31, 2019.

General and Administrative Expense

General and administrative expenses were $21.0 million during the year ended December 31, 2019 compared with $22.1 million during the year ended December 31, 2018. The $1.1 million decrease is primarily due to the decrease in legal and related costs associated with various matters, including litigation activities, related to the departure of certain executives and directors that occurred in 2018.

Research and Product Development Expense

Research and product development expenses were $6.9 million for the year ended December 31, 2019 compared with $5.6 million during the year ended December 31, 2018. The increase of $1.3 million was due to the Company's commitment to investing in and building its medical capabilities mentioned above, including generating data from studies and real-world use of Dialysate Triferic to support medical education and development efforts for Dialysate Triferic, as well as the expansion of the Company's internal medical affairs staff. The Company expects its research and product development expenses to increase in the future due to additional clinical development of Dialysate Triferic and I.V. Triferic, including the pediatric clinical trial for Dialysate Triferic, and investments we are making in our medical platform to support medical education efforts, the collection and analysis of real-world data for Dialysate Triferic and additional studies of Triferic in new indications.

Settlement Expense

Settlement expense was $0.4 million for the year ended December 31, 2019, compared to $1.0 million in for the year ended December 31, 2018. Settlement expense for the year ended December 31, 2018 reflected the terms of the confidential settlement agreement and mutual release entered into with the Company's former CEO, former CFO and a former and then current director. Settlement expense for the year ended December 31, 2019 reflected the Company's contribution of the Settlement Amount relating to the consolidated class action. See Note 15 on the condensed consolidated financial statements herein for more detail.

Other Income, Net

Other income for each of the years ended December 31, 2019 and 2018 was $0.4 million and $0.3 million, respectively. The amounts consist primarily of interest income.

Liquidity and Capital Resources

As of December 31, 2019, we had approximately $26.0 million of cash, cash equivalents and investments available-for-sale, and working capital of $24.5 million. Net cash used in operating activities for the year ended December 31, 2019 was approximately $27.3 million. On June 20, 2019, the Company closed a public offering of 5,833,334 shares of common stock at a

price of $3.00 per share. On July 9, 2019, the underwriters of the public offering partially exercised their over-allotment option to purchase an additional 425,800 shares of common stock at a price of $3.00 per share, which closed on July 11, 2019.

On March 22, 2019, the Company entered into a sales agreement with Cantor Fitzgerald & Co. (the "Agent"), pursuant to which the Company may offer and sell from time to time shares of the Company's common stock through the Agent up to $40,000,000. As of December 31, 2019, the Company sold 1,840,443 shares of its common stock pursuant to the Sales Agreement for gross proceeds of $5,383,079, at a weighted average selling price of approximately $2.92. The Company paid $309,479 in commissions and offering fees related to the sale of the common stock. As of December 31, 2019, approximately $34.6 million remains available for issuance under this facility.

On February 4, 2020, the Company entered into an underwriting agreement (the "Underwriting Agreement") with Cantor Fitzgerald & Co., as underwriter (the "Underwriter"), pursuant to which the Company (i) agreed to issue and sell an aggregate of 3,191,489 shares of its common stock (the "Shares") to the Underwriter and (ii) granted the Underwriter an over-allotment option for 30 days to purchase up to an additional 478,723 shares that may be sold upon the exercise of such option by the Underwriter (the "Offering"). The Shares were purchased by the Underwriter from the Company at a price of $2.22 per share. The Offering closed on February 6, 2020. On February 19, 2020, the Underwriter exercised its over-allotment option in full and an additional 478,723 shares were sold to the underwriter on February 21, 2020. The Company raised a total of $8.0 million, net of estimated issuance costs of $0.2 million, relating to the Offering.

On March 16, 2020, Rockwell Medical, Inc. and Rockwell Transportation, Inc., as Borrowers, entered into a Loan and Security Agreement (the "Loan Agreement") with Innovatus Life Sciences Lending Fund I, LP, as collateral agent and the lenders party thereto to obtain term loans in an amount up to $35.0 million. $22.5 million was drawn under the Loan Agreement on the date of closing, and the remaining $12.5 million will be available for subsequent draws based on our achievement of certain milestones. Net proceeds at closing were approximately $21 million after deducting estimated fees and expenses of $1.5 million. Interest on the loans will accrue either in cash or a combination of cash and in kind interest, at our election. Cash interest will accrue at a rate equal to the greater of (i) Prime Rate (as defined in the Loan Agreement) and (ii) 4.75% plus 4.00%, for an initial interest rate of 8.75% per annum. We have the option, under certain circumstances, to add 1.00% of such interest rate amount to the then outstanding principal balance in lieu of paying such amount in cash. We are entitled to make interest-only payments for thirty months, or up to thirty-six months if certain conditions are met. The Loan Agreement contains representations and warranties, affirmative and negative covenants, and events of default that are customary for credit facilities of this type. The term loans will mature on March 16, 2025.

Based on the capital raise and debt financing noted above, management believes the Company currently has sufficient funds to meet its operating requirements for at least the next twelve months from the date of the filing of this report.

The Company will require additional capital to sustain its operations and make the investments it needs to execute upon its longer-term business plan, including the commercialization of Dialysate Triferic and I.V. Triferic, if approved, and executing plans for enhancing its medical capabilities and generating additional data for Triferic. If the Company is unable to generate sufficient revenue from its existing long-term business plan, the Company will need to obtain additional equity or debt financing. If the Company attempts to obtain additional debt or equity financing, the Company cannot assume that such financing will be available on favorable terms, if at all.

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; 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, or if at all; and (ii) strategic transactions, including potential alliances and collaborations focused on markets outside the United States, 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 though we began 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 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 stockholders' 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 $27.3 million for the year ended December 31, 2019. The net loss for this period was higher than net cash used in operating activities by $6.8 million, which was primarily attributable to non-cash expenses of $8.8 million, consisting primarily of $5.0 million of stock-based compensation, $1.9 million of amortization of the right to use assets, $1.3 million of inventory reserves, $0.8 million of depreciation and amortization, and a $2.0 million net change in assets and liabilities.

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.

Cash (Used in) Provided by Investing Activities

Net cash used in investing activities was $4.7 million during the year ended December 31, 2019. The net cash used was primarily due to the purchase of investments available-for-sale of $41.7 million, offset by $38.3 million sale of our available-for-sale investments, $0.6 million for the purchase of equipment and $0.8 million for the purchase of research and development licenses acquired from a related party.

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.

Cash Provided by Financing Activities

Net cash provided by financing activities was $21.1 million during the year ended December 31, 2019. The net cash provided was primarily due to net proceeds of $17.3 million and $5.1 million from the sale of our common stock, related to our public offering and our at-the market offerings, respectively, partially offset by payment of $1.1 million related to a short term note payable.

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.

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.

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 expensed 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 recoverable. Impairment losses are then measured by comparing the fair value of assets to their carrying amounts. For the years ended December 31, 2019 and 2018, 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 $2.0 million and $2.1 million related to the Baxter agreement during the years ended December 31, 2019 and 2018, 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, 2019 and 2018, respectively. Deferred revenue related to the Wanbang agreement totaled $2.9 million and $3.2 million as of December 31, 2019 and 2018, 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 judgment. For the years ended December 31, 2019 and 2018, 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 can be uncertain and future events unpredictable. If we determine that the deferred tax asset will be realized in the future, it may result in a material beneficial effect on earnings.

New Accounting Pronouncements

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.

Per §229.305 of Regulation S-K, the Company, designated a Smaller Reporting Company as defined in §229.10(f)(1) of Regulation S-K, is not required to provide the disclosure required by this Item.

Item 8. Financial Statements and Supplementary Data.

The Consolidated Financial Statements of the Registrant and other information required by this item are set forth beginning on page F-1 immediately following the signature page hereof and incorporated herein by reference.

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

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

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, 2019. 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.

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, 2019. 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 below, we concluded that we did not maintain effective control over financial reporting at a reasonable assurance level as of December 31, 2019.

As of December 31, 2019, we had 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. Specifically, management identified control deficiencies related to Information Technology General Controls ("ITGC") in connection with change management, user access controls and segregation of duties as it relates to user access controls. 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. The ITGC material weakness in our ERP 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 represents a material weakness in the Company's internal control over financial reporting. The Company's management, including the Chief Executive Officer, Chief Financial Officer and Principal Accounting 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 has taken a number of steps with the intention of remediating the deficiencies described above. In June 2019, we hired a new Principal Accounting Officer with experience in SEC reporting and internal control over financial reporting. We updated and implemented change management and user access policies. We added additional review controls to support change management and user access protocols outside of policy procedures.

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.

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, 2019. Marcum's report, which expresses an adverse opinion on the effectiveness of our internal control over financial reporting due to the 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, our management is taking action intended to remediate such material weaknesses.

As described in our 2018 Form 10-K filed on March 15, 2019, our management identified material weaknesses in our internal control over financial reporting and continues to remediate items identified.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item 10 is incorporated herein by reference to information in our proxy statement for our 2020 Annual Meeting of Stockholders (the "2020 Proxy Statement"), which we expect to be filed with the SEC within 120 days of the end of our fiscal year ended December 31, 2019, including under headings "Election of Directors," "Executive Officers" and "Corporate Governance."

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 information required by this Item 11 is incorporated herein by reference to information in our 2020 Proxy Statement, including under headings "Compensation of Executive Officers" and "Director Compensation."

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

The information required by this Item 12 is incorporated herein by reference to information in our 2020 Proxy Statement, including under heading "Voting Securities and Principal Holders."

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, 2019:

Plan Category	Number of securities to be issued upon exercise of outstanding options and restricted stock units	Weighted-average exercise price of outstanding options	Number of securities remaining available for future issuance under (excluding securities reflected in column (a))
	(a)	(b)	(c)
Equity compensation plans approved by security holders (1)	7,925,935	$ 7.06	967,608
Equity compensation plans not approved by security holders (2)	2,124,958	$ 4.70	—
Total	10,050,893	$ 6.56	967,608

(1) Consists of 7,571,899 stock options with a weighted average exercise price of $7.06 and 354,036 restricted stock units.
(2) Consists of 1,026,250 stock options with a weighted average exercise price of $4.70 and 1,098,708 restricted stock units.

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

The information required by this Item 13 is incorporated herein by reference to information in our 2020 Proxy Statement, including under headings "Independence" and "Related Party Transactions."

Item 14. Principal Accounting Fees and Services.

The information required by this Item 14 is incorporated herein by reference to information in our 2020 Proxy Statement, including under heading "Independent Accountants."

Item 15. Exhibits, Financial Statement Schedules.

