2020 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, 2020

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.)
30142 S. Wixom Road, Wixom, Michigan	**48393**
(Address of principal executive offices)	(Zip Code)

(248) 960-9009

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class:	**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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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, 2020 (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 $111,970,531.

Number of shares outstanding of the registrant's Common Stock, par value $0.0001, as of March 29, 2021: 93,585,780 shares.

Documents Incorporated by Reference

Portions of the Registrant's definitive Proxy Statement pertaining to the 2021 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, 2020, 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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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 current expectations and possible or assumed future results of our operations. When we use words such as "may," "might," "will," "should," "believe," "expect," "anticipate," "estimate," "continue," "could," "plan," "potential," "predict", "forecast", "projected," "intend" or similar expressions, or make statements regarding our intent, belief, or current expectations, we are making forward-looking statements. Our forward looking statements also include, without limitation, statements about our liquidity and capital resources; our plans and ability to successfully commercialize our products; our ability to successfully launch U.S. Food and Drug Administration ("FDA")-approved Triferic AVNU; our ability to develop Ferric Pyrophosphate Citrate ("FPC") for other indications; our ability to successfully execute on our business strategy and development of new indications; and statements regarding our anticipated future financial condition, operating results, cash flows and business plans. 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. Such business, economic and competitive uncertainties include:

- the effects of the COVID-19 pandemic on patients, our customers and distributors, and our business, including manufacturing operations and suppliers, as well as the actions by governments, businesses and individuals in response to the pandemic;
- 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 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 factors identified in this Annual Report on Form 10-K under the headings "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and in other filings we periodically make with the SEC.

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.

Readers 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. We do not undertake, and expressly disclaim, any intention 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.

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.

Unless otherwise indicated in this Annual Report on Form 10-K "we," "our," "us," the "the Company," "Rockwell," "Rockwell Medical" and other similar terms refer to Rockwell Medical, Inc., together with its consolidated subsidiaries. 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 Securities and Exchange Commission ("SEC"). In particular, please read our definitive proxy statement, which will be filed with the SEC in connection with our 2021 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.

OVERVIEW OF BUSINESS

Business

Rockwell Medical is a commercial-stage, biopharmaceutical company developing and commercializing our next-generation parenteral iron technology platform, Ferric Pyrophosphate Citrate ("FPC"), which we believe has the potential to lead to transformative treatments for iron deficiency in multiple disease states, that we believe could reduce healthcare costs and improve patients' lives. We are also one of the two major suppliers of life-saving hemodialysis concentrate products to kidney dialysis clinics in the United States.

We have two novel, FDA approved therapies, Triferic and Triferic AVNU, which are the first two products developed from our FPC platform. We are marketing both products to kidney dialysis centers for their patients receiving dialysis. In 2021, we intend to advance our FPC platform strategy by starting a Phase II trial for the treatment of iron deficiency anemia in patients outside of dialysis, who are receiving intravenous ("IV") medications in the home infusion setting. The trend toward providing medical care, including the delivery of medicines, at home make the home infusion market a rapidly growing area of healthcare. We believe that the home infusion setting is a natural path for expansion of our platform as many of the patients suffer from diseases that are associated with iron deficiency and anemia. In our R&D pipeline, we are also investigating FPC's impact in the treatment of hospitalized patients with acute heart failure, with the potential to begin another Phase II program in these patients in 2022.

We are the second largest supplier of hemodialysis concentrates in the United States, with a reputation for excellent service, quality, and reliability. We believe that this reputation, which is based on over 25 years of service to the kidney dialysis centers, combined with about $60 million in annual revenue, approximately 300 dedicated employees, expertise in manufacturing and logistics and the added expertise in pharmaceutical development and commercialization brought to the Company by recent additions to our management team, gives us a solid foundation on which to grow.

At Rockwell Medical, we are dedicated to replacing the currently inadequate standard of care for treatment of iron deficiency in acute and chronic disease by leveraging our proprietary FPC platform technology. Our proprietary drug platform, FPC, is a next-generation parenteral iron therapeutic. We believe our FPC platform has several advantages over other parenteral iron therapies. Importantly, it provides iron that is immediately available for critical body processes once it is administered. It has been demonstrated to be safe and well-tolerated, with a safety profile similar to placebo.

Iron deficiency can develop into a serious medical condition that is often overlooked and undertreated in several illnesses because it is hard to treat. It is a common comorbidity in many disease states, such as end-stage kidney disease, chronic kidney disease, acute heart failure, cancer and multiple chronic gastrointestinal conditions. Iron deficiency impacts patients' health in many ways, including anemia, organ dysfunction, slower recovery, diminished energy and reduced quality of life.

Strategy Evolution and Overview

Rockwell Medical has evolved its strategy over the past year to develop into a more medically-, scientifically- and data-driven company. We believe future clinical, regulatory and commercial success require the right people with the right

experience to navigate us to the right data. There has been an evolution of both our management and board, providing us with greater relevant experience. In particular, we have added board members and employees with significant medical and commercial experience in iron deficiency anemia and the dialysis sector, drug development and commercialization, small-cap public company finance and management and clinical nurse educator patient support. We believe these changes support an improved execution of our strategy to generate data that will support future commercial growth, fair reimbursement and regulatory approvals.

Our strategy is to accelerate Rockwell's growth by creating and developing pharmaceutical products based on our FPC technology for disease states where patients can benefit the most from an effective treatment for iron deficiency, while concurrently refining our dialysis business to drive incremental growth and efficiencies. We plan to leverage and build on the foundation provided by our current dialysis business serving kidney dialysis centers by developing a pipeline of additional potential drug therapies in multiple disease states. We've preliminarily identified three disease states where we believe FPC may have the biggest impact.

Dialysis Business: We are the second largest supplier, and one of the two major suppliers of hemodialysis concentrates in the United States. We manufacture, sell and deliver hemodialysis concentrates, which are used to maintain human life by removing toxins and balancing electrolytes in the dialysis patient's bloodstream. We have core capabilities in manufacturing hemodialysis concentrates in three facilities, totaling 159,000 square feet, located in Michigan, Texas and South Carolina. We also have core capabilities in the logistics of delivering these products to dialysis clinics throughout most of the United States.

Our first two branded products from our FPC platform, Triferic® (dialysate) and Triferic AVNU® (IV), are used to maintain hemoglobin in patients undergoing hemodialysis. We are building on our reputation and industry presence by commercializing then to medium and small dialysis organizations. We began commercializing Triferic and Triferic AVNU in the United States in the second half of 2019 and in early 2021, respectively. Our strategy for increasing Triferic adoption is to continue to generate data in clinics showing the benefits of Triferic in real world protocols. In addition, we expect to study Triferic use with the innovations that we believe have the potential to change future medical practices (e.g. introduction and adoption of HIF-PHIs as described below). We believe that positive data from these studies would better position Triferic for long-term growth. We are developing strategic alliance partners for development, regulatory approval and commercialization of Triferic outside of the United States.

Home Infusion Program: We are initiating a clinical trial program of FPC for the treatment of iron deficiency anemia in the home-infusion setting. Many patient groups requiring home infusion therapies suffer from chronic diseases that are associated with a high incidence of iron deficiency and anemia. Home infusion represents a large and rapidly-growing segment of healthcare where we believe FPC may have distinct advantages over currently available iron replacement therapy options.

Pipeline Development: We are investigating the use of our FPC platform for the treatment of hospitalized patients with acute heart failure. We believe that FPC may deliver rapidly bioavailable iron to the heart and improve cardiac energetics. This effect could help patients recover faster, resulting in shorter hospital stays and fewer 30-day re-admissions, which would be a meaningful reduction healthcare costs and human suffering.

General Information

We were incorporated in the state of Michigan in 1996, and re-domiciled to the state of Delaware in 2019. Our headquarters is located at 30142 Wixom Road, Wixom Michigan 48393. Our telephone number is (248) 960-9009 and our website is http://www.rockwellmed.com. The information contained on, or that can be accessed through, our website is not part of this Annual Report on Form 10-K. We have included our website in this Annual Report on Form 10-K solely as an inactive textual reference.

Triferic®, CitraPure®, RenalPure® and SteriLyte® are registered trademarks of Rockwell. This Annual Report on Form 10-K contains references to our trademarks and trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this Annual Report, including logos, artwork, and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other company.

STRATEGY

Our Growth Strategy

We plan to accelerate our growth by combining the solid foundation, strength and reputation of our dialysis business with the high-growth potential from therapeutics derived (or generated) from our FPC platform in multiple disease states where patients can benefit the most from an effective treatment for iron deficiency. In parallel with continually seeking to drive incremental growth and efficiencies in our dialysis business unit, our strategy is to accelerate the growth of our business in large, higher-margin markets by creating and developing pharmaceutical products based on our proprietary FPC technology that address iron deficiency in patients who are currently under-treated.

Dialysis Business:

We are one of the two major suppliers of hemodialysis concentrates in the United States. Over the past 25 years we have developed a core expertise in manufacturing and delivering hemodialysis concentrates. Because these concentrates are used to maintain human life by removing toxins and balancing electrolytes in the dialysis patient's bloodstream, we manufacture them under cGMP regulations as described below. Our concentrates are manufactured in three facilities, totaling 159,000 square feet, located in Michigan, Texas and South Carolina, from which we deliver these products to dialysis clinics throughout most of the United States. We utilize our own delivery fleet as well as third parties. We employ approximately 300 people in the concentrates unit of our dialysis business.