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

(b) Exhibits

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

3.1	Restated Articles of Incorporation, as amended as of August 28, 2019 (Company's Form 8-K filed August 30, 2019).
3.2	Amended and Restated Bylaws (Company's Form 8-K filed August 30, 2019).
4.1	Form of Common Stock Warrant, dated October 17, 2018 (Company's Form 8-K filed October 19, 2018).
4.2	Description of Securities.
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	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).
10.4	Investment Agreement, dated October 2, 2014, by and between the Company and Baxter Healthcare Corporation (Company's Form 10-K filed March 3, 2015).
*10.5	Amendment to October 1, 2014 Stock Option Agreement with Robert L. Chioini (Company's Form 10-K filed March 3, 2015).
*10.6	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).
*10.7	Rockwell Medical, Inc. 2018 Long Term Incentive Plan (Company's Proxy Statement for the 2018 Annual Meeting of Shareholders filed on April 30, 2018).
*10.8	Form of Nonqualified Stock Option Agreement (2007 Long Term Incentive Plan) (Director Version) (Company's Form 8-K filed December 20, 2007).
*10.9	Form of Nonqualified Stock Option Agreement (2007 Long Term Incentive Plan) (Employee Version) (Company's Form 8-K filed December 20, 2007).
*10.10	Form of Restricted Stock Award Agreement (2007 Long Term Incentive Plan) (Director Version) (Company's Form 10 K filed February 29, 2016).
*10.11	Form of Restricted Stock Award Agreement (2007 Long Term Incentive Plan) (Executive Version) (Company's Form 10-Q filed May 12, 2014).
*10.12	Form of Performance Share Award Agreement March 2017 (Executive Version) (Company's Form 10-Q filed May 9, 2017).
*10.13	Form of Performance Share Award Agreement March 2017 (Director Version) (Company's Form 10-Q filed May 9, 2017).
*10.14	Form of Stock Option Agreement (2018 Long Term Incentive Plan) (Employee Version) (Company's Form 8-K filed March 21, 2018).
*10.15	Form of Contingent Option Agreement for Directors (2018 Long Term Incentive Plan) (Company's Form 8-K filed March 21, 2018).
*10.16	Amendment to October 2, 2015 Stock Option Agreement with Robert L. Chioini (Company's Form 10 K filed February 29, 2016).
10.17	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).
*10.18	Form of Indemnification Agreement (Company's Form 8-K filed August 30, 2019).
10.19	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).

*10.20	Approval of Independent Director Compensation (Company's Form 8-K filed March 21, 2018).
*10.21	Ajay Gupta Employment Agreement, dated October 7, 2018 (Company's Form 8-K filed October 12, 2018).
10.22	Registration Rights Agreement, dated October 17, 2018 (Company's Form 8-K filed October 19, 2018).
*10.23	Angus Smith Employment Agreement, dated October 26, 2018 (Company's Form 8-K filed November 2, 2018).
10.24	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).
10.25	Master Services and IP Agreement, dated October 7, 2018, by and among the Company, Charak, LLC and Dr. Ajay Gupta (Company's Form 10-K filed on March 18, 2019).
10.26	Amendment to License Agreement, dated October 7, 2018, by and among the Company, Charak, LLC and Dr. Ajay Gupta (Company's Form 10-K filed on March 18, 2019).
10.27	Commercialization and Technology License Agreement IV Triferic, dated October 7, 2018, by and among the Company, Charak, LLC and Dr. Ajay Gupta (Company's Form 10-K filed on March 18, 2019).
10.28	Technology License Agreement TPN Triferic, dated October 7, 2018, by and among the Company, Charak, LLC and Dr. Ajay Gupta (Company's Form 10-K filed on March 18, 2019).
10.29	Sales Agreement dated March 22, 2019, between Rockwell Medical, Inc. and Cantor Fitzgerald & Co. (Company's Form 8-K filed March 22, 2019).
10.30+	Products Purchase Agreement, dated July 1, 2019, by and between the Company and DaVita Inc. (f/k/a DaVita Healthcare Partners Inc.) (Company's Form 10-Q filed November 12, 2019).
21.1	List of Subsidiaries.
23.1	Consent of Marcum LLP.
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.

\+ Certain confidential portions of this exhibit were omitted by means of marking such portions with asterisks because the identified confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.

Item 16. Form 10-K Summary.

None.

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 16, 2020

POWER OF ATTORNEY

KNOW BY ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Stuart Paul and Angus Smith, and each of them, with full power of substitution and resubstitution and full power to act without the other, as his true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file, any and all documents in connection therewith, with the Securities and Exchange commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their and his or her substitute or substitutes, may lawfully do or cause to be done by virtue thereof.

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 16, 2020
/s/ Angus Smith Angus Smith	Chief Financial Officer (Principal Financial Officer)	March 16, 2020
/s/ Paul E. McGarry Paul E. McGarry	Principal Accounting Officer	March 16, 2020
/s/ Lisa Colleran Lisa Colleran	Director	March 16, 2020
/s/ John G. Cooper John G. Cooper	Director	March 16, 2020
/s/ John P. McLaughlin John P. McLaughlin	Director	March 16, 2020
/s/ Mark H. Ravich Mark H. Ravich	Director	March 16, 2020
/s/ Russell H. Ellison Russell H. Ellison	Director	March 16, 2020

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Rockwell Medical Inc. and Subsidiaries (the "Company") as of December 31, 2019 and 2018, the related consolidated statements of operations, comprehensive loss, changes in stockholders' equity and cash flows for each of the two years in the period ended December 31, 2019, and the related notes (collectively referred to as the "financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2019 and 2018, and the results of its consolidated operations and its cash flows for each of the two years in the period ended December 31, 2019, 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, 2019, 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 16, 2020, expressed an adverse opinion on the effectiveness of the Company's internal control over financial reporting because of the existence of material weaknesses.

Adoption of New Accounting Standard - Leases

As discussed in Note 3 to the consolidated financial statements, the Company changed its method of accounting for leases in 2019 due to the adoption of ASU No. 2016-02, Leases (Topic 842), as amended, effective January 1, 2019, using the modified retrospective approach.

Basis for Opinion

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

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

/s/ Marcum LLP
Marcum LLP

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

Chicago, IL
March 16, 2020

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, 2019, 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, 2019, 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:"

> The Company has control deficiencies related to Information Technology General Controls ("ITGC") in connection with change management, user access controls and segregation of duties as it relates to user access controls. 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. The ITGC material weakness in the Company's ERP 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 represents 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, 2019 consolidated financial statements, and this report does not affect our report dated March 16, 2020, 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 sheets as of December 31, 2019 and 2018, and the related consolidated statements of operations, comprehensive loss, changes in stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2019 of the Company and our report dated March 16, 2020 expressed an unqualified opinion on those consolidated financial statements and which report included an emphasis of a matter paragraph due to the Company's adoption of a new accounting standard effective January 1, 2019, ASU No. 2016-02 as amended (Topic 842), Leases, using the modified retrospective method.

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 16, 2020

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

	December 31, 2019	December 31, 2018
ASSETS		
Cash and Cash Equivalents	$ 11,794,526	$ 22,713,980
Investments Available-for -Sale	14,250,176	10,818,059
Accounts Receivable, net of a reserve of $8,932 in 2019 and $2,104 in 2018	4,202,725	6,979,514
Insurance Receivable	—	371,217
Inventory	3,646,906	4,038,778
Prepaid and Other Current Assets	2,979,504	1,903,682
Total Current Assets	**36,873,837**	**46,825,230**
Property and Equipment, net	2,433,405	2,638,293
Inventory, Non-Current	441,000	1,637,000
Right of Use Assets, net	3,212,530	—
Goodwill	920,745	920,745
Other Non-current Assets	434,935	536,516
Total Assets	**$ 44,316,452**	**$ 52,557,784**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts Payable	$ 3,018,424	$ 4,492,071
Accrued Liabilities	4,517,732	5,129,761
Settlement Payable	104,000	416,668
Lease Liability - Current	1,493,394	—
Deferred License Revenue	2,233,640	2,252,868
Insurance Financing Note Payable	763,422	—
Customer Deposits	55,100	63,143
Other Current Liability - Related Party	187,849	850,000
Total Current Liabilities	**12,373,561**	**13,204,511**
Lease Liability - Long-Term	1,780,626	—
Deferred License Revenue - Long-Term	9,842,762	12,076,399
Total Liabilities	**23,996,949**	**25,280,910**
Commitments and Contingencies (See Note 15)		
Stockholders' Equity:		
Preferred Stock, $0.0001 par value, 2,000,000 shares authorized, no shares issued and outstanding at December 31, 2019 and 2018	—	—
Common Stock, $0.0001 par value, 65,378,890 and 57,034,154 shares issued and outstanding at December 31, 2019 and 2018, respectively	6,538	5,703
Additional Paid-in Capital	326,777,250	299,596,257
Accumulated Deficit	(306,516,265)	(272,388,234)
Accumulated Other Comprehensive Income (Loss)	51,980	63,148
Total Stockholders' Equity	**20,319,503**	**27,276,874**
Total Liabilities And Stockholders' Equity	**$ 44,316,452**	**$ 52,557,784**

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

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

For The Years Ended December 31, 2019 and 2018

	2019	2018
Net Sales	**$ 61,302,801**	**$ 63,388,617**
Cost of Sales	58,463,859	64,973,157
Gross Profit (Loss)	2,838,942	(1,584,540)
Selling and Marketing	9,050,033	1,004,584
General and Administrative	20,997,948	22,077,720
Settlement Expense, net of Reimbursement	430,000	1,030,000
Research and Product Development	6,886,251	5,642,317
Research and Development - Licenses Acquired (Related Party)	—	1,100,000
Operating Loss	**(34,525,290)**	**(32,439,161)**
Other Income (Expense)		
Realized Gain (Loss) on Investments	30,182	(222,338)
Interest Income	367,077	535,641
Total Other Income	**397,259**	**313,303**
Net Loss	**$(34,128,031)**	**$(32,125,858)**
Basic and Diluted Net Loss per Share	**$ (0.56)**	**$ (0.61)**
Basic and Diluted Weighted Average Shares Outstanding	**60,918,544**	**52,824,486**

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

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

For The Years Ended December 31, 2019 and 2018

	2019	2018
Net Loss	**$(34,128,031)**	**$(32,125,858)**
Unrealized Gain on Available-for-Sale Investments	(10,395)	109,293
Foreign Currency Translation Adjustments	(773)	(10,762)
Comprehensive Loss	**$(34,139,199)**	**$(32,027,327)**

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

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

For The Years Ended December 31, 2019 and 2018

	COMMON STOCK		ADDITIONAL PAID-IN CAPITAL	ACCUMULATED DEFICIT	ACCUMULATED OTHER COMPREHENSIVE INCOME / (LOSS)	TOTAL STOCKHOLDERS' EQUITY
	SHARES	AMOUNT				
Balance as of December 31, 2017	**51,768,424**	**$ 5,177**	**$ 273,205,730**	**$ (240,262,376)**	**$ (35,383)**	**$ 32,913,148**
Net Loss	—	—	—	(32,125,858)	—	(32,125,858)
Unrealized Gain on Available-for-Sale Investments	—	—	—	—	109,293	109,293
Foreign Currency Translation Adjustments	—	—	—	—	(10,762)	(10,762)
Issuance of Common Stock	57,368	6	67,542	—	—	67,548
Shares Issued in Exchange for Services	5,541,562	554	21,935,397	—	—	21,935,951
Stock Tendered in Satisfaction of Tax Liabilities	(333,200)	(33)	33	—	—	—
Stock-based Compensation	—	—	4,387,554	—	—	4,387,554
Balance as of December 31, 2018	**57,034,154**	**$ 5,704**	**$ 299,596,256**	**$ (272,388,234)**	**$ 63,148**	**$ 27,276,874**
Net Loss	—	—		(34,128,031)	—	(34,128,031)
Unrealized Gain on Available-for-Sale Investments	—	—		—	(10,395)	(10,395)
Foreign Currency Translation Adjustments	—	—	—	—	(773)	(773)
Exercise of Employee Stock Options, Net of Tax	30,000	3	147,897	—	—	147,900
Delivery of Common Stock underlying Restricted Stock Units, net of tax	215,079	21	(279,368)	—	—	(279,347)
Issuance of Common Stock, net of Issuance Costs	6,259,214	626	17,287,272	—	—	17,287,898
Issuance of Common Stock, net of Issuance Costs / At-the-market offerings	1,840,443	184	5,073,416	—	—	5,073,600
Stock-based Compensation	—	—	4,951,777	—	—	4,951,777
Balance as of December 31, 2019	**65,378,890**	**$ 6,538**	**$ 326,777,250**	**$ (306,516,265)**	**$ 51,980**	**$ 20,319,503**

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

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

For the years ended December 31, 2019 and 2018

	2019	2018
Cash Flows From Operating Activities:		
Net Loss	**$ (34,128,031)**	**$ (32,125,858)**
Adjustments To Reconcile Net Loss To Net Cash Used In Operating Activities:		
Depreciation and Amortization	788,175	650,142
Stock-based Compensation	4,951,777	4,387,554
Research and Development - Licenses Acquired (Related Party)	—	1,100,000
Increase in Inventory Reserves	1,271,000	8,784,000
Amortization of Right of Use Asset	1,864,538	—
Loss on Disposal of Assets	4,561	4,752
Realized (Gain) Loss on Sale of Investments Available-for-Sale	(30,182)	222,338
Foreign Currency Translation Adjustment	(773)	(10,762)
Changes in Assets and Liabilities:		
Decrease (Increase) in Insurance Receivable	371,217	(371,217)
Decrease (Increase) in Accounts Receivable, net	2,776,789	(623,948)
Decrease (Increase) in Inventory	316,872	(835,641)
Decrease (Increase) in Other Assets	933,960	(165,712)
(Decrease) Increase in Accounts Payable	(1,473,648)	269,912
(Decrease) Increase in Settlement Payable	(312,668)	416,668
Decrease in Lease Liability	(1,803,048)	—
(Decrease) Increase in Other Liabilities	(532,222)	271,889
Decrease in Deferred License Revenue	(2,252,865)	(2,394,051)
Changes in Assets and Liabilities	(1,975,613)	(3,432,100)
Cash Used In Operating Activities	**(27,254,548)**	**(20,419,934)**
Cash Flows From Investing Activities:		
Purchase of Investments Available-for-Sale	(41,677,994)	(20,178,127)
Sale of Investments Available-for-Sale	38,265,664	33,895,481
Purchase of Equipment	(587,452)	(744,256)
Purchase of Research and Development Licenses (Related Party)	(750,000)	(250,000)
Proceeds on Sale of Assets	—	400
Cash (Used in) Provided By Investing Activities	**(4,749,782)**	**12,723,498**
Cash Flows From Financing Activities:		
Payments on Short Term Note Payable	(1,145,132)	—
Proceeds from the Issuance of Common Stock / Public Offering	18,777,642	22,000,000
Offering Costs from the Issuance of Common Stock / Public Offering	(1,489,787)	(64,049)
Proceeds from the Issuance of Common Stock / At-the Market Offerings	5,383,079	—
Offering Costs from the Issuance of Common Stock / At-the Market Offerings	(309,479)	—
Proceeds from the Exercise of Employee Stock Options, Net of Tax	147,900	67,548
Repurchase of Common Stock to Pay Employee Withholding Taxes	(279,347)	—
Cash Provided By Financing Activities	**21,084,876**	**22,003,499**
(Decrease) Increase In Cash and Cash Equivalents	(10,919,454)	14,307,063
Cash At Beginning Of Period	22,713,980	8,406,917
Cash At End Of Period	**$ 11,794,526**	**$ 22,713,980**
Supplemental Disclosure of Noncash Investing Activities:		
Change in Unrealized Gain on Marketable Securities Available-for-Sale	$ (10,395)	$ 109,293
Research and Development Licenses (Related Party)	$ —	$ 850,000
Insurance Financing Note Payable	$ 763,422	$ —

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

Note 1. Description of Business

Rockwell Medical, Inc. and subsidiaries (collectively, "we", "our", "us", or the "Company"), is a biopharmaceutical company dedicated to improving outcomes for patients with anemia, with an initial focus on end-stage renal disease ("ESRD"). We are also a manufacturer of hemodialysis concentrates for dialysis providers and distributors in the United States and abroad. We supply the 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. Substantially, all of our sales have been concentrate products and ancillary items, though we initiated commercial sales of our proprietary therapeutic, Dialysate Triferic, during the second quarter of 2019.

Our mission is to transform anemia management in a wide variety of disease states across the globe while improving patients' lives. Accordingly, we are building the foundation to become a leading medical and commercial organization in the field of dialysis.

Triferic® is a registered trademark of Rockwell Medical, Inc.

Note 2. Liquidity and Capital Resources

As of December 31, 2019, the Company had approximate balances of $11.8 million of cash and cash equivalents, $14.3 million of investments available-for-sale, working capital of $24.5 million and an accumulated deficit of $306.5 million. Net cash used in operating activities for the year ended December 31, 2019 was approximately $27.3 million. The Company evaluated the Company's ability to continue as going concern for at least the next 12 months from the filing of this report.

On February 4, 2020, and February 19, 2020, the Company raised capital in the amount of $8 million, net of estimated issuance costs. On March 16, 2020, the Company closed a debt financing transaction with net proceeds at closing of approximately $21 million, net of estimated fees and expenses (See Note 18 for further detail).

Based on the currently available working capital, capital raise and debt financing noted above, management believes the Company currently has sufficient funds to meet its operating requirements for at least the next twelve months from the date of the filing of this report.

The Company will require additional capital to sustain its operations and make the investments it needs to execute upon its longer-term business plan, including the commercialization of Dialysate Triferic and I.V. Triferic, if approved, and executing plans for enhancing its medical capabilities and generating additional data for Triferic. If the Company is unable to generate sufficient revenue from its existing long-term business plan, the Company will need to obtain additional equity or debt financing. If the Company attempts to obtain additional debt or equity financing, the Company cannot assume that such financing will be available on favorable terms, if at all.

Note 3. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, Rockwell Transportation, Inc. and Rockwell Medical India Private Limited. Rockwell Medical India Private Limited was formed in 2017 for the purpose of conducting certain commercial activities in India. All intercompany balances and transactions have been eliminated in consolidation.

Certain reclassifications have been made to the 2018 financial statements and notes to conform to the 2019 presentation.

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.

Nature of goods and services

The following is a description of principal activities from which the Company generates its revenue.

Product sales –The Company accounts for individual products and services separately if they are distinct (i.e., if a product or service is separately identifiable from other items and if a customer can benefit from it on its own or with other resources that are readily available to the customer). The consideration, including any discounts, is allocated between separate products and services based on their stand-alone selling prices. The stand-alone selling prices are determined based on the cost plus margin approach.

Drug and dialysis concentrate products are sold directly to dialysis clinics and to wholesale distributors in both domestic and international markets. Distribution and license agreements for which upfront fees are received are evaluated upon execution or modification of the agreement to determine if the agreement creates a separate performance obligation from the underlying product sales. For all existing distribution and license agreements, the distribution and license agreement is not a distinct performance obligation from the product sales. In instances where regulatory approval of the product has not been established and the Company does not have sufficient experience with the foreign regulatory body to conclude that regulatory approval is probable, the revenue for the performance obligation is recognized over the term of the license agreement (over time recognition). Conversely, when regulatory approval already exists or is probable, revenue is recognized at the point in time that control of the product transfers to the customer.

The Company received upfront fees under two distribution and license agreements that have been deferred as a contract liability. The amounts received from Wanbang Biopharmaceuticals Co., Ltd. (“Wanbang”) are recognized as revenue over the estimated term of the distribution and license agreement as regulatory approval was not received and the Company did not have sufficient experience in China to determine that regulatory approval was probable as of the execution of the agreement. The amounts received from Baxter Healthcare Corporation (“Baxter”) are recognized as revenue at the point in time that the estimated product sales under the agreement occur.

For the business under the Company’s distribution agreement with Baxter (the “Baxter Agreement”) and for the majority of the Company’s international customers, the Company recognizes revenue at the shipping point, which is generally the Company’s plant or warehouse. For other business, the Company recognizes revenue based on when the customer takes control of the product. The amount of revenue recognized is based on the purchase order less returns and adjusted for any rebates, discounts, chargebacks or other amounts paid to customers. There were no such adjustments for the periods reported. Customers typically pay for the product based on customary business practices with payment terms averaging 30 days, while distributor payment terms average 45 days.

Disaggregation of revenue

Revenue is disaggregated by primary geographical market, major product line, and timing of revenue recognition.

In thousands of US dollars ($)	Year Ended December 31, 2019		
Products By Geographic Area	Total	U.S.	Rest of World
Drug Revenues			
Product Sales - Point-in-time	$ 272	$ 272	$ —
License Fee – Over time	273	—	273
Total Drug Products	545	272	273
Concentrate Products			
Product Sales – Point-in-time	58,778	52,540	6,238
License Fee – Point-in-time	1,980	1,980	—
Total Concentrate Products	60,758	54,520	6,238
Net Revenue	$ 61,303	$ 54,792	$ 6,511

	Year Ended December 31, 2018		
Products By Geographic Area	Total	U.S.	Rest of World
Drug Revenues			
License Fee – Over time	$ 273	$ —	$ 273
Concentrate Products			
Product Sales – Point-in-time	60,995	52,264	8,731
License Fee – Point-in-time	2,121	2,121	—
Total Concentrate Products	63,116	54,385	8,731
Net Revenue	$ 63,389	$ 54,385	$ 9,004

For the years ended December 31, 2019 and 2018, license fee revenue was $2.3 million and $2.4 million, respectively. For the years ended December 31, 2019 and 2018, product sales revenue was $59.0 million and $61.0 million, respectively.

Contract balances

The following table provides information about receivables, contract assets, and contract liabilities from contracts with customers.

In thousands of US dollars ($)	December 31, 2019	December 31, 2018
Receivables, which are included in "Trade and other receivables"	$ 4,203	$ 6,980
Contract liabilities	$ 12,076	$ 14,329

There were no impairment losses recognized related to any receivables arising from the Company's contracts with customers for the years ended December 31, 2019 and 2018, respectively.