The "Rockwell Medical" name has earned a reputation for dependability, quality and service within our customer base. This reputation was further strengthened during the recent challenges presented, not only by the COVID-19 pandemic, but also by the multitude of recent natural disasters where our team has been challenged by hurricanes, flooding and freezing, while still meeting production demands.

Our dialysis business in concentrates and our growth opportunities with FPC technology are synergistic. We are leveraging our leadership position in the dialysis sector to commercialize our first two FPC-based products, Triferic and Triferic AVNU, which are indicated for the replacement of iron to maintain hemoglobin in adult patients with hemodialysis-dependent chronic kidney disease. We commercialize the Triferic products ourselves in the United States, and are partnering with established local pharmaceutical companies for the regulatory approval and commercialization outside of the United States.

Although we have an excellent reputation for dependability and service within the dialysis sector, with concentrates and Triferic, our growth opportunities for both in the US dialysis market are challenged by the consolidated ownership of dialysis clinics, a capitated reimbursement model and the demographics of the patient population. The two largest dialysis organizations treat approximately 73% of the patients in the United States. One manufactures its own concentrates and IV iron and we already supply concentrates to the other. Through our partnership with Baxter International, we currently supply concentrates to a significant percentage of the small and medium sized dialysis organizations. In a sector, such as kidney dialysis, with capitated reimbursement for the dialysis procedure and all included inputs, new product success depends on compelling data demonstrating improved patient outcomes and/or pharmacoeconomics versus the current standard of care in practice in the clinics. Once Medicare determined that Triferic and Triferic AVNU would be reimbursed under the fixed bundled rate, market adoption became more dependent on the generation of these data, which were not required for the drug's approval from the FDA.

Notwithstanding the growth limitations mentioned above, we have made progress and continue to be confident that Triferic has the potential to be the treatment of choice for the maintenance of hemoglobin in dialysis patients. Toward this end, we have increased our efforts in generating real world data in clinics with current protocols, which we believe will help with the adoption of Triferic and Triferic AVNU as these results are developed and disseminated over time. In addition, we believe the hemodialysis industry may experience a great deal of change over the next several years. We plan to take the steps necessary to generate the data necessary to potentially allow Triferic and Triferic AVNU to benefit from these new innovations, such as the potential approval of a class of drugs, known as hypoxia-inducible factor prolyl hydroxylase inhibitors ("HIF-PHIs"), as well as the new, solid-state dialysis equipment in development. We plan to study Triferic in combination with these potential new innovations as they become available.

A key element of our dialysis business strategy is to also improve the strength of our concentrates business by creating efficiencies and enhancing our manufacturing and transportation operations. We have launched projects to identify ways to improve the overall profitability of these core operations. Specifically, we are reviewing our entire supply chain to identify opportunities for improvement, prioritizing initiatives that will have the largest impact on long-term efficiency, profitability and growth.

Home Infusion:

Our accelerated growth strategy is to go beyond our foundational business in dialysis by leveraging the efficacy and safety data from Triferic. We are planning to develop an FPC-based therapeutic for iron deficiency to be given in the home infusion setting. The number of patients served by home infusion therapy has grown from approximately 800,000 in 2010 to over 3,000,000 in 2019. The home infusion setting is expected to continue this rapid expansion, which has been further supported in the COVID-19 environment. Many patient groups requiring home infusion therapies suffer from diseases that are associated with an incidence of iron deficiency and anemia. For example, it is estimated that 40%-55% of all home parenteral nutrition patients are iron deficient (see Market Opportunity below). We believe, based on our data with hemodialysis patients, FPC as a home infusion therapy for iron deficiency anemia may have distinct advantages over currently available iron replacement therapy options (see Platform Technology below).

Based on feedback received in March 2021 from the FDA, we plan on initiating a Phase 2 clinical study in home infusion patients with iron deficient anemia during the second half of 2021 to confirm the dose and duration of FPC treatment. We expect data from the trial in the second half of 2022 (see Clinical Pipeline below).

Pipeline Development

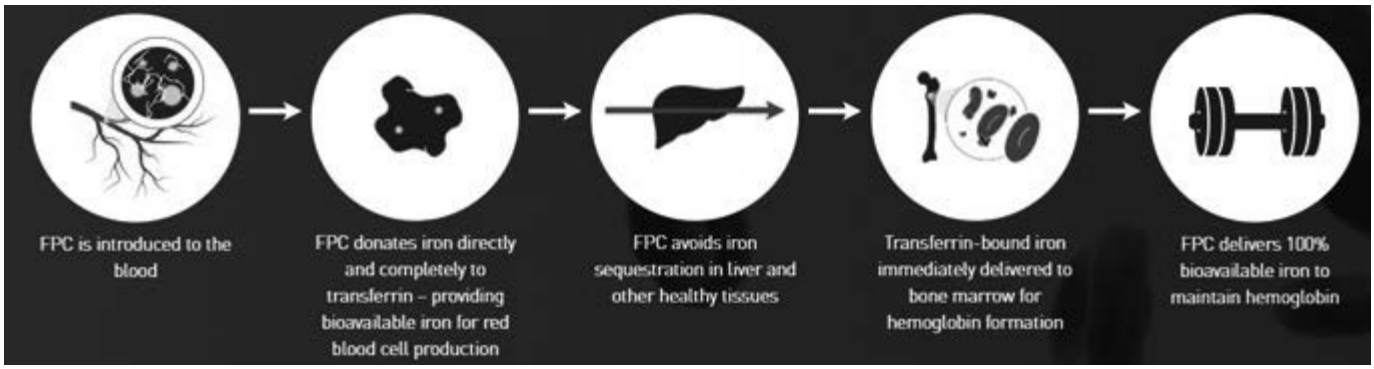
In our R&D pipeline, we are also exploring FPC's impact in the treatment of hospitalized heart failure patients. More than one million people in the United States are hospitalized each year for acute heart failure. Clinical improvement in heart failure has already been demonstrated with older first-generation forms of IV iron in clinical trials in the outpatient setting. We believe that FPC may deliver rapidly bioavailable iron to the heart and improve cardiac energetics during hospitalization. This effect could help patients recover faster resulting in shorter hospital stays and fewer 30-day re-admissions. If so, these outcomes would translate into a meaningful reduction in healthcare costs and human suffering. We expect to communicate with the FDA in 2021 regarding a development pathway for this indication.

We continue exploring other potential patient populations for application of our technology. We are considering disease states where patients can benefit the most from an effective treatment for iron deficiency, and where the development path, cost estimates and reimbursement are the most favorable.

Platform Technology - Ferric Pyrophosphate Citrate

Ferric Pyrophosphate Citrate ("FPC") is a next-generation parenteral iron that is an important advance in the treatment of iron deficiency anemia, with the potential to be developed for numerous indications. FPC is structurally and functionally different from traditional macromolecular IV iron, or parenteral iron carbohydrate complexes. It is unique in molecular structure and mode-of-action. All components of FPC are normal constituents in the blood. Importantly, FPC has already been shown to be efficacious in clinical trials and is well-tolerated with over one million doses administered to date. The first two formulations based upon the FPC platform received approval for the replacement of iron to maintain hemoglobin in adult patients with hemodialysis-dependent chronic kidney disease ("HDD-CKD"). Other formulations of our FPC platform, in other disease states, are currently being researched and developed.

FPC is a novel complex iron salt, developed to replace iron losses in patients with anemia in an entirely new way. This unique and differentiated molecule consists of an iron atom complexed to one pyrophosphate and two citrate anions. FPC is a form of protected iron in which citrate and pyrophosphate are tightly complexed to the iron. The molecule is water soluble, making the iron completely bioavailable, and has the ability to deliver iron directly and completely to transferrin, the body's iron transport protein. This transferrin-bound iron is immediately delivered to the bone marrow to be incorporated into hemoglobin, as well as to other tissues such as skeletal muscle and smooth muscle (e.g. the heart). As a result, this novel approach to iron management has the potential for application in the treatment of iron disorders and iron deficiency anemia in multiple disease states. This mechanism uses the body's own means to transport iron safely to tissues that need iron (e.g. red blood cells and muscle).



The structure of FPC minimizes the potential for the iron to be taken up into the body's storage cells, such as those present in the liver and other tissues, which is a problem with traditional macromolecular IV iron. Iron release from body storage cells can be slowed or blocked when inflammation is present. Because of its mechanism of action, FPC increases bioavailable iron unimpeded by inflammation without excessively increasing body iron stores or causing inflammation, iron toxicity, or oxidative stress.

FPC iron is delivered to the bone marrow regardless of other underlying conditions that might otherwise block the release of iron. Some of the challenges of managing iron in sick patients, including inflammation, hepcidin block, and functional iron deficiency, can be overcome with FPC due to its ability to provide immediately bioavailable iron.