For the years ended December 31, 2019 and 2018, the Company did not recognize material bad-debt expense and there were no material contract assets recorded on the consolidated balance sheet as of December 31, 2019 and 2018, respectively. The Company does not generally accept returns of its concentrate products and no reserve for returns of concentrate products was established as of December 31, 2019 or December 31, 2018.

The contract liabilities primarily relate to upfront payments and consideration received from customers that are received in advance of the customer assuming control of the related products.

Transaction price allocated to remaining performance obligations

For the year ended December 31, 2019, revenue recognized from performance obligations related to prior periods was not material.

Revenue expected to be recognized in any future year related to remaining performance obligations, excluding revenue pertaining to contracts that have an original expected duration of one year or less, contracts where revenue is recognized as invoiced and contracts with variable consideration related to undelivered performance obligations, totaled $12.1 million and $14.3 million for each of the years ended December 31, 2019 and 2018. The amount relates primarily to upfront payments and consideration received from customers that are received in advance of the customer assuming control of the related products. The Company applies the practical expedient in paragraph 606-10-50-14 and does not disclose information about remaining performance obligations that have original expected durations of one year or less. The Baxter Agreement includes minimum commitments of product sales over the duration of the agreement. Unfulfilled performance obligations related to the Baxter Agreement are product sales totaling $9.1 million, which will be amortized through expiration of the agreement on October 2, 2024.

Use of Estimates

The preparation of the consolidated financial statements in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP") requires management to make estimates and assumptions that may affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and reported amounts of expenses during the reporting period. Actual results could differ from those estimates. The most significant accounting estimates inherent in the preparation of our financial statements include estimates associated with revenue recognition, allowance for doubtful accounts, inventory reserves, accrued expenses, deferred license revenue, stock-based compensation, impairments of long-lived assets, and accounting for income taxes.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with original maturities of 90 days or less at acquisition to be cash equivalents excluding items held in Investments - Available for Sale as noted below. Cash and cash equivalents include cash held in banks, money market mutual funds and unrestricted certificates of deposit. The Company's cash and cash equivalents exceeds the Federal Deposit Insurance Corporation insured limits. The Company has not experienced any credit losses for amounts in excess of insured limits. Currently the Company does not reasonably believe a significant risk of credit loss exists.

Fair Value Measurement

The Company applies the guidance issued with ASC 820, *Fair Value Measurements*, which provides guidance on the development and disclosure of fair value measurements. Under this accounting guidance, fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability.

The accounting guidance classifies fair value measurements in one of the following three categories for disclosure purposes:

Level 1: Quoted prices in active markets for identical assets or liabilities.

Level 2: Inputs other than Level 1 prices for similar assets or liabilities that are directly or indirectly observable in the marketplace.

Level 3: Unobservable inputs which are supported by little or no market activity ad values determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant judgment or estimation.

Investments – Available for Sale

The Company has designated its short term investments as of each balance sheet date as available-for-sale securities and accounts for them at their respective fair values. Available-for-sale securities are measured at fair value, including accrued interest, with temporary unrealized gains and losses reported as a component of stockholders' equity until their disposition. We review all available-for-sale securities at each period end to determine if they remain available-for-sale based on our then current intent and ability to sell the security if required to do so. The cost of securities sold is based on the specific identification method.

All of our investments available-for-sale are subject to periodic impairment review. We recognize an impairment charge when a decline in the fair value of our investments below the cost basis is judged to be other than temporary.

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 expensed 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 recoverable. Impairment losses are then measured by comparing the fair value of assets to their carrying amounts. For the years ended December 31, 2019 and 2018, 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 during each of years ended December 31, 2019 and 2018, respectively. Deferred revenue related to the Baxter agreement totaled $9.1 million and $11.1 million as of December 31, 2019 and 2018, respectively.

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. In the event of a Refund Trigger Event occurring from January 1, 2019 to December 31, 2021, Baxter would be eligible for a 25% refund of the Agreement's Upfront Payment.

During the year ended December 31, 2017, 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 each of the years ended December 31, 2019 and 2018. Deferred revenue related to the Wanbang agreement totaled $2.9 million and $3.2 million as of December 31, 2019 and 2018, respectively.

Income Taxes

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

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

Research and Product Development

The Company recognizes research and product development expenses as incurred. The Company incurred product development and research costs related to the commercial development, patent approval and regulatory approval of new products aggregating approximately $6.9 million and $5.6 million for the years ended December 31, 2019 and 2018, respectively. During the year ended December 31, 2018, an additional $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.

Stock-Based Compensation

Service-Based Stock Unit Awards

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 judgment. For the years ended December 31, 2019 and 2018, 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 (See Note 13).

Market and Performance-Based Stock Unit Awards

In addition to awards with service-based vesting conditions, the Company has granted performance share units with market and performance conditions, to certain of its executives. The fair value of awards with performance conditions are based on the fair value of the Company's common stock on the date of grant. The fair value of awards with market conditions are based on a Monte Carlo simulation model. Assumptions and estimates utilized in the calculation of the fair value of the market awards include the risk-free interest rate, dividend yield, average closing price, expected volatility based on the historical volatility of the Company, and the remaining period of the award.

The awards with performance conditions vest and result in issuance, at settlement, of common stock for each recipient based upon the recipient's continued employment with the Company through the settlement date of the award and the Company's achievement of specified milestones. The requisite service period of the awards with performance conditions is generally 1-2

years. In the case of awards with performance conditions, the Company recognizes stock-based compensation expense based on the grant date fair value of the award when achievement of the underlying performance-based targets become probable.

The awards with market conditions vest and result in the issuance of common stock based upon the recipient's continuing employment with the Company through the settlement date of the award related to the market capitalization criteria. The fair value related to the awards with market conditions is recorded as stock-based compensation expense over the period from date of grant to the settlement date regardless of whether the market capitalization is achieved.

Commitments and Contingencies

In the normal course of business, the Company may become subject to loss contingencies, such as legal proceedings and claims arising out of its business, including government investigations. An accrual for a loss contingency is recognized when it is probable that an asset had been impaired or a liability had been incurred and the amount of loss can be reasonably estimated. The Company expenses legal costs associated with loss contingencies as they are incurred.

Loss Per Share

ASC 260, Earnings Per Share, requires dual presentation of basic and diluted earnings per share ("EPS"), with a reconciliation of the numerator and denominator of the basic EPS computation to the numerator and denominator of the diluted EPS computation. Basic EPS excludes dilution. Diluted EPS reflects the potential dilution that could occur if securities or other contracts to issued common stock were exercised or converted into common stock or resulted in the issuance of common stock that are then shared in the earnings of the entity.

Basic net loss per share of common stock excludes dilution and is computed by dividing the net loss by the weighted average number of shares outstanding during the period. Diluted net loss per share of common stock reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock or resulted in the issuance of common stock that are then shared in the earnings of the entity unless inclusion of such shares would be anti-dilutive. The Company has only incurred losses, therefore, basic and diluted net loss per share is the same. Securities that could potentially dilute loss per share in the future that were not included in the computation of diluted loss per share for the years ended December 31, 2019 and 2018 were as follows:

	As of December 31,	
	2019	2018
Options to purchase common stock	8,598,149	8,244,605
Unvested restricted stock awards	146,800	146,800
Unvested restricted stock units	1,452,744	1,461,917
Warrants to purchase common stock	2,770,781	2,770,781
	12,968,474	12,624,103

Accumulated Other Comprehensive Income (Loss)

Accumulated other comprehensive income (loss) includes all changes in equity during a period except those that resulted from investments by or distributions to the Company's stockholders. Accumulated other comprehensive income (loss) refers to revenues, expenses, gains and losses that are included in comprehensive income (loss), but excluded from net income (loss) as these amounts are recorded directly as an adjustment to stockholders' equity. Accumulated other comprehensive income (loss) consists of unrealized gains and losses on available-for-sale investment securities and foreign currency translation adjustments.

Adoption of Recent Accounting Pronouncements

The Company continually assesses any new accounting pronouncements to determine their applicability. When it is determined that a new accounting pronouncement affects the Company's financial reporting, the Company undertakes a study to determine the consequences of the change to its consolidated financial statements and assures that there are proper controls in place to ascertain that the Company's consolidated financial statements properly reflect the change.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* in order to increase transparency and comparability among organizations by, and among other provisions, recognizing lease assets and lease liabilities on the balance sheet for those leases classified as operating leases under previous U.S. GAAP. For public companies, ASU 2016-2 is effective for fiscal years

beginning after December 15, 2018 (including interim periods within those periods) using a modified retrospective approach and early adoption is permitted. In transition, entities may also elect a package of practical expedients that must be applied in its entirety to all leases commencing before the adoption date, unless the lease is modified, and permits entities to not reassess (a) the existence of a lease, (b) lease classification or (c) determination of initial direct costs, as of the adoption date, which effectively allows entities to carryforward accounting conclusions under previous U.S. GAAP. In July 2018, the FASB issued ASU 2018-11, *Leases (Topic 842)*: *Targeted Improvements*, which provides entities an optional transition method to apply the guidance under Topic 842 as of the adoption date, rather than as of the earliest period presented. The Company adopted Topic 842 on January 1, 2019, using the optional transition method to apply the new guidance as of January 1, 2019, rather than as of the earliest period presented, and elected the package of practical expedients described above. The Company adopted this new standard on January 1, 2019 and recognized, on the Company's consolidated balance sheet, additional operating liabilities of $3.5 million, with corresponding ROU assets of approximately the same amount as of January 1, 2019 based on the present value of the remaining lease payments.

In June 2018, the FASB issued ASU 2018-17, *Improvements to Nonemployee Share-Based Payment Accounting,* which simplifies the accounting for share-based payments granted to nonemployees for goods and services. Under ASU 2018-17, most of the guidance on such payments to nonemployees would be aligned with the requirements for share-based payments granted to employees. The amendments are effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. Early adoption is permitted, but no earlier than an entity's adoption of Topic 606. The Company adopted this new standard on January 1, 2019 and the adoption did not have a material impact on its consolidated financial statements and related disclosures.

In August 2018, the Securities and Exchange Commission ("SEC"), adopted the final rule under SEC Release No. 33-10532, "Disclosure Update and Simplification," amending certain disclosure requirements that were redundant, duplicative, overlapping, outdated or superseded. In addition, the amendments expanded the disclosure requirements on the analysis of stockholders' equity presented in the balance sheet must be provide in a note or separate statement. The analysis should represent a reconciliation of the beginning balance to the ending balance for each period for which a statement of comprehensive income is required to be filed. This final rule is effective on November 5, 2018. The Company implemented this change on the Company's Form 10Q filed May 10, 2019 and the adoption did not have a material impact on its consolidated financial statements and related disclosures.

Note 4. Investments - Available-for-Sale

Investments available-for-sale consisted of the following as of December 31, 2019 and 2018:

	December 31, 2019			
	Amortized Cost	Unrealized Gain	Unrealized Loss	Fair Value
Available-for-Sale Securities				
Bonds	$ 14,238,161	$ 13,321	$ (1,306)	$ 14,250,176

	December 31, 2018			
	Amortized Cost	Unrealized Gain	Unrealized Loss	Fair Value
Available-for-Sale Securities				
Bonds	$ 10,801,836	$ 17,415	$ (1,192)	$ 10,818,059

The fair value of investments available-for-sale are determined using quoted market prices from daily exchange-traded markets based on the closing price as of the balance sheet date and are classified as Level 1, as described in Note 3, Fair Value Measurement to our consolidated financial statements.