Our first FPC-based product, Triferic, is used proactively in hemodialysis patients to maintain iron homeostasis, such that the amount of iron delivered to the patient and to the bone marrow for erythropoiesis closely approximates the amount lost during hemodialysis. FPC bypasses the hepcidin induced block caused by inflammation, of iron-release from the macrophages and liver (see "Our Triferic Portfolio" below). Consequently, tissue iron overload is avoided, unlike when traditional macromolecular IV iron are administered proactively. FPC delivers iron and maintains hemoglobin without increasing iron stores (ferritin) and thus addresses an unmet need in hemodialysis patients.

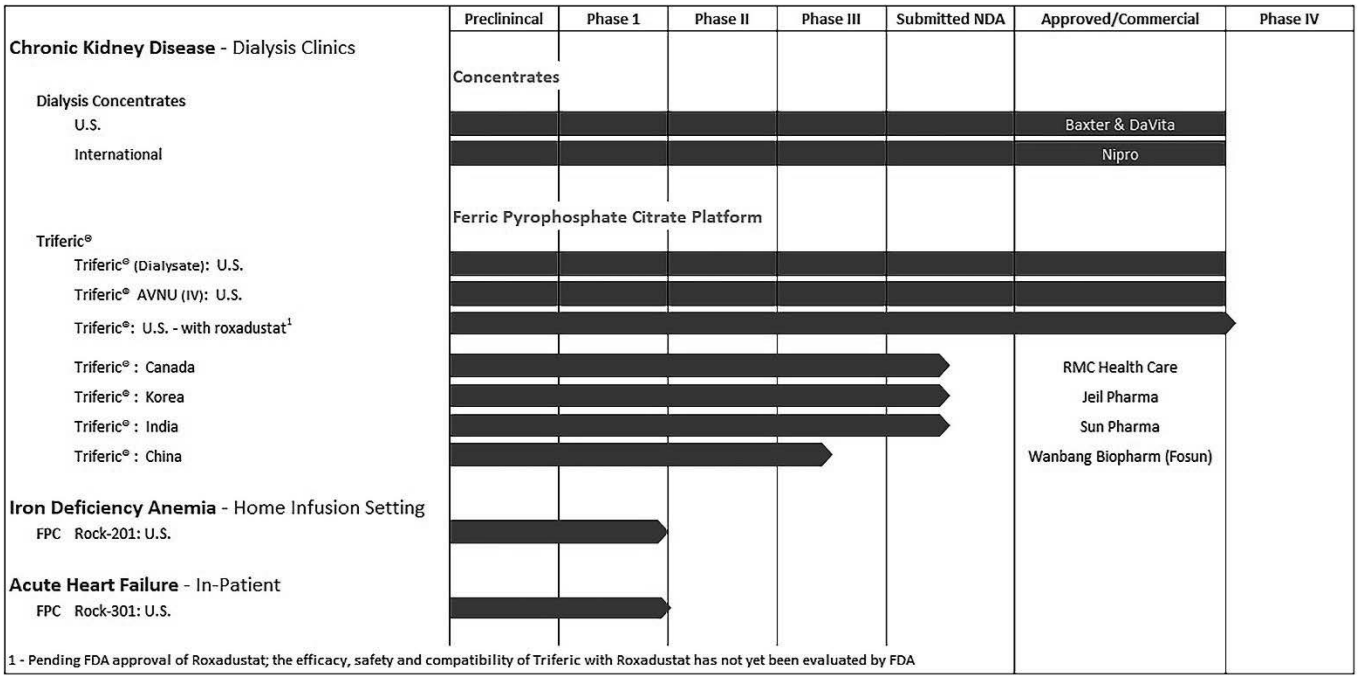
FPC has demonstrated an excellent safety profile. No reported instances of anaphylaxis or other serious adverse events have been received during more than 1.2 million doses administered. Triferic may be administered even to patients with history of allergic reactions to IV iron.

We are actively evaluating additional indications for potential development (see "Pipeline" below).

PRODUCTS

Pipeline

We currently commercialize Triferic, Triferic AVNU and our dialysis concentrates portfolio of products. We partner with Baxter Healthcare Corporation, a subsidiary of Baxter International, Inc. ("Baxter"), for commercialization of our concentrates products in the United States and certain other countries. We partner with Nipro Medical Corporation for our concentrate products in certain countries not included in our Baxter agreement, as described below. Our clinical development programs are all based on FPC, our proprietary platform technology. We are directly executing on clinical development programs in the United States, while our international development efforts in dialysis for local regulatory approval are conducted by our partners.



Our Dialysis Concentrate Products

We are an established leader in manufacturing and delivering high-quality hemodialysis concentrates and dialysates, along with certain ancillary products, 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 End-Stage Kidney Disease ("ESKD"). 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 2020, we estimate that we supplied approximately 27% of the United States domestic market with dialysis concentrates, with the majority of our sales are 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.

All of our concentrate products are manufactured according to Association for the Advancement of Medical Instrumentation guidelines and the FDA's Current Good Manufacturing Practice ("cGMP"). 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, 6% bleach for disinfection, citric and descale, filtration salts and other supplies used by hemodialysis providers.

Our Triferic Portfolio

Triferic - The First and Only FDA-Approved Therapy to Replace Iron and Maintain Hemoglobin.

Triferic (dialysate) and Triferic AVNU (IV) are currently the only FDA-approved therapies indicated to replace iron and maintain hemoglobin in adult hemodialysis patients. These were our first products based on our FPC platform technology. Triferic (dialysate) in a liquid form was approved in 2015. In 2016, the powder version of Triferic (dialysate) was also approved. These two formulations provide a convenient means to administer Triferic (dialysate) in a clinical setting. Triferic AVNU, approved in 2020, has the same indication for use as Triferic (dialysate), but it is formulated for delivery as an IV infusion.

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 the vascular access. This blood loss, when combined with repeated blood draws, increased blood loss from the gastrointestinal ("GI") tract and stimulation of erythropoiesis by use of erythropoiesis stimulating agents ("ESAs"), frequently results in iron deficiency in hemodialysis patients. Hemodialysis-related blood loss averages about 1g to 1.5g 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 ESKD patients. Triferic's unique mode-of-action (see "Platform Technology" above) distinguishes it from traditional macromolecular IV iron because Triferic donates iron to transferrin, immediately, and completely, as soon as it enters the blood, providing immediately bioavailable iron to the body. The iron bound to transferrin is transported to the bone marrow to facility the body's manufacture of hemoglobin. Triferic delivers approximately 5 mg to 7 mg of iron to the bone marrow with every hemodialysis treatment and maintains hemoglobin without increasing iron stores (ferritin).

Triferic (dialysate)

Triferic (dialysate) and Triferic AVNU are currently the only FDA-approved therapy indicated to replace iron to maintain hemoglobin in adult hemodialysis patients. We believe that Triferic, due to its unique mechanism of action, facilitates both 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. 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.

The first presentation of Triferic (dialysate) is a liquid, single-patient dose, which was approved by the FDA in 2015. The second presentation is a powder packet, multiple-use formulation of Triferic (dialysate), which was approved by the FDA in 2016. We built a commercial organization for our Triferic products and launched both Triferic products in the United States in May 2019.

CRUISE Studies

In 2013, we successfully completed two pivotal Phase 3 efficacy trials, called CRUISE-1 and CRUISE-2, for Triferic. The CRUISE studies were identical single-blind, placebo controlled, parallel group, multi-center studies comparing Triferic delivered via hemodialysis bicarbonate concentrate to a 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

withheld, and ESA doses were held constant. Both CRUISE studies successfully met their primary endpoint, demonstrating a statistically significant difference in hemoglobin concentrations between the placebo group and Triferic. 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.

PRIME Study

A supportive clinical trial, called the PRIME study, demonstrated that Triferic (dialysate) 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, overall patients treated with Triferic in this study used 51% less IV iron than those treated with the placebo.

Safety Study

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.

Reimbursement

Triferic (dialysate) received a reimbursement J-code on January 1, 2016 from the Centers for Medicare & Medicaid Services ("CMS"), providing that it would be reimbursed for administration to dialysis patients within the existing fixed-price "bundle" of payments that CMS provides to dialysis providers. In June 2018, the Company determined, based on feedback provided from CMS's Innovation Center ("CMMI"), that Triferic (dialysate) 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 Triferic (dialysate) with reimbursement within the bundle of payments to dialysis providers, while continuing to develop Triferic AVNU (IV). On April 26, 2019, we were notified of a preliminary recommendation by CMS to grant our powder packet formulation of Triferic (dialysate) a separate J-Code, which became effective on July 1, 2019.We commercially launched Triferic (dialysate) in May 2019.

Triferic AVNU (IV)

We also developed Triferic AVNU, an IV formulation of Triferic, for use by hemodialysis patients in the United States as well as international markets. Triferic AVNU 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 Triferic AVNU. As a result, rather than conducting additional safety and efficacy trials, the FDA agreed that our NDA would be acceptable, if we were able to show equivalence between Triferic AVNU and Triferic (dialysate) by comparing pharmacokinetic ("PK") parameters of total iron and transferrin-bound iron of Triferic AVNU to Triferic (dialysate). The formal equivalence study was completed during 2018, and Triferic AVNU met bioequivalence criteria compared with Triferic (dialysate). Triferic AVNU was approved by the FDA on March 27, 2020. The approval and commercial availability of Triferic AVNU is an important advance for the portfolio given that Triferic AVNU can be administered to any hemodialysis patient regardless of the type of bicarbonate technology, or machine technology including hemodiafiltration, used. Use of Triferic (dialysate) is limited to clinics that use a central loop or liquid jugs to deliver bicarbonate. However, Triferic AVNU must be delivered at every dialysis session via slow IV infusion, over 3-4 hours, which may be logistically challenging for some clinics.