As of December 31, 2019 and 2018, the amortized cost and estimated fair value of our available-for-sale securities were due in one year or less.

Note 5. Significant Market Segments and Customers

We operate in one market segment, the hemodialysis market, which involves the manufacture, sale and distribution of hemodialysis products to hemodialysis clinics, including pharmaceutical, dialysis concentrates, dialysis kits and other ancillary products used in the dialysis process.

One customer, DaVita, Inc. ("DaVita"), accounted for 49% of our sales in 2019 and 46% of our sales in 2018. Our accounts receivable from this customer were $1,166,603 and $2,538,503 as of December 31, 2019 and 2018, respectively.

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 2019 and 2018, our direct sales to Baxter aggregated approximately 27% and 26% of sales, respectively, and we had a receivable from Baxter of $2,015,438 and $2,824,051 as of December 31, 2019 and 2018, respectively.

DaVita and Baxter and the accounts administered by Baxter are important to our business, financial condition and results of operations. The loss of any significant accounts could have a material adverse effect on our business, financial condition and results of operations. No other domestic customers accounted for more than 10% of our sales in any of the last two years.

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 sales to foreign customers and distributors accounted for approximately 11% and 14% of our total sales in 2019 and 2018, respectively. One international customer, Nipro Medical Corporation, accounted for 9% and 10% of our sales for 2019 and 2018 respectively.

Note 6. Distribution Agreement

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

Pursuant to the Distribution Agreement, Baxter paid us $20 million in cash in October 2014 (the “Upfront Fee”). The Upfront Fee has been deferred and is being recognized as revenue based on the proportion of product shipments to Baxter in each period to total expected sales volume over the term of the Distribution Agreement. We recognized revenue associated with the Upfront Fee totaling $2.1 million for each of the years ended December 31, 2019, and 2018, respectively.

Under the Distribution Agreement, Baxter purchases products from us at established gross margin-based prices per unit, adjusted each year during the term. We continue to manage customer service, transportation and certain other functions for our current customers on Baxter’s behalf, in exchange for which Baxter will pay us an amount equal to our related costs to provide such functions plus a slight mark-up.

The Distribution Agreement also requires Baxter to meet minimum annual gallon-equivalent purchase levels, subject to a cure period and certain other relief, in order to maintain its exclusive distribution rights. The minimum purchase levels increase each year over the term of the Distribution Agreement. Orders in any contract year that exceed the minimum will be carried forward and applied to future years’ minimum requirements. The Distribution Agreement also contains provisions governing the operating relationship between the parties, our obligations to maintain specified manufacturing capacity and quality levels, remedies, as well as representations, warranties and indemnification obligations of the parties.

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

If a “Refund Trigger Event” occurs, we would be obligated to repay 25% of the Upfront Fee and Facility Fee (described below) if the event occurs in 2019, 2020 or 2021. A “Refund Trigger Event” means any of the following: (1) a change of control of the Company involving any of certain specified companies; (2) a termination by Baxter due to the Company’s bankruptcy or breach, or due to price increases that exceed the stated thresholds; (3) a termination by either party due to a force majeure;

(4) settlement or adjudication of any claim, action or litigation relating to a covered product that materially and adversely affects Baxter's commercialization of the product; and (5) any regulatory action or ruling relating to a covered product that materially and adversely affects Baxter's commercialization of the product.

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

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

Note 7. Inventory

Components of inventory, net of reserves as of December 31, 2019 and 2018 are as follows:

	December 31, 2019	December 31, 2018
Raw Materials	$ 2,471,234	$ 3,621,548
Work in Process	184,382	256,129
Finished Goods	1,432,290	1,798,101
Total	$ 4,087,906	$ 5,675,778

As of December 31, 2019 and 2018, we classified $0.4 million and $1.6 million, respectively, of inventory as non-current all of which was related to Triferic or the active pharmaceutical ingredient for Triferic. As of December 31, 2019 and 2018, we had total Triferic inventory aggregating $3.5 million and $8.0 million respectively, against which we had reserved $2.8 million and $5.8 million, respectively.

For the year ended December 31, 2019, the Company's inventory reserves and write-offs increased by $1.3 million, which related to Triferic. For the year ended December 31, 2018, inventory reserves and write-offs increased by $8.8 million, consisting of $8.1 million related to Triferic and $0.7 million related to Calcitriol.

The $0.7 million net value of Triferic inventory consisted of $0.2 million of Dialysate Triferic finished goods with expiration dates ranging from March 2020 to May 2021, and $0.5 million of Triferic API with estimated useful lives extending through 2023. The Company increased its inventory reserve for Triferic by $1.3 million for the year ended December 31, 2019 due to, among other factors, the impact of the Centers for Medicare & Medicaid Services ("CMS") Final Rule on October 31, 2019 and its current volume forecasts for Triferic across the globe.

Note 8. Property and Equipment

As of December 31, 2019 and 2018, the Company's property and equipment consisted of the following:

	2019	2018
Leasehold Improvements	$ 1,162,328	$ 929,849
Machinery and Equipment	4,672,724	4,800,774
Information Technology & Office Equipment	1,810,246	2,459,832
Laboratory Equipment	653,075	668,977
Transportation Equipment	—	—
	8,298,373	8,859,432
Accumulated Depreciation	(5,864,968)	(6,221,139)
Net Property and Equipment	$ 2,433,405	$ 2,638,293

Depreciation expense during the years ended December 31, 2019 and 2018 is as follows:

	2019	2018
Depreciation expense	$ 787,822	$ 649,789

Note 9. Goodwill and Intangible Assets

Total goodwill was $0.9 million at December 31, 2019 and 2018. We completed our annual impairment tests as of December 31, 2019 and 2018, and determined that no adjustment for impairment of goodwill was required during the years ended December 31, 2019 and 2018.

We entered into global licensing agreements for certain patents covering our Triferic products. We received FDA approval for Dialysate Triferic in January 2015. We have capitalized the licensing fees paid for the rights to use this patented technology as an intangible asset.

	2019	2018
Capitalized Licensing Fees	$ 1,070,126	$ 1,070,126
Accumulated Amortization	(1,066,804)	(1,066,451)
Capitalized Licensing Fees, Net of Amortization	$ 3,322	$ 3,675
Amortization Expense	$ 353	$ 353

Our policy is to amortize licensing fees over the life of the patents pertaining to certain licensing agreements and to amortize patent costs over the life of the patent. Amortization expense was $353 for capitalized patent costs for each of the years ended December 31, 2019 and 2018, respectively.

Note 10. Accrued Liabilities

Accrued liabilities as of December 31, 2019 and 2018 consisted of the following:

	2019	2018
Accrued Research & Development Expense	$ 283,407	$ 86,820
Accrued Compensation and Benefits	1,018,196	1,525,599
Accrued Legal Expenses	181,597	170,334
Accrued Marketing Expenses	61,164	5,000
Other Accrued Liabilities	2,973,368	3,342,008
Total Accrued Liabilities	$ 4,517,732	$ 5,129,761

Note 11. Insurance Financing Note Payable

On June 3, 2019, the Company entered into a short-term note payable for $1.9 million, bearing interest at 4.65% per annum to finance various insurance policies. Principal and interest payments related to this note began on July 3, 2019 and are paid on a straight-line amortization over a 10-month period with the final payment due on April 3, 2020. As of December 31, 2019, the Company's insurance note payable balance was $0.8 million. Interest expense was $24,547 for the year ended December 31, 2019. Interest expense is included under other income (expense) within the Interest Income item on the consolidated statement of operations herein.

Note 12. Stockholders' Equity

The Company's new authorized capital stock consists of 170 million shares of common stock, $0.0001 par value per share, and 2,000,000 shares of preferred stock, $0.0001 par value per share.

At the 2019 Annual Meeting of Shareholders, the Company's shareholders voted and approved to reincorporate the Company from the State of Michigan to the State of Delaware (the "Reincorporation"). The Reincorporation became effective on August 30, 2019 and was accomplished by the filing of (i) a certificate of conversion with the Bureau of Commercial Services of the Michigan Department of Labor & Economic Growth; (ii) a certificate of conversion with the Secretary of State of the State of Delaware; and (iii) a Certificate of Incorporation with the Secretary of State of the State of Delaware.

Also at the 2019 Annual Meeting, the Company obtained shareholder approval to increase the number of authorized shares of the Company's common stock by 50,000,000 shares from 120,000,000 shares to 170,000,000 shares. On July 30, 2019,

the Company amended its Articles of Incorporation to reflect this increase in authorized shares from 120,000,000 to 170,000,000 shares.

Preferred Stock

As of December 31, 2019 and 2018, there were 2,000,000 shares of preferred stock, $0.0001 par value per share, authorized and no shares of preferred stock issued or outstanding.

Common Stock

As of December 31, 2019 and 2018, there were 170,000,000 shares of common stock, $0.0001 par value per share, authorized and 65,378,890 and 57,034,154 shares issued and outstanding, respectively.

During the year ended December 31, 2018, 267,500 vested employee stock options were exercised for net cash proceeds of $67,548 at a weighted average exercise price of $3.09 per share. The Company withheld 210,132 of these shares of common stock at a cost of $759,028, or a weighted average cost of $3.61 per share, to cover the employee withholding taxes and other expenses related to these exercises.

During the year ended December 31, 2019, 30,000 vested employee stock options were exercised for net cash proceeds of $147,900 at a weighted average exercise price of $4.93 per share.

Controlled Equity Offering

On March 22, 2019, the Company entered into a sales agreement (the "Sales Agreement") with Cantor Fitzgerald & Co. (the "Agent"), pursuant to which the Company may offer and sell from time to time shares of the Company's common stock through the Agent. The offering and sale of up to $40.0 million of the shares has been registered under the Securities Act of 1933, as amended, pursuant to the Company's registration statement on Form S-3 (File No. 333-227363), which was originally filed with the SEC on September 14, 2018 and declared effective by the SEC on October 1, 2018. The base prospectus contained within the registration statement, and a prospectus supplement was filed with the SEC on March 22, 2019.

Sales of the shares, if any, pursuant to the Sales Agreement, may be made in sales deemed to be a "at the market offering" as defined in Rule 415(a) of the Securities Act, including sales made directly through The Nasdaq Global Market or on any other existing trading market for the Company's common stock. The Company intends to use the proceeds from the offering for working capital and other general corporate purposes. The Company may suspend or terminate the Sales Agreement at any time.

As of December 31, 2019, the Company sold 1,840,443 shares of its common stock pursuant to the Sales Agreement for gross proceeds of $5,383,079, at a weighted average selling price of approximately $2.92. The Company paid $309,479 in commissions and offering fees related to the sale of the common stock. As of December 31, 2019, approximately $34.6 million remains available for issuance under this facility.