In November 2018, CMS issued interpretive guidance on the availability of Medicare reimbursement for certain products indicated to treat renal disease. Under this guidance, Triferic (dialysate) is ineligible for add-on reimbursement under the CMS Transitional Drug Add On Pricing Adjustment ("TDAPA") program. However, based on that guidance, we believed that Triferic AVNU would remain eligible for add-on reimbursement, so long as it was approved by the FDA on or after

January 1, 2020. In October 2019, CMS revised its guidance to significantly limit the eligibility of new products for TDAPA to only certain NDA types, as classified by the FDA. Based on the guidance issued by CMS in 2019, Triferic AVNU is not eligible for add-on reimbursement and will be reimbursed within the "bundle," as with Triferic (dialysate).

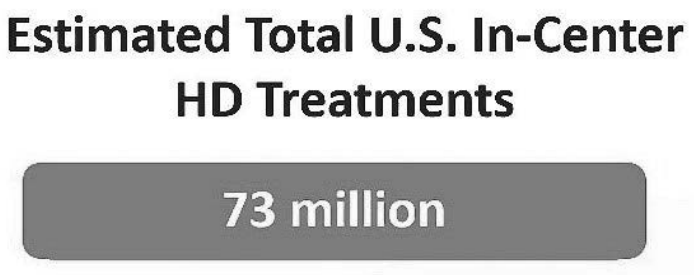
We are also continuing to research other presentations of, and delivery methodologies for, Triferic for potential application in ESKD patients within the dialysis sector in an effort to maximize the commercial potential of Triferic. Furthermore, we intend to initiate clinical studies that would assess Triferic with new prolyl hydroxylase inhibitors in the clinical setting (See Clinical Development and R&D below). Once a new prolyl hydroxylase inhibitor is available for use, we expect to initiate a study of Triferic to maintain hemoglobin levels.

MARKETING, SALES AND INTERNATIONAL

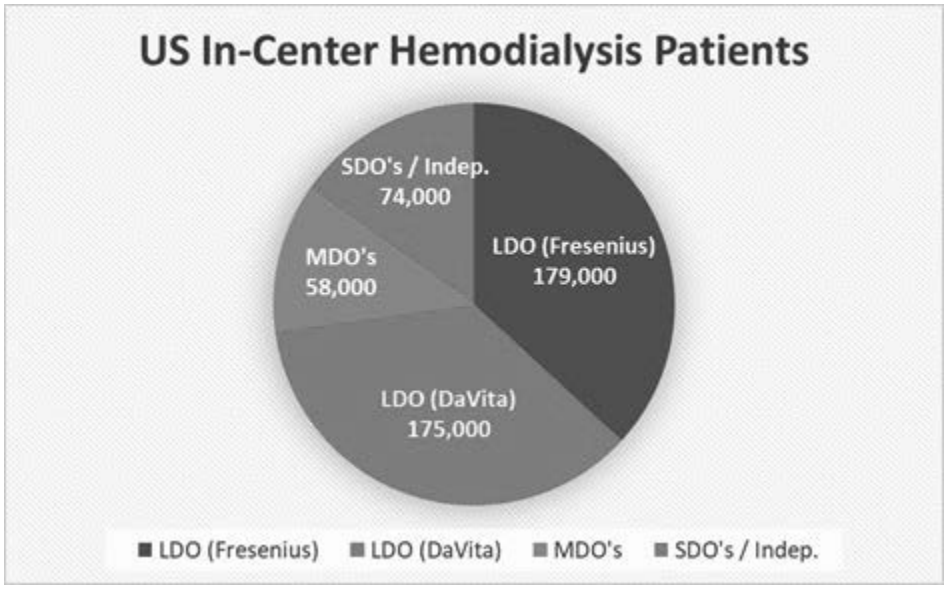
Market Opportunity

Hemodialysis

The United States hemodialysis market is currently the largest market in the world for dialysis products. As of 2018, there were an estimated 551,000 hemodialysis patients.



Hemodialysis is the primary treatment modality for ESKD employed in the United States, with approximately 88% of all dialysis patients receiving in-center hemodialysis. There were an estimated 485,000 in-center hemodialysis patients in the United States, representing approximately 73 million treatments annually. We do not currently compete in the other two segments, peritoneal, representing approximately 10% of the total patients, or home dialysis, representing approximately 2% of the total patients. Hemodialysis treatments are primarily performed in freestanding clinics and in some hospitals.



LDO = Large Dialysis Organization MDO = Mid-sized Dialysis Organization SDO = Small Dialysis Organization

Based on a global market study published by a major dialysis products manufacturer, the global ESKD 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 ESKD 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 ESKD 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 153 times per year. Most patients have their dialysis treatment performed at a free-standing clinic for permanent loss of kidney function. These are commonly referred to as "chronic" patients. Patients that have their treatment performed at hospitals for temporary loss of kidney function are typically referred to as "acute" patients. The small percentage of chronic patients that receives their treatment at home are referred to as "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.

Limitations of Existing Anemia Therapies for HDD-CKD Patients

The primary causes of anemia in dialysis patients are loss of renal erythropoietin ("EPO") production and iron deficiency due to chronic inflammation and increased blood losses related to uremia and hemodialysis. The result is an iron loss of~5–7mg per dialysis session. The current standard of care for treating anemia in HDD-CKD patients are injectable ESAs and traditional macromolecular IV iron. ESAs and traditional macromolecular IV iron are often used together.

HDD-CKD patients have abnormalities in iron metabolism caused by ongoing blood loss during the hemodialysis treatment, repeated blood draws to follow laboratory parameters and a limited diet. Furthermore, absorption of iron from the diet and mobilization from body stores is reduced due to increases in a peptide called hepcidin. Hepcidin is the master regulator of iron uptake and distribution and is elevated in patients with inflammation, such as ESKD patients on dialysis. Since iron is a critical component of hemoglobin production, reduced levels of iron can cause iron deficiency anemia.

EPO is a hormone that is produced by the kidneys and stimulates red blood cell production in the bone marrow. In patients with HDD-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 HDD-CKD patients to stimulate red blood cell 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.

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. Traditional IV iron carbohydrate products are macromolecular carbohydrate complexes which are taken up by macrophages which transfer to the liver 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 elevated, 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 macromolecular IV iron finds a depot in macrophages, it is administered in large doses and is, therefore, suited as a replacement therapy in iron depleted patients. Consistent with this mechanism of action, traditional macromolecular IV iron was 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.

Since macromolecular 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 intravenously to hemodialysis

patients, a significant portion of the iron is sequestered, therefore, the dose needed to deliver sufficient iron to the bone marrow far exceeds the amount of iron lost, 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 high doses of macromolecular IV iron over time may lead to complications such as infections and cardiovascular disease, which are potentially hazardous to patients' long-term health. Furthermore, the carbohydrate moiety in IV iron complexes is thought to be responsible for anaphylactic reactions occasionally seen in IV iron complexes.

HIF-PHI Opportunity

A class of drugs, known as hypoxia-inducible factor prolyl hydroxylase inhibitors ("HIF-PHIs"), 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 an NDA for roxadustat was submitted in the United States in December 2019 and remains pending FDA review. If approved, HIF-PHIs could potentially offer a more convenient alternative to injectable ESAs for treatment of anemia in CKD patients, while potentially increasing iron availability for hemoglobin synthesis.

Based on published presentations of data from a roxadustat trial, we believe the introduction of HIF-PHIs may be an opportunity for us to establish Triferic as a preferred therapy for iron replacement with this new class of drugs. Based on our understanding of the trial, Triferic given at each dialysis could be sufficient for the iron needs of the average roxadustat dialysis patient (see Clinical Pipeline below for more information on our study plans).

Home Infusion

General

Home infusion therapy includes specialized services that allow patients to receive intravenous medications at home. Providers are specialized, closed-door pharmacies with expertise in sterile compounding and clinical management of IV therapies. The therapy is supported by multi-disciplinary clinical teams (pharmacists, nurses, dietitians and doctors).

Many patient groups requiring home infusion therapies suffer from chronic diseases that are associated with a risk of iron deficiency and anemia. As an example, one group in particular at high risk for developing iron deficiency anemia ("IDA") is patients who require parenteral nutrition. It is estimated that 40-55% of all patients on parenteral nutrition are iron deficient. Patients with IDA can exhibit symptoms of fatigue, shortness of breath, rapid or irregular heartbeats and glossitis - all which affect quality of life. The majority of these patients are undertreated, due in part to limitations with currently available IV iron products. Home infusion represents a large and rapidly growing segment of healthcare where we believe FPC may have distinct advantages over currently available iron replacement therapy options.