We are not required to sell any shares at any time during the term of the facility. Our ability to sell common stock under the facility may be limited by several factors including, among other things, the trading volume of our common stock and certain black-out periods that we may impose upon the facility, among other things.

Public Offering of Common Stock

On October 15, 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.

On June 17, 2019, the Company entered into an underwriting agreement with Piper Jaffray & Co., and Cantor Fitzgerald & Co., pursuant to which the Company agreed to issue and sell up to 6,708,334 shares of common stock, which included 875,000 optional shares that may be sold pursuant to an option granted to the underwriters. On June 20, 2019, the Company closed the sale of 5,833,334 shares of its common stock for gross proceeds of $17,500,002 at the public offering price of $3.00 per share (the "Offering"). The Company paid $1,379,323 in underwriters' commissions and fees related to the sale of the common stock. The Offering was made pursuant to the Company's effective registration statement on Form S-3 (File No. 333-227363), which was previously filed with the SEC. On July 9, 2019, the Underwriters exercised their over-allotment option to purchase an additional 425,800 shares of common stock at a price of $3.00 per share, which closed on July 11, 2019. The total proceeds to the Company

(net of underwriting commissions and offering fees) from the exercise of the over-allotment option were approximately $1.2 million.

Restricted Common Stock

On August 7, 2018, 333,200 shares of restricted stock were forfeited. Forfeitures of restricted stock were related to a settlement agreement between the Company and its former CEO, CFO, and two former Directors. (see Note 15).

During the year ended December 31, 2019, 322,820 shares of common stock related to fully vested restricted stock units were delivered to officers of the Company. The Company withheld 107,741 of these shares of common stock at a fair value of $279,346 to cover the officer's withholding taxes related to the vesting of restricted stock units.

Note 13. Stock-Based Compensation

The Board of Directors adopted the Rockwell Medical, Inc., 2007 Long Term Incentive Plan ("2007 LTIP") on April 11, 2007. The 2007 LTIP expired on April 11, 2017 and no equity awards were granted under the 2007 LTIP following its expiration. There were 11,500,000 shares of common stock reserved for issuance under the 2007 LTIP. The Board of Directors adopted the 2018 Long-Term Incentive Plan ("2018 LTIP") on January 29, 2018 as a replacement for the 2007 LTIP. There are 3,300,000 shares of common stock reserved for issuance under the 2018 LTIP. The Compensation Committee of the Board of Directors (the "Committee") is responsible for the administration of the 2007 LTIP and 2018 LTIP, including the grant of stock based awards and other financial incentives including performance based incentives to employees, non-employee directors and consultants.

Our standard stock option agreement under the 2007 LTIP and 2018 LTIP allows for the payment of the exercise price of vested stock options either through cash remittance in exchange for newly issued shares, or through non-cash exchange of previously issued shares held by the recipient for at least six months in exchange for our newly issued shares. The 2007 LTIP and 2018 LTIP also allow for the retention of shares in payment of the exercise price and income tax withholding. The latter method results in no cash being received by us, but also results in a lower number of total shares being outstanding subsequently as a direct result of this exchange of shares. Shares returned to us in this manner would be retired.

The Company recognized total stock-based compensation expense during the years ended December 31, 2019 and 2018 as follows:

	Year Ended	
	2019	2018
Service based awards:		
Restricted stock awards	$ (33,419)	$ 1,292,125
Restricted stock units	1,600,289	840,477
Stock option awards	2,300,323	1,588,291
	$ 3,867,193	$ 3,720,893
Performance based awards:		
Restricted stock units	$ 641,517	$ 505,999
Stock option awards	443,110	160,662
	1,084,627	666,661
Total	$ 4,951,820	$ 4,387,554

Restricted Stock Awards

A summary of the Company's restricted stock awards during the years ended December 31, 2019 and 2018 is as follows:

	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested at January 1, 2018	480,000	$ 7.27
Forfeited	(333,200)	$ 5.70
Unvested at December 31, 2018	146,800	$ 5.70
Unvested at December 31, 2019	146,800	$ 5.70

During the year ended December 31, 2018, forfeitures of performance based restricted stock awards totaled 333,200 related to the settlement agreement with the Company's former CEO, CFO, and two former Directors. (see Note 15.)

The fair value of restricted stock awards are measured based on their fair value on the date of grant and amortized over the vesting period of 20 months. As of December 31, 2019, unvested restricted stock awards of 146,800 were related to performance based awards. Stock-based compensation expense of nil and $1.3 million was recognized during the year ended December 31, 2019 and 2018, respectively. As of December 31, 2019, there is no unrecognized stock-based compensation expense related to restricted stock awards.

Service Based Restricted Stock Units

A summary of the Company's service based restricted stock units during the year ended December 31, 2019 is as follows:

	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested at December 31, 2018	472,959	$ 4.32
Granted	244,063	4.09
Forfeited	(28,916)	4.32
Vested	(224,320)	4.19
Unvested at December 31, 2019	463,786	$ 4.26

The fair value of service based restricted stock units are measured based on their fair value on the date of grant and amortized over the vesting period. The vesting periods range from 1-3 years. Stock-based compensation expense of $1.6 million and $0.8 million was recognized during the year ended December 31, 2019 and 2018, respectively. As of December 31, 2019, the unrecognized stock-based compensation expense was $0.9 million.

Performance Based Restricted Stock Units

A summary of the Company's performance based restricted stock units during the year ended December 31, 2019 is as follows:

	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested at December 31, 2018	988,958	$ 4.48
Unvested at December 31, 2019	988,958	$ 4.48

Stock-based compensation expense recognized for performance based restricted stock units was $0.6 million and $0.5 million for the year ended December 31, 2019 and 2018, respectively. As of December 31, 2019, the unrecognized stock-based compensation expense related to performance based restricted stock units was $0.9 million. The performance based restricted stock unit compensation was reduced by $0.7 million for the year ended December 31, 2019 due to a change in vesting criteria from probable to improbable for certain performance based awards. The Company will continue to review this performance award criteria and recognize compensation costs as it relates to the probability of vesting.

A performance unit may be comprised of either a performance based award or a market-based award. Performance based awards vest from the grant date through the remaining service period, and the fair value is the market price of one common share on the grant date. Evaluation of the expected vesting period is reviewed quarterly. Market-based awards vest upon the achievement of the market-based performance goal, provided the continued employment of the Company's employee. The fair value of each market-based restricted stock unit was determined through the use of the Monte Carlo simulation method. Over the performance period, the number of shares expected to be issued is adjusted upward or downward based upon probability of achievement of performance targets. The ultimate number of shares issued and the related compensation cost recognized is based on a comparison of the final performance metrics to the specified targets.

In accordance with ASC 718, *Share-Based Payments,* the market-based restricted stock units were assigned a fair value of $4.07 per share on the date of grant using the Monte Carlo simulation model. The following assumptions were used in the model in fiscal year 2018:

Expected stock price volatility	70.0%
Risk-free interest rate	2.9% - 3.1%
Dividend yield rate	—
Term (years)	10.0

Service Based Stock Options

The fair value of the service based stock options granted for the years ended December 31, 2019 and 2018 were based on the following assumptions:

	December 31,	
	2019	**2018**
Exercise price	$1.91 - $6.55	$3.17 - $5.75
Expected stock price volatility	67.5% - 70.3%	67.5% - 69.9%
Risk-free interest rate	1.4% - 2.6%	2.7% - 3.2%
Term (years)	3.38 - 6.5	5.0 - 6.5

A summary of the Company's service based stock option activity for the years ended December 31, 2019 and 2018 is as follows:

	Shares Underlying Options	**Weighted Average Exercise Price**	**Weighted Average Remaining Contractual Term**	**Aggregate Intrinsic Value**
Outstanding at January 1, 2018	6,906,001	$ 7.92	5.1	$ 976,355
Granted	1,447,479	$ 4.55	9.3	
Exercised	(267,500)	$ 3.09	—	
Forfeited	(229,500)	$ 6.59	—	
Outstanding at December 31, 2018	7,856,480	$ 7.50	5.2	$ —
Granted	1,103,938	$ 3.37	9.0	107,150
Exercised	(30,000)	$ 4.93	—	
Forfeited	(720,394)	$ (6.24)	—	
Outstanding at December 31, 2019	8,210,024	$ 7.06	5.1	$ 107,150
Exercisable at December 31, 2019	6,481,095	$ 7.97	4.1	$ —

The aggregate intrinsic value in the table above is calculated as the difference between the closing price of our common stock and the exercise price of the stock options that had strike prices below the closing price.

During the year ended December 31, 2018, the Company accelerated the vesting of 258,334 and 71,667 unvested stock options of the former Chief Executive Officer ("CEO") and the Chief Financial Officer ("CFO") in accordance with the terms of

the Settlement Agreement (defined in Note 15). As a result of this acceleration of stock options, the Company recorded additional stock-based compensation of approximately $162,000.

During the year ended December 31, 2019 and 2018, the service based stock options granted consisted of 1,103,938 and 1,447,479 options granted to employees, respectively. As of December 31, 2019, 6,481,095 vested options were exercisable at a weighted average price of 7.97 per share and 1,728,929 unvested options were exercisable at a weighted average price of 3.66 per share.

During the year ended December 31, 2019 and 2018, stock-based compensation expense of $2.3 million and $1.6 million was recognized, respectively. As of December 31, 2019, total stock-based compensation expense related to unvested options not yet recognized totaled approximately $2.2 million.

Performance Based Stock Options

A summary of the performance based stock options granted for the year ended December 31, 2019, is as follows:

	Number of Shares	Weighted Average Exercise Price
Outstanding at December 31, 2018	388,125	$ 4.70
Outstanding at December 31, 2019	388,125	$ 4.70
Exercisable at December 31, 2019	—	$ —

Stock-based compensation expense recognized for performance based stock options was $0.4 million and $0.2 million for the year ended December 31, 2019 and 2018. As of December 31, 2019, the unrecognized stock-based compensation expense related to performance based stock options was $0.5 million.

A performance option may be comprised of either a performance based award or a market-based award. Performance based awards start vesting on the grant date through the probability date of the measured performance, and the fair value is the market price of one common share on the grant date. Evaluation of the expected vesting period is reviewed quarterly. Market-based awards vest upon the achievement of the market-based performance goal, provided the continued employment of the Company's employee. The fair value of each market-based stock option was determined through the use of the Monte Carlo simulation method. Over the performance period, the number of shares expected to be issued is adjusted upward or downward based upon probability of achievement of performance targets. The ultimate number of shares issued and the related compensation cost recognized is based on a comparison of the final performance metrics to the specified targets.

In accordance with ASC 718, *Share-Based Payments,* the market-based stock options were assigned an average fair value of $2.71 per share on the date of grant using the Monte Carlo simulation model. The following assumptions were used in the model in fiscal year 2018:

Expected stock price volatility	70.0%
Risk-free interest rate	2.9%
Dividend yield rate	—
Term (years)	10.0

Note 14. Related Party Transactions

Product License Agreements

The Company is a party to a Licensing Agreement between the Company and Charak, LLC ("Charak") dated January 7, 2002 (the "2002 Agreement") that grants the Company exclusive worldwide rights to certain patents and information related to our Triferic® product. On October 7, 2018, the Company entered into a Master Services and IP Agreement (the "Charak MSA") with Charak and Dr. Ajay Gupta, who serves as Executive Vice President and Chief Scientific Officer of the Company. Pursuant to the 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 $1.0 million 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 Company recorded $1.1 million as Research and Development Expense - License Acquired (Related Party) for the twelve months ended December 31, 2018. As of December 31, 2019, the Company paid all four of the quarterly installments totaling $1.0 million and accrued $0.1 million for the reimbursement of certain legal expenses. As of December 31, 2019 and 2018, the Company accrued $0.1 million and $0.9 million, respectively, as a related party payable on the condensed consolidated balance sheet.

Pursuant to the Charak MSA, the aforementioned parties entered into an Amendment, dated as of October 7, 2018 (the "Charak Amendment"), to 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 be no 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 IV 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 not 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 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 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 not 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 transaction was accounted for as an asset acquisition pursuant to ASU 2017-1, *Business Combinations (Topic 805), Clarifying the Definition of a Business,* as the majority of the fair value of the assets acquired was concentrated in a group of similar assets, and the acquired assets did not have outputs or employees. The assets acquired under the MSA include a license of SFP. Because SFP has not yet received regulatory approval, the $1.1 million purchase price paid and accrued to date for these assets has been expensed in the Company's statement of operations for the year ended December 31, 2018. In addition, the potential milestone payments are not yet considered probable, and no milestone payments have been accrued at December 31, 2019.

Director Compensation

In 2018, the Company compensated non-employee directors with a cash retainer and a stock option grant, which was approved at the 2018 Annual Meeting of Shareholders in conjunction with the approval of the Company's 2018 Long Term Incentive Plan. Following the removal of the Company's then Chief Executive Officer and Chief Financial Officer in May 2018, independent directors Lisa Colleran, John Cooper and Benjamin Wolin were appointed to a special committee of the Board, which committee was delegated the responsibility to provide Board-level oversight of management on a more frequent basis until the appointment of a new Chief Executive Officer and Chief Financial Officer in the third and fourth quarters of 2018, as well as to provide Board-level oversight over the Company's legal matters during this time. Subsequent to the appointment of this committee, the Compensation Committee of the Board recommended, and the Board approved, additional aggregate cash compensation of

$330,000 payable to the directors who served on this committee in light of the substantial investment of additional time required in this role during the Company's transition in 2018.

In 2019, the Company compensated non-employee directors with a cash retainer, which was approved by the Board of Directors, to serve on a special Advisory Committee of the Board, which committee was delegated to provide Board-level oversight of senior management and not have any management authority within the Company. Independent directors Lisa Colleran and John Cooper were appointed to the Advisory Committee. The aggregate compensation paid to the members of the advisory Committee for the year ended December 31, 2019 was $202,500.

Note 15. Commitments and Contingencies

Leases

We lease our production facilities and administrative offices as well as certain equipment used in our operations including leases on transportation equipment used in the delivery of our products. The lease terms range from monthly to seven years. We occupy a 51,000 square foot facility and a 17,500 square foot facility in Wixom, Michigan under a lease expiring in August 2021. We also occupy 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 February 2023. 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.

The following summarizes quantitative information about the Company's operating leases:

	For the year ended December 31, 2019
Operating leases	
Operating lease cost	$ 2,076,037
Variable lease cost	317,788
Operating lease expense	2,393,825
Short-term lease rent expense	16,626
Total rent expense	$ 2,410,451
Other information	
Operating cash flows from operating leases	$ 2,014,548
Right of use assets exchanged for operating lease liabilities	$ 5,077,068
Weighted-average remaining lease term - operating leases	1.9
Weighted-average discount rate - operating leases	6.8%

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

Year ending December 31, 2020	$ 1,623,260
Year ending December 31, 2021	1,044,798
Year ending December 31, 2022	587,189
Year ending December 31, 2023	237,410
Year ending December 31, 2024	97,423
Total	3,590,080
Less present value discount	(316,060)
Operating lease liabilities.	$ 3,274,020

Insurance

We evaluate various kinds of risk that we are exposed to in our business. In our evaluation of risk, we evaluate options and alternatives to mitigating such risks. For certain insurable risks, we may acquire insurance policies to protect against potential losses or to partially insure against certain risks. For our subsidiary, Rockwell Transportation, Inc., we maintain a partially self-

insured workers' compensation policy. Under the policy, our self-insurance retention is $350,000 per occurrence and $663,282 in aggregate coverage for the policy year ending July 1, 2020. The total amount at December 31, 2019 by which retention limits exceed the claims paid and accrued is approximately $662,000 for the policy year ending July 1, 2020. Estimated loss and additional future claims of approximately $195,000 have been reserved and accrued for the year ended December 31, 2019.

As of December 31, 2019, approximately $0.3 million was held in cash collateral and escrow by the insurance carrier for workers' compensation insurance. At December 31, 2019, amounts held in cash collateral and escrow are included in prepaid expenses and other non-current assets in the consolidated financial statements.

Purchase Obligations

We have contracts for anticipated future obligations through December 31, 2020 of approximately $24.9 million, which include $23.7 million for concentrate manufacturing and $1.2 million in ancillary supplies.

Demand Notice

In February 2020, the Company received a letter from a supplier relating to a supply agreement entered into in 2015 between the Company and the supplier. The supplier alleged the Company did not meet certain annual minimums under the supply agreement, and has requested $3.0 million in penalties, plus payment of the cost for certain raw materials. Based upon current information, the Company believes it has several defenses to the supplier's claims. No lawsuit has been filed. The Company intends cooperate with the supplier in an effort to amicably resolve its claim. If a resolution cannot be concluded; however, the Company intends to vigorously defend itself from the supplier's allegations.

Litigation

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, and 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 in May 2018, 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 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 313,600 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 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.

On August 7, 2019, all parties to the class action entered into a settlement of the consolidated class action. Pursuant to the terms and conditions of the settlement agreement, the Company will pay the Plaintiffs $3.7 million (the "Settlement Amount") in exchange for a full release of all liability as to all defendants. Of the Settlement Amount, the Company will be contributing approximately $0.4 million, which represents the remaining retention amount under the Company's director and officer liability insurance policy. The remainder of the settlement amount will be funded by the Company's director and officer insurance policy. The settlement was approved by the court on February 26, 2020.

Shareholder Derivative Actions

Plaintiff Bill Le Clair filed a Verified Stockholder Derivative Complaint on April 23, 2019 in Case No. 1:19-cv-02373, and Plaintiff John Post filed a Verified Stockholder Derivative Complaint on May 10, 2019 in Case No. 1:19-cv-02774 (the "Derivative Complaints") in the United States District Court in the Eastern District of New York, purportedly on behalf of the Company (as nominal defendant) and against certain of the Company's current and former directors (the "Individual Defendants"). The Derivative Complaints assert causes of actions against the Individual Defendants for breach of fiduciary duty, waste of corporate assets, and unjust enrichment. The Derivative Complaints allege the Individual Defendants breached duties by, among other things, permitting alleged misstatements to be made in public filings regarding the status of separate reimbursement for Triferic from CMS, the adequacy of the Company's reserves and internal controls. The Derivative Complaints demand a jury trial, seeking monetary damages, corporate governance and internal procedure reform, injunctive relief on the Individual Directors' trading activities, restitution, and attorneys' fees. The cases have been consolidated and the parties are in advanced settlement discussions. If a settlement is not reached, the Defendants anticipate filing motions to dismiss.

The Company has tendered the above shareholder derivative actions 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 will be exhausted upon payment of the Company's share of the Settlement Amount from the settlement of the class action described above.

The Company also has received requests from stockholders to investigate issues relating in part to allegations raised in the securities and derivative lawsuits. The Audit Committee of the Board of Directors engaged independent counsel to investigate these issues. The investigation concluded, among other things that there was no merit to the claims raised in the stockholder requests and the investigation has been concluded.

Note 16. Settlement Agreements

On August 7, 2018, the Company entered into a confidential settlement agreement and mutual release (the "Settlement Agreement") with its former CEO, former CFO and a former and then current director. For more details see Note 14 in Form 10-K filed on March 18, 2019. The Company accrued approximately $1.5 million related to this Settlement Agreement and as of December 31, 2018, the Company has paid $1.1 million. The Company is also entitled to a partial reimbursement for this accrual from the Company's insurance company of approximately $0.5 million which was collected in October 2018. This resulted in a net settlement expense of approximately $1.0 million for the year ended December 31, 2018.

On August 7, 2019, the Company entered into a settlement agreement relating to the class action lawsuits. This resulted in a settlement expense of approximately $0.4 million for the year ended December 31, 2019. See Note 15 above for further details. The settlement was approved by the court on February 26, 2020.

Note 17. Income Taxes

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

	2019	2018
Tax Expense (Benefit) Computed at 22.79 % and 22.79% of Pretax Income (Loss)	$ (7,780,323)	$ (7,299,026)
Changes in Tax Laws	—	—
Foreign Income Tax Expense	—	—
Effect of Change in Valuation Allowance	7,780,323	7,299,026
Total Income Tax Expense	$ —	$ —

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

	December 31,	
	2019	2018
Deferred tax assets:		
Net Operating Loss Carryforward	$ 52,935,000	$ 45,055,000
Stock Based Compensation	7,514,000	6,405,000
Deferred Revenue	2,752,000	3,266,000
General Business Credit	6,872,000	6,872,000
Accrued Expenses	280,000	426,000
Inventories	866,000	1,685,000
Book over Tax Depreciation	18,000	13,000
Other Deferred Tax Assets	22,000	—
Total Deferred Tax Assets	71,259,000	63,722,000
Deferred Tax Liabilities:		
Goodwill & Intangible Assets	136,000	122,000
Prepaid Expenses	332,000	187,000
Total Deferred Tax Liabilities	468,000	309,000
Subtotal	70,791,000	63,413,000
Valuation Allowance	(70,791,000)	(63,413,000)
Net Deferred Tax Asset	$ —	$ —

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

Deferred tax assets result primarily from net operating loss carryforwards. For tax purposes, we have net operating loss carryforwards of approximately $232,300,000, of which $169,000,000 that expire between 2020 and 2037.

In assessing the potential for realization of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will be realized upon the generation of future taxable income during the periods

in which those temporary differences become deductible. We recognized no income tax expense or benefit for the years ended December 31, 2019, and 2018. We expect to incur operating losses until our drug products are marketed and generating sufficient profits to offset our operating expenses. Due to our history of recurring net losses, management has placed a full valuation allowance against the net deferred tax assets as of December 31, 2019 and 2018. The portion of the valuation allowance resulting from excess tax benefits on share based compensation that would be credited directly to contributed capital if recognized in subsequent periods is 3.8 million.

We account for our uncertain tax positions in accordance with ASC 740-10, *Income Taxes* and the amount of unrecognized tax benefits related to tax positions is not significant at December 31, 2019 and 2018. We have not been under tax examination in any jurisdiction for the years ended December 31, 2019 and 2018.