Diseases Often Treated With Infusion Therapy At Home

Diseases commonly requiring infusion therapy include infections that are unresponsive to oral antibiotics, cancer and cancer-related pain, dehydration, gastrointestinal diseases or disorders which prevent normal functioning of the gastrointestinal system, and more. A recent National Home Infusion Association (NHIA) study found that in 2019 home infusion and specialty providers cared for more than 3 million patients in the United States, representing a 300% increase since the last industry study in 2008.

	Therapy	Unique Patients (annually)
Traditional Infusion Therapies (daily)...	Anti-infectives	1,441,520
	Parenteral Nutrition	112,984
	Hydration	159,736
	Pain Management	50,648
	Inotropic	85,712
	Antineoplastic Chemotherapy	132,464
	Catheter Care	214,280
	Other (e.g., steroids, ant-emetics)	720,760
	Biologics, Immune Globulin, etc.	306,323
	TOTAL	**3,224,427**

SOURCE: NHIA Infusion Industry Trends Report 2020.

Until the 1980s, patients receiving infusion therapy had to remain in the inpatient setting for the duration of their therapy, which often lasted for several hours. Heightened emphasis on cost-containment in health care, as well as developments in the clinical administration of the therapy, led to strategies to administer infusion therapy in alternate settings. For individuals requiring long-term therapy, inpatient care is not only tremendously expensive but also prevents the individual from resuming normal lifestyle and work activities.

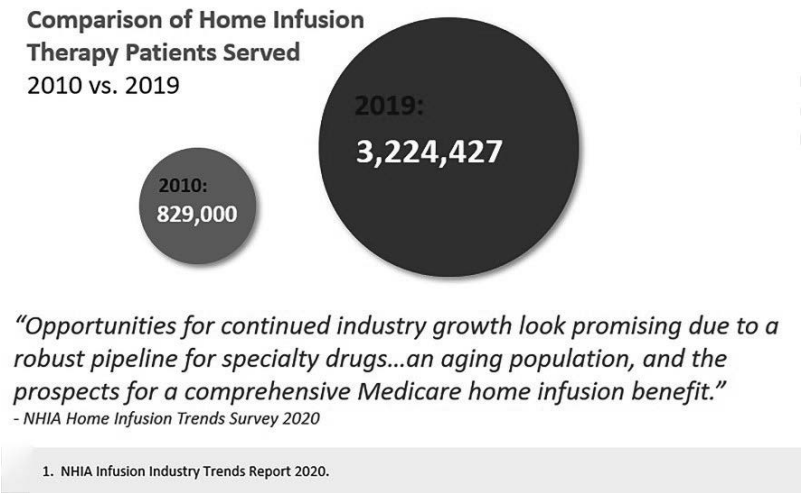
The technological advances that enabled safe and effective administration of infusion therapies in the home, the desire of patients to resume normal lifestyles and work activities while recovering from illness, and the cost-effectiveness of home care are important. Consequently, home infusion therapy has evolved into a comprehensive medical therapy that is a much less costly alternative to inpatient treatment in a hospital or skilled nursing facility.

Home infusion has been proven to be a safe and effective alternative to inpatient care for many disease states and therapies. For many patients, receiving treatment at home or in an outpatient infusion suite setting is preferable to inpatient care. A thorough patient assessment and home assessment are performed before initiating infusion therapy at home to ensure that the patient is an appropriate candidate for home care (Source: www.nhia.org).

Home infusion therapy allows patients that require multiple on-going infusions of medications to receive them in the comfort of their own home. The benefits include, increased quality of life, shorter hospital/skilled nursing facility length of stay, lower rates of depression and fatigue, less opioid use and reduced risk of hospital/facility acquired infections.

Growth In Home Infusion

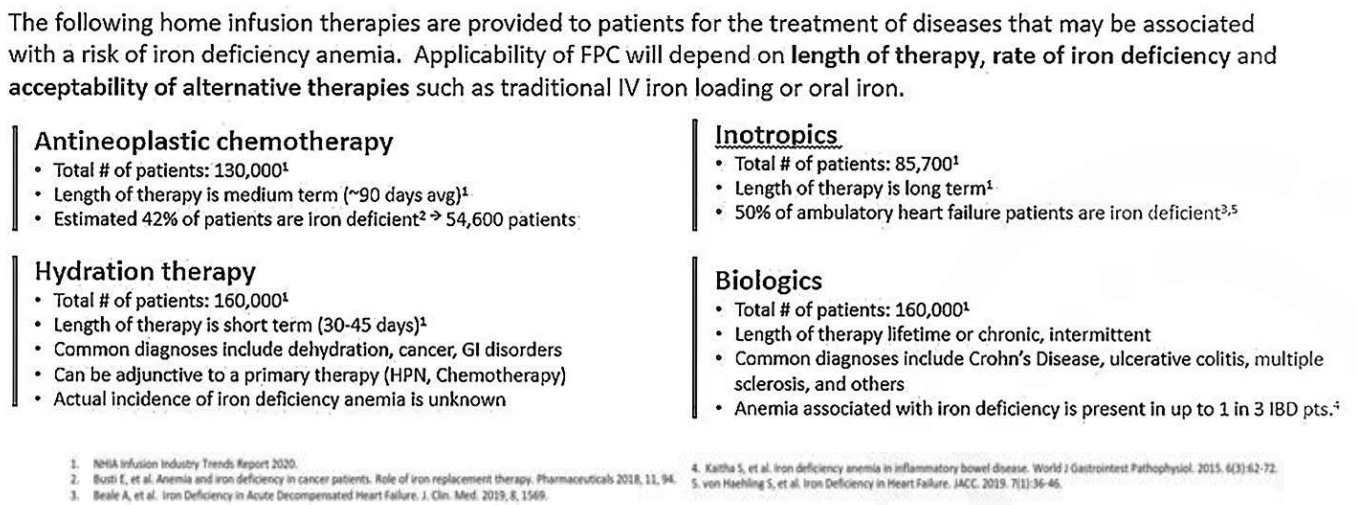
The home and specialty infusion marketplace is experiencing rapid growth and provides a favorable reimbursement opportunity for suitable drugs because of the benefits listed above. In addition to these factors, COVID-19 and its impact has accelerated existing trends.



We believe the home infusion sector will continue to grow in the future. Growth will be driven by: (1) high rates of patient demand, and satisfaction with services, (2) site of care optimization programs driving by commercial payers, (3) legislation to expand coverage for Medicare beneficiaries and (4) a robust pipeline of specialty IV treatments.

Iron Deficiency Anemia In Home Infusion

IDA is a common comorbidity for many different types of patients with diseases that are treated with home infusion therapy.



It is recommended that patients receiving home parenteral nutrition be screened regularly for anemia. Treatment with parenteral iron for these patients with iron deficiency is recommended. Inadequate response to treatment may be related to continued blood loss, inflammation, ineffective absorption or poor adherence to therapy. Treatment patterns are inadequate for patients on home infusion therapy with IDA. IV iron supplementation is more effective than oral formulations, however, concern for adverse events is a deterrent. Home infusion of traditional macromolecular IV iron is limited due to the risk of hypersensitivity and need for medical supervision of the injection, and concerns about incompatibility with other infused drugs (e.g., stability of parenteral nutrition lipids when delivered with carbohydrate-based IV iron preparations). An office visit for infusion of IV iron is costly, inconvenient, and often does not fit the physician practice care model. Limitations with the current approach can lead to a vicious cycle of late diagnosis and treatment, inconsistent follow-up, and increased risk of office visits or hospitalizations.

For home parenteral nutrition ("HPN") patients specifically, there is a significant opportunity for FPC for home infusion and an unmet need for effective proactive iron maintenance therapy. There are approximately 113,000 HPN patients annually, of which 83,000 patients require short-term care (averaging 45 days) and 30,000 patients require long-term care. An estimated 40% to 55% of such patients are iron deficient and the majority of patients have a negative iron balance due to low/no dietary iron absorption and inflammation. The current treatment for these patients is daily infusions of parenteral nutrition

supplements, which last for 8 to 12 hours per day. Traditional parenteral iron is infrequently used due to risk of hypersensitivity and concerns regarding incompatibility with lipids. Oral iron is also considered to be inadequate due to patient inability to absorb. We believe that the inadequacy and burden of current treatments presents an opportunity for our FPC pipeline.

We believe FPC is uniquely suited for use as a home infusion therapy:

- Home infusion clinicians are hesitant to recommend macromolecular IV iron supplementation at home due to the potential for severe hypersensitivity risk - however rare. FPC has been demonstrated to have a safety profile similar to placebo in prospective randomized clinical trials.

- Treatment with loading doses of traditional IV iron therapy can temporarily address iron deficiency, but iron deficiency may persist due to inflammation. FPC provides 100% immediately bioavailable iron, bypassing storage in the liver. Iron from FPC is bioavailable even in the presence of inflammation and elevated hepcidin.

- Managing iron with loading doses of macromolecular IV iron is inconsistent for home infusion patients. FPC can be dosed consistently in low doses as a physiologic maintenance dose to address an on-going negative iron balance and prevent iron deficiency anemia.

Sales and Marketing

Domestic Dialysis

Concentrates

We use Baxter as our exclusive commercial partner responsible for marketing our Dialysis Concentrate Products within 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 (the "Products Purchase Agreement") with DaVita. 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. In March 2020, we entered into a Second Amendment to the Exclusive Distribution Agreement with Baxter (the "Second Amendment"). The Second Amendment provides for, among other things, a commitment by Rockwell to maintain a specified manufacturing capacity for Baxter, a cap upon the net amount of reimbursable transportation expenses and modified extension terms.

We also supply dialysis concentrates to distributors serving a number of foreign countries, primarily in the Americas and the Pacific Rim. Nipro Medical Corporation is our primary distributor of our dialysis concentrates in certain countries in Latin America that are not covered under the Baxter Distribution Agreement.

Dialysate concentrates accounted for approximately 98.5% of our 2020 revenue. Approximately 91.0% of our 2020 sales were to distributors and customers for use in the United States.

Triferic In The United States

Our primary customers in the United States for sales of Triferic (dialysate), Triferic AVNU and our dialysis concentrates are dialysis provider organizations. The dialysis provider market is considerably consolidated, with the top 10 provider organizations treating approximately 90% of in-center hemodialysis patients. We market and sell Triferic (dialysate), Triferic AVNU directly to these medium-sized, and independent dialysis chains.

Triferic (dialysate). We have assembled a sales and marketing leadership team and a field-based sales team to support the commercialization of Triferic (dialysate) in the United States. The team consists of sales and marketing leaders who have extensive experience selling and marketing products within the ESKD marketplace. This leadership is supported by experienced sales representatives responsible for effectively promoting the product within the United States and clinical nurse educators and medical science liaisons responsible for supporting the integration of Triferic (dialysate) and Triferic AVNU into United States dialysis clinics. We believe this sales force is appropriately sized for marketing Triferic to the nephrology community within the United States.

Our initial target customers include selected medium and small sized dialysis chains and independent dialysis centers. The launch of Triferic (dialysate) 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.

Triferic AVNU (IV). Triferic AVNU (IV) was FDA approved on March 27, 2020. We initiated a limited evaluation program with sample product in the fourth quarter of 2020 and we began commercial sales of Triferic AVNU in the first quarter of 2021.

Research to Support the Triferic Value Proposition. The kidney dialysis market in the U.S. is a concentrated market, where two companies service 73% of the patients. The dialysis procedure, including all inputs, is reimbursed under capitated reimbursement, which means it is a fixed price. This means any new product success depends on compelling data demonstrating improved patient outcomes and/or pharmacoeconomics versus the current standard of care in practice in the clinics. Once it was determined by Medicare that Triferic would be reimbursed under the fixed bundled rate, market adoption became dependent on the generation of these data, which were not required for approval from the FDA.

We have made progress and continue to be confident that Triferic has the potential to be the treatment of choice for the maintenance of hemoglobin in dialysis patients. Toward this end, we have increased our efforts in generating real world data in clinics with current protocols, which we believe will help with the adoption of Triferic as these results are created and disseminated over time. In addition, we believe the hemodialysis industry may experience a great deal of change over the next several years. We plan to take the steps necessary to generate the data necessary to potentially allow Triferic to benefit from these new innovations, such as the potential approval of a class of drugs, known as hypoxia-inducible factor prolyl hydroxylase inhibitors ("HIF-PHIs"), as well as the new, solid-state equipment in development. We plan to study Triferic in combination with these potential new innovations as they become available (see Clinical Pipeline below).

International Dialysis.

Our strategy for growth includes the expansion of Triferic sales outside the United States by licensing it to key partners for development and/or commercialization. Partnering in these regions allows us to better leverage the development, regulatory, commercial presence and expertise of business partners to accelerate sales of our products throughout the world. To date, we have established partnerships in China, India, Korea, Canada, Peru and Chile. We continue to pursue international licensing opportunities in other countries and regions.

China:

In 2016, we licensed the commercialization rights for Triferic (dialysate) and Triferic AVNU for the Chinese market to Wanbang Biopharmaceutical ("Wanbang"), a subsidiary of Shanghai Fosun Pharmaceutical (Group) Co., Ltd.. Wanbang estimates there are almost 600,000 patients receiving hemodialysis in the People's Republic of China and it is expected to become the largest ESRD market in the world over the next several years. Wanbang recently enrolled patients in a Phase III trial. If approved, Wanbang will commence commercialization of Triferic following the regulatory approval (for more information see Clinical Development below).

India:

We have licensed the commercialization rights for Triferic (dialysate) for the Indian market to a wholly-owned subsidiary of Sun Pharmaceutical Industries Ltd. (together, "Sun Pharma"). It is estimated there are approximately 120,000 patients receiving hemodialysis in India.

Sun Pharma has submitted the NDA for Triferic in India and is currently working with the Indian Central Drugs Standard Control Organization for the optimal regulatory path for approval of Triferic (dialysate) in India. A Joint Alliance Committee, comprised of members from the Company and Sun Pharma, will guide the development and execution for Triferic (dialysate) in India. Sun Pharma will be responsible for all clinical, regulatory and commercialization activities.

Korea:

We have licensed the commercialization rights for Triferic (dialysate) and Triferic AVNU for the Korean market to Jeil Pharmaceuticals ("Jeil"). It is estimated there are approximately 78,000 hemodialysis patients in Korea. Jeil has recently submitted the NDA for both Triferic (dialysate) and Triferic AVNU with the goal of being able to commercially launch Triferic (AVNU) in 2022.

Canada:

We have also executed a distribution agreement to market our Triferic products in Canada with RMC Health Care Inc. We filed for regulatory approval of Triferic AVNU (IV) in May of 2020, and if approved and granted favorable placement on both national and providence formularies, we would be entitled to receive a transfer price based on our partner's sales price in Canada. It is estimated that approximately 17,000 patients are receiving hemodialysis in Canada.

Peru:

In 2017, we licensed the liquid formulation of Triferic (dialysate) to Quimica Europea in Peru. In January 2019, we received regulatory approval for Triferic (dialysate) in Peru, representing the first approval of a Triferic product outside the United States. Quimica Europea is currently working on submission of Triferic (dialysate) for placement upon Peru's national formulary.

Chile:

In 2017, we licensed the liquid formulation of Triferic (dialysate) to Commercializadora Biorenal SpA (Biorenal) in Chile. In June 2020 we received regulatory approval for Triferic (dialysate) in Chile. Biorenal is currently working on submission of Triferic (dialysate) for placement upon Chile's national formulary.

Concentrates:

In territories that are not governed under our agreement with Baxter, our primary distributor is Nipro Medical Corporation which distributes our concentrates products within the LATAM region; however, we also sell through independent sales agents, distributors and direct.

Customers

We currently 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.

DaVita, Inc., accounted for 50% of our concentrate sales in 2020 and 49% of our concentrate sales in 2019. Our accounts receivable from this customer were $1.1 million and $1.2 million as of December 31, 2020 and 2019, 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 and March 2020, pursuant to which Baxter received exclusive distribution rights for our concentrate products in the United States, a commitment by Rockwell to maintain a specified manufacturing capacity for Baxter, a cap upon the net amount of reimbursable transportation expenses and modified extension terms. 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 2020 and 2019, our direct sales to Baxter aggregated approximately 25% and 27% of sales, respectively, and we had a receivable from Baxter of $1.6 million and $2.0 million as of December 31, 2020 and 2019, respectively.

Another customer, Nipro Medical Corporation, accounted for 7% and 9% of our sales in 2020 and 2019, respectively. No other customers accounted for more than 10% of our sales in any of the last three years.

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.

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 9% and 11% of our overall sales in 2020 and 2019, respectively.

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

Competition

Dialysis Concentrate Solutions and Dialysis Products Market Competition

In the United States, our principal competitor for concentrate products is Fresenius Medical Care NA ("Fresenius"), a vertically integrated manufacturer and marketer of dialysis devices, drugs and supplies and operator of dialysis clinics, 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 (dialysate) and Triferic AVNU 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, macromolecular IV iron have been used to treat iron deficiency anemia, and currently, the drug Venofer® is generally regarded as having dominant market share in dialysis over other Macromolecular 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 Macromolecular IV iron competitors include Actavis' generic Macromolecular IV iron drug, Nulecit®. Since macromolecular IV iron products are indicated for repletion therapy and not explicitly for iron maintenance therapy, they are not technically direct competitors to Triferic. The molecular structures, modes-of-action and FDA-approved clinical indications are different. Both therapies are needed to treat dialysis patients, where Triferic is given at every dialysis treatment to maintain iron levels, macromolecular IV iron are intended to be administered only to treat excessively low (or absolute) iron deficiency. Accordingly, as Triferic gains market share, we expect Macromolecular IV iron use will decline.

The markets for drug products are highly competitive. Competition in drug delivery systems is generally based on marketing strength, product performance characteristics (i.e., reliability, safety, patient convenience) and product price. Acceptance by dialysis providers and nephrologists is also critical to the success of a product. The first product on the market in a particular therapeutic area typically is able to obtain and maintain a significant market share. In a highly competitive marketplace and with evolving technology, additional product introductions or developments by others could render our products or technologies noncompetitive or obsolete. In addition, pharmaceutical and medical device companies are largely dependent upon health care providers being reimbursed by private insurers and government payers. Drugs approved by the FDA might not receive reimbursement from private insurers or government payers.