Note 18. Subsequent Events

License and Supply Agreement

On January 14, 2020, the Company entered into license and supply agreements with a wholly-owned subsidiary of Sun Pharmaceutical Industries Ltd. (together, "Sun Pharma"), for the rights to commercialize Dialysate Triferic (ferric pyrophosphate citrate) in India. Under the terms of the agreements, Sun Pharma will be the exclusive development and commercialization partner for Dialysate Triferic in India and the Company will supply the product to Sun Pharma. In consideration for the license, the Company will receive an upfront fee, and will be eligible for milestone payments and royalties on net sales. A Joint Alliance Committee, comprised of members from the Company and Sun Pharma, will guide the development and execution for Dialysate Triferic in India. Sun Pharma will be responsible for all clinical, regulatory and commercialization activities.

Public Offering

On February 4, 2020, the Company entered into an underwriting agreement (the "Underwriting Agreement") with Cantor Fitzgerald & Co., as underwriter (the "Underwriter"), pursuant to which the Company (i) agreed to issue and sell an aggregate of 3,191,489 shares of its common stock (the "Shares") to the Underwriter and (ii) granted the Underwriter an over-allotment option for 30 days to purchase up to an additional 478,723 shares that may be sold upon the exercise of such option by the Underwriter (the "Offering"). The Shares were purchased by the Underwriter from the Company at a price of $2.22 per share.

The Offering was made pursuant to the Company's effective Registration Statement on Form S-3 (File No. 333-227363), which was previously filed with the SEC under the Securities Act. The Offering closed on February 6, 2020. On February 19, 2020, the Underwriter exercised its over-allotment option in full and an additional 478,723 shares were sold to the underwriter on February 21, 2020. The Company raised a total of $8.0 million, net of an estimated issuance costs of $0.2 million, relating to the sale of the common stock.

Loan and Security Agreement

On March 16, 2020, Rockwell Medical, Inc. and Rockwell Transportation, Inc., as Borrowers, entered into a Loan and Security Agreement (the "Loan Agreement") with Innovatus Life Sciences Lending Fund I, LP, as collateral agent and the lenders party thereto to obtain term loans in an amount up to $35 million. $22.5 million, under the Loan Agreement was drawn on the date of closing, and the remaining $12.5 million will be available for subsequent draws based on our achievement of certain milestones. Net draw down proceeds was $21 million with estimated closing costs of $1.5 million. Interest on the loans will accrue either in cash or a combination of cash and in kind interest, at our election. Cash interest will accrue at a rate equal to the greater of (i) Prime Rate and (ii) 4.75%, plus 4.00%, for an initial interest rate of 8.75% per annum. We have the option, under certain circumstances, to add 1.00% of such interest rate amount to the then outstanding principal balance in lieu of paying such amount in cash. The Company is entitled to make interest-only payments for thirty months, or up to thirty-six months if certain conditions are met. The Loan Agreement contains representations and warranties, affirmative and negative covenants, and events of default that are customary for credit facilities of this type. The term loans will mature on March 16, 2025.

Distribution Agreement

On March 16, 2020, we entered into the Second Amendment to the Exclusive Distribution Agreement with Baxter (the "Second Amendment"). Pursuant to the Second Amendment, the parties agreed to remove Baxter's consent right over transactions granting a security interest on the assets used to manufacture or commercialize our concentrates products, and amended certain other terms of the agreement related to manufacturing and failure to supply, reimbursement for certain transportation costs, and conditions for extension of the contract in 2024.

Exhibit 23.1

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the incorporation by reference in the Registration Statements of Rockwell Medical Inc. and Subsidiaries (the "Company") on Forms S-3 (Registration No.'s 333-228437, 333-227363, 333-135872, 333-148601, and 333-160710) and S-8 (Registration No.'s 333-227365, 333-66791, 333-126627, 333-135896, 333-146817, 333-176524, 333-153046, 333-160135, 333-169003, 333-182043, 333-189586, 333-196752, and 333-204653) of our report dated March 16, 2020 (which report includes an emphasis of a matter paragraph due to the Company's adoption of a new accounting standard on Topic 842 - Leases) with respect to our audits of the consolidated financial statements of Rockwell Medical Inc. and Subsidiaries as of December 31, 2019 and 2018, and for each of the two years in the period ended December 31, 2019, and our report dated March 16, 2020 with respect to our audit of the effectiveness of internal control over financial reporting of the Company as of December 31, 2019, which reports are included in this Annual Report on Form 10-K of Rockwell Medical Inc. and Subsidiaries for the year ended December 31, 2019. Our report on the effectiveness of internal control over financial reporting expressed an adverse opinion because of the existence of material weaknesses.

/s/ Marcum LLP
Marcum LLP
Chicago, IL
March 16, 2020

Exhibit 4.2

DESCRIPTION OF REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

The following description of our capital stock is intended as a summary only and therefore is not a complete description of our capital stock. This description is based upon, and is qualified by reference to, our certificate of incorporation, our bylaws and applicable provisions of Delaware corporate law. You should read our certificate of incorporation and bylaws, which are filed as exhibits to our Annual Report on Form 10-K, to which this exhibit is also appended.

Our authorized capital stock consists of 170,000,000 shares of common stock and 2,000,000 shares of preferred stock.

Common Stock

Holders of our common stock are entitled to one vote for each share held of record on all matters on which stockholders are generally entitled to vote. The majority of votes cast by the holders of shares entitled to vote on an action at a meeting at which a quorum is present is generally required to take stockholder action, unless a greater vote is required by law. Directors are elected by a plurality of the votes cast at any election and there is no cumulative voting of shares.

Holders of our common stock are entitled to receive dividends when, as and if declared by our board of directors out of funds legally available for the payment of dividends. Upon the liquidation, dissolution or winding up of the company, holders of common stock are entitled to share pro rata in any assets available for distribution to stockholders after payment of all obligations of the company and after provision has been made with respect to each class of stock, if any, having preference over the common stock. Holders of common stock do not have cumulative voting rights or preemptive, subscription or conversion rights and shares of common stock are not redeemable. The shares of common stock presently outstanding are duly authorized, validly issued, fully paid and non-assessable. There will be a prospectus supplement relating to any offering of common stock offered by this prospectus.

The directors of the company serve staggered three-year terms. Directors may not be removed without cause. The certificate of incorporation provides that the Board of Directors shall consist of such number of directors as shall be determined from time to time solely by resolution adopted by the affirmative vote of a majority of the voting power of the total number of directors then authorized.

Our certificate of incorporation and bylaws contain provisions that could have the effect of delaying, deterring or preventing a merger, tender offer or other takeover attempt. Our certificate of incorporation authorize the Board of Directors to issue up to 170 million shares of common stock (less shares already outstanding or reserved for issuance) and up to two million shares of preferred stock without stockholder approval. In addition, our certificate of incorporation provide that stockholder action without a meeting requires the unanimous consent of the stockholders, unless the applicable action has been approved by the Board of Directors prior to execution of the stockholder consent. Our bylaws permit incumbent directors to fill any vacancies on the Board of Directors, however occurring, whether by an increase in the number of directors, death, resignation, retirement, disqualification, removal from office or otherwise, unless filled by proper action of the stockholders. Furthermore, our bylaws require stockholders to give advance notice of director nominations and proposals to be presented at meetings of stockholders.

These provisions may delay stockholder actions with respect to business combinations and the election of new members to our Board of Directors. As such, the provisions could discourage open market purchases of our common stock because a stockholder who desires to participate in a business combination or elect a new director may consider them disadvantageous.

Subject to certain exceptions, Section 203 of the Delaware General Corporation Law prevents a publicly-held Delaware corporation from engaging in a "business combination" with any "interested stockholder" for three years following the date that the person became an interested stockholder, unless the interested stockholder attained such status with the approval of our Board of Directors or unless the business combination is approved in a prescribed manner. A "business combination" includes, among other things, a merger or consolidation involving us and the "interested stockholder" and the sale of more than 10% of our assets. In general, an "interested stockholder" is any entity or person beneficially owning 15% or more of our outstanding voting stock and any entity or person affiliated with or controlling or controlled by such entity or person. We are currently not subject to Section 203 but may opt in at any time by amending our certificate of incorporation.

Listing

Our common stock is listed and traded on The Nasdaq Global Market under the symbol "RMTI."

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer and Trust Company.

Preferred Stock

Our Board of Directors currently has the authority, without further action by our stockholders, to issue up to 2,000,000 shares of preferred stock, $0.001 par value per share, in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of common stock.

The issuance of our preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon our liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control of our company or other corporate action. No shares of preferred stock are currently outstanding.

Exhibit 31.1

SECTION 302 CERTIFICATION

I, Stuart Paul, certify that:

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

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

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

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

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

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: March 16, 2020

/s/ Stuart Paul

Stuart Paul

Chief Executive Officer

(Principal Executive Officer)

Exhibit 31.2

SECTION 302 CERTIFICATION

I, Angus Smith, certify that:

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

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

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

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

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

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: March 16, 2020

/s/ Angus Smith

Angus Smith
Chief Financial Officer
(Principal Financial Officer)

EXHIBIT 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
AND CHIEF FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Rockwell Medical, Inc. (the "Company") for the year ended December 31, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Periodic Report"), each of the undersigned officers of the Company hereby certifies, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes Oxley Act of 2002, that to the best of his knowledge:

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

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

Dated: March 16, 2020

/s/ Stuart Paul
Stuart Paul
Chief Executive Officer
(Principal Executive Officer)

Dated: March 16, 2020

/s/ Angus Smith
Angus Smith
Chief Financial Officer
(Principal Financial Officer)

The foregoing certification is being furnished solely to accompany the Periodic Report pursuant to 18 U.S.C. §1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Note: A signed original of this written statement required by §906 has been provided to Rockwell Medical, Inc. and will be retained by Rockwell Medical, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

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ROCKWELL MEDICAL, INC.

Corporate Information

Annual Meeting

The Annual Meeting of the Stockholders will be held:

Monday May 18, 2020
At 10:00 am ET
Virtual Stockholder Meeting
www.virtualshareholdermeeting.com/RMTI2020

Form 10-K & Annual Report

A copy of this Annual Report to Stockholders or the Form 10-K filed with the Securities and Exchange Commission for the year ended December 31, 2019 is available upon written request to:

Investor Relations
Rockwell Medical, Inc.
411 Hackensack Avenue, Suite 501
Hackensack, New Jersey 07601

To view or request an annual report on-line go to: www.rockwellmed.com

Reports and exhibits are available on-line through our website at www.rockwellmed.com or through the SEC website, http://www.sec.gov/edgar/searchedgar/companysearch.html

Transfer Agent and Registrar

American Stock Transfer and Trust Co.
59 Maiden Lane
New York, New York 10038
Shareholder Services (800) 937-5449

Stockholder Information

Shares of common stock are traded on the Nasdaq Global Market under the symbol "RMTI".

2019 ANNUAL REPORT

www.rockwellmed.com