Reimbursement

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 typically viewed by providers as an additional cost that must be provided within the fixed bundled payment. Both Triferic (dialysate) and Triferic AVNU are reimbursed within the bundle for dialysis treatment. This reimbursement status makes commercialization more difficult, as dialysis centers may view Triferic as increasing their costs and lowering their operating margins. To counter this, we must show improved patient outcomes and experiences, which would justify the lower operating margins for dialysis providers.

Medical Affairs

We believe that Triferic represents innovation for iron replacement within ESKD. 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 ESKD patients. Medical affairs will be increasingly important as additional data on the use of Triferic become available, as discussed above and in "Clinical Pipeline" below.

CLINICAL PIPELINE

Dialysis

Triferic portfolio

HIF-PHI

Rockwell plans to conduct a study to evaluate the efficacy, safety and compatibility of Triferic and roxadustat for the maintenance of hemoglobin in HDD-CKD patients. The primary objective of the study will be to evaluate the efficacy of roxadustat-Triferic in maintaining erythropoiesis in adult patients with chronic kidney disease receiving hemodialysis. Efficacy will be measured primarily by the change from baseline in hemoglobin (Hgb). Secondary objectives will include: the efficacy of roxadustat-Triferic as compared to roxadustat alone based on Hgb response and level during the study, the need for IV iron use in subjects treated with roxadustat-Triferic as compared to roxadustat alone, and the efficacy of roxadustat-Triferic based on Hgb response in inflamed subjects (stratify). Commencement of the study is pending FDA approval of roxadustat and its commercial availability in the United States. As of March 2021, the FDA has recommended an advisory panel review the new drug application for roxadustat.

Real World Data

To support the sales of our Triferic products, we are evaluating potential clinical studies and are conducting real-world data initiatives that we believe have the potential to support the value proposition for both Triferic (dialysate) and Triferic AVNU (IV). 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 part of this program we are collecting data from sites that are purchasing Triferic (dialysate) in the United States so that we can assess the impact of Triferic (dialysate) on various clinical and pharmacoeconomic measures.

Results from a study, conducted by New York University and reported in Critical Care Medicine, showed $296,000 in cost savings from Triferic. The study, which was independent of Rockwell, reviewed the effects of long-term use of Triferic in a large outpatient dialysis clinic, and showed substantial cost savings due to reductions in ESA and macromolecular IV iron use without impacting patient safety and hemoglobin targets. In a retrospective data review of 100 patients that were followed before and after implementation of Triferic dialysate, there was a relative reduction in average weekly ESA dose of 26.4%, total use of IV iron replacement therapy decreased with a relative reduction in the use of all iron products (iron sucrose 65.7%, sodium ferric gluconate 98.2%) while anemia targets were met. This clinic determined that the reduction of these agents resulted in a net savings of more than $296,000 in one fiscal year.

Pediatric Study

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 (dialysate) 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 began enrollment in the study during 2020.

International

China: 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 confirm that according to previously received guidance they would be sufficient to support a regulatory submission for Triferic (dialysate) in China. During the meeting, we and Wanbang received new guidance from NMPA that an additional clinical Phase 3 study would be required to support a regulatory submission. The start of this clinical study was impacted by the COVID-19 pandemic. Wanbang recently initiated patient enrollment in this clinical study in January 2021. Under the Wanbang Agreement, Wanbang is responsible for all clinical development costs required to support the approval of Triferic in China.

Europe: We have received regulatory guidance from the European Medicines Agency ("EMA") regarding the clinical studies that are needed to file for approval of Triferic AVNU 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. We may request additional guidance depending on the uptake of Roxadustat after its approval and launch in the EU.

Home Infusion

The FDA has feedback on our proposed clinical development plans which we intend to incorporate into the next iteration of clinical protocols and FDA correspondence and dialogue. FDA has accepted our proposed development strategy to pursue an approval via the 505(b)(1) pathway as a novel NDA for FPC for treatment of IDA in adult patients. The FDA further agreed with our approach to cross-reference non-clinical pharmacology and toxicology from our prior INDs and does not foresee the need for additional studies in these areas.

We plan to take advantage of the early consultation opportunities provided by FDA in a pre-IND meeting to further clarify study design, patient selection and study endpoints for our Phase II study of a FPC for treatment of IDA in adult patients receiving home infusion therapies. We currently expect to have this meeting and be able to initiate the clinical trial in the second half of this year.

Other Therapeutic Product Candidates in Development

Heart Failure

We plan to investigate the potential for FPC as a treatment for hospitalized acute heart failure patients. Iron deficiency, which is independent of anemia, is a common co-morbidity in all forms of heart failure (50-70%). Iron deficiency can worsen cardiac function, but is currently under-recognized and under treated, which we believe represents a significant unmet need. There is a significant body of clinical evidence to support the use of IV iron therapy for improvement of cardiac energetics and cardiac function in the outpatient setting (not for the improvement of Hgb). Iron uptake, and thereby the clinical benefit during a hospital stay, is limited by the bioavailability for current traditional macromolecular IV iron. FPC uniquely suited for hospitalized acute heart failure – 200mg of immediately bioavailable iron can be delivered during an average 5-day hospital stay (equivalent to over 1 gram of currently available traditional macromolecular IV iron).

We expect to request advice from the FDA in second half of 2021 to review a proposed clinical development program, starting with a mechanistic clinical proof of concept study that would determine if FPC administration can impact myocardial energetics and cardiac function.

Operations

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.

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 rigorous 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 CMOs 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.

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 CMO's 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 Triferic (dialysate) and one fill and finish vendor for the liquid formulation of Triferic (dialysate) and Triferic AVNU. 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.

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.

MATERIAL AGREEMENTS

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 to clinics other than DaVita 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 the Distribution Agreement with Baxter (the "Amendment"). The Amendment provides for, among other things, reduced pricing on certain accounts and incentives to Baxter to pursue new customers and increase future sales. In March 2020, we entered into the Second Amendment to the Distribution Agreement with Baxter (the "Second Amendment"). The Second Amendment provides for, among other things, a commitment by Rockwell to maintain a specified manufacturing capacity for Baxter, a cap upon the net amount of reimbursable transportation expenses and modified extension terms.

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, as amended by the Second Amendment, also contains provisions regarding our obligations to maintain specified manufacturing capacity and quality levels. We continue to manage customer service, transportation and certain other functions for our current customers. For customer service, Baxter pays us an amount equal to our related costs plus a slight mark-up for these services. For transportation costs, Baxter pays us an amount equal to our related costs, subject to the defined caps contained within the Second Amendment, which are based upon defined percentages of liquid concentrate product being shipped.

The Distribution Agreement also provides that, upon the mutual determination of us and Baxter, Baxter will pay us up to $10 million to build a new manufacturing facility in the Pacific time-zone that would serve customers in the western United States. The fee payable in connection with construction of 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 in October 2014. If a "Refund Trigger Event" occurs prior to December 31, 2021, we would be obligated to repay 25% 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.

The Distribution Agreement may be extended for 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.

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 is the former 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 patent 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 patent 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 Triferic IV, 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 Total Parenteral Nutrition (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 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.

GOVERNMENT REGULATION

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.

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, Triferic AVNU and other candidates utilizing the FPC Platform. 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, indications, routes of administration, dosage forms or 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.

PATENTS, TRADEMARKS AND TRADE SECRETS

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, 2020, we owned or had the rights to 30 issued patents (4 U.S. and 26 foreign) and 56 pending applications (6 U.S. and 50 foreign). Patents and patent applications owned or licensed by us include claims to FPC in both dialysate and IV 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 (IV and Dialysate)	2	2029 (1)	1	3 (2)	2028 (1)	29
Triferic (ESA Sparing)	—	2034	2	13 (3)	2034	21
Triferic (TPN)	1	2029	—	9 (4)	2026	—
Other	1	—	3	1	—	—
Total	4		6	26		50

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 28 European states (not included in total).
3. Two European patents 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.

Human Capital

As of December 31, 2020, we had 300 employees, substantially all of whom are full time employees. Our arrangements with our employees are not governed by any collective bargaining agreement. Our employees are employed on an "at-will" basis.

Our key human capital management objectives are to identify, recruit, integrate, retain and motivate our new and existing employees. We believe that our compensation and benefit programs are appropriately designed to attract and retain qualified talent. Employees receive an annual base salary and are eligible to earn performance-based cash bonuses. To create and maintain a successful work environment, we offer a comprehensive package of additional benefits that support the physical and mental health and wellness of all of our employees and their families. Additionally, we grant equity awards in order to allow for directors, officers and senior-level employees to share in the performance of the Company.

We are committed to a safe workplace for our employees and have implemented health and safety management processes into our operations. In response to the COVID-19 pandemic, we have implemented additional safety measures for the protection of our employees, including work-from-home measures for applicable employees and additional cleaning and protective measures.

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.

RISK FACTOR SUMMARY

Investing in our common stock involves significant risks. You should carefully consider the risks described below before making a decision to invest in our common stock. If we are unable to successfully address these risks and challenges, our business, financial condition, results of operations, or prospects could be materially adversely affected. In such case, the trading price of our common stock would likely decline, and you may lose all or part of your investment. Below is a summary of some of the risks we face.

- The long-term success of our business depends on our ability to leverage the FPC platform to develop new therapies in disease states that currently have an unmet need for management of iron deficiency. If we are unable to develop, obtain regulatory approval for or successfully commercialize these new therapies, or if we experience significant delays in doing so, our business will be materially harmed.
- The near-term success of our business depends substantially on the successful commercialization of Triferic (dialysate) and Triferic AVNU. If these Triferic products fail to gain broader market acceptance, our business may be harmed.
- The ongoing COVID-19 pandemic has resulted in significant disruptions to our business operations, including the commercial launch of our Triferic products and our clinical trials, which could have a material adverse effect on our business.
- Our ability to market Triferic (dialysate) and Triferic AVNU is limited by the FDA to those specific indications and conditions for which clinical safety and efficacy have been demonstrated.
- Clinical drug development involves a lengthy and expensive process with uncertain timelines and uncertain outcomes, and the results of prior preclinical or clinical trials are not necessarily predictive of our future results.
- Our FPC pipeline product candidates have not received regulatory approval in the disease state we are investigating. If we are unable to obtain regulatory approvals to market such product candidates, our business will be adversely affected.

- The ongoing COVID-19 pandemic has resulted in, and may continue to result in significant disruptions to our concentrates business operations, which could have a material adverse effect on our business.
- 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.

RISKS RELATED TO OUR DRUG BUSINESS

The long-term success of our business depends on our ability to leverage the FPC platform to develop new therapies in disease states that currently have an unmet need for management of iron deficiency. If we are unable to develop, obtain regulatory approval for or successfully commercialize these new therapies, or if we experience significant delays in doing so, our business will be materially harmed.

Successful development and ultimate regulatory approval of new therapies based on our FPC platform in disease states outside of ESRD where iron replacement is required is critical to the future success of our business. We conducted an evaluation of the potential utility of FPC in certain disease states and believe that, based on the results of this analysis, FPC would be viable. However, there is no assurance that our findings regarding the clinical and commercial viability of FPC are accurate or provide a complete portrayal of the medical and commercial challenges FPC will face. Furthermore, new legislation, reimbursement guidance, regulatory requirements or medical developments may negatively impact our conclusion that FPC is economically and clinically viable.

The development of new therapies is lengthy, time-consuming and expensive. We expect to incur substantial expense for both preclinical studies 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 properly, 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.

We expect that we will need to raise additional funds to develop new therapies based on our FPC platform. We may not be able to obtain or secure the funding necessary to complete such development or initiate or complete the necessary clinical trials. In addition, there is no assurance that such funding will be available to us or that it will be obtained on terms favorable to us or will provide us with sufficient funds to meet our objectives. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies.

The near-term success of our business depends substantially on the successful commercialization of Triferic (dialysate) and Triferic AVNU. If these Triferic products fail to gain broader market acceptance, our business may be harmed.

Triferic (dialysate) launched commercially in the United States in May 2019 and recorded sales of $1.2 million through December 31, 2020. Triferic AVNU was approved by the FDA in March 2020 and made commercially available in February 2021. There are many challenges associated with the commercialization of Triferic (dialysate) and Triferic AVNU (collectively referred to as "Triferic"), including challenges associated with reimbursement, market penetration and acceptance, competition and implementation. There is no assurance that Triferic will gain broad market acceptance or that we will be successful in the ongoing commercialization of these products.

The commercial success and ultimate profitability of Triferic depends in part on reimbursement of Triferic by government and commercial payors. Both formulations of Triferic are 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 constraint has resulted and may continue to result in a slower rate of commercial adoption than initially anticipated. In order to address this constraint, we are working with dialysis providers to demonstrate with healthcare economic data the improved patient outcomes and reduction in utilization of other anemia therapies associated with Triferic, as well as the resulting savings that offset the costs associated with Triferic. The commercial success of the Triferic portfolio would be significantly impacted if we are unable to generate additional positive healthcare economic data used in these conversations.

In order to gain broad market acceptance, we expect that we will need to penetrate the dialysis market, which is highly concentrated in the United States. DaVita and Fresenius own or manage a large number of the outpatient dialysis facilities in the United States, which account for approximately 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. To date, neither Fresenius nor DaVita have adopted Triferic in their dialysis facilities. We do not expect to be able to successfully penetrate a large portion of the total addressable market in the United States without Fresenius or DaVita.

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

- the rate of adoption of the Triferic portfolio 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;
- 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 Triferic paid by us based on the profitability of Triferic;
- our ability to avoid third party patent interference or patent infringement claims;
- our ability to maintain a continued acceptable safety profile of Triferic; and
- 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.

Additionally, Triferic competes against current anemia therapies (including macromolecular intravenous iron and the ESA class of drugs) and may in the future compete with products such as HIF-PHIs, if approved. It has been difficult to gain market acceptance from dialysis chains, anemia managers and nephrologists. Implementation of Triferic in clinics requires changes to established customer protocols, formularies, administration methods and operational practices. There is no assurance that we can persuade dialysis centers to adopt their protocols and utilize the drugs in a manner consistent with state regulatory agencies. This challenge has been enhanced by the ongoing COVID-19 pandemic, as dialysis centers are often unable or unwilling to make such changes. In addition, clinics typically need to adjust their protocols to optimize the financial impact of Triferic. We expect that the success of the commercialization of Triferic will be contingent upon being able to overcome these hurdles which may continue to be slower than anticipated, if at all.

We encounter additional challenges in gaining market acceptance with dialysis clinics specific to Triferic (dialysate) and Triferic AVNU. Specifically, Triferic (dialysate) may only be used in clinics that utilize liquid bicarbonate, either in the form of a central tank delivery system or single use jugs. We continue to observe a trend of clinics converting from liquid bicarbonate to dry bicarbonate, which thereby prohibits utilization of Triferic (dialysate). In addition, the utilization of Triferic (dialysate) involves mixing the powder form into the central loop dialysate system or placing the 5mL ampule into the single use jugs, which clinics may be hesitant to do. We have also received feedback from clinics that it is difficult to identify a convenient method for delivering Triferic AVNU via slow infusion. While we anticipated this might be a challenge in some cases and we have been actively working to develop alternative administration methods that can be more widely adopted, we may not be able to identify a delivery method that clinics find to be convenient and feasible. Failure to overcome these challenges could prevent a widespread adoption of Triferic.

The commercial success and ultimate profitability of Triferic will also depend on the effectiveness of our marketing, sales and distribution strategies and operations for commercialization and our ability to execute our marketing strategy without significant additional expenditures. While we hired a sales force for the launch of Triferic (dialysate) in 2019, we did not hire additional sales representatives or invest heavily into the launch of the commercialization of Triferic AVNU. This investment strategy could negatively impact the adaptation of Triferic AVNU within clinics.

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, 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, our continued success may depend on adoption of Triferic by the limited number of existing dialysis providers.

The ongoing COVID-19 pandemic has resulted in significant disruptions to our business operations, including the commercial launch of our Triferic products and our clinical trials, which could have a material adverse effect on our business.

Our business and its operations, including but not limited to our sales and marketing efforts and our research and development activities, have been and are expected to continue to be adversely affected by the COVID-19 pandemic. In response to public health directives and orders related to COVID-19, we have implemented work-from-home policies for substantially all employees, excluding our essential manufacturing and distribution employees. The effects of executive and similar government orders, shelter-in-place orders and our work-from-home policies have negatively impacted our growth and productivity in our commercial efforts of our Triferic products, disrupted our business, including our sales and marketing activities, and delayed our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition.

Quarantines, shelter-in-place, executive and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to COVID-19 or other infectious diseases, may impact personnel at our manufacturing facilities and third-party manufacturing facilities in the United States, Europe and other countries, or the availability or cost of materials we use or require to conduct our business, including product development, which would disrupt our supply chain. If the COVID-19 pandemic were to negatively affect our manufacturing facilities, the costs related to such manufacturing may increase and the productivity of our facilities may decrease. Furthermore, some of our manufacturers and suppliers are in Europe and may be impacted by port closures and other restrictions resulting from the COVID-19 pandemic, which may disrupt our supply chain or limit our ability to obtain sufficient materials for our drug products.

We commercially launched Triferic (dialysate) in the United States in May 2019 and Triferic AVNU in February 2021. Quarantines, shelter-in-place, executive and similar government orders, or changes in prospective customer practices in response to the COVID-19 outbreak, have had and may continue to have a negative impact on our sales and marketing activities, particularly, our sales representatives are unable to interact with current and potential customers to the same extent as before the onset of the COVID-19 pandemic. Depending on the severity of the impact on our sales and marketing efforts, market acceptance of Triferic could be hampered and commercial uptick slower than normal.

In addition, we may face decreased demand for Triferic if dialysis patients are unable to travel to dialysis clinics or if dialysis clinics, if dialysis patients are found to be disproportionally affected by COVID-19 due to their heighten risk status, or if dialysis clinics are unable to make additional protocol changes that are required for Triferic. In order to ensure the safety of patients and staff at the dialysis clinics that use our Triferic products, we expect the dialysis clinics will implement a number of changes to their safety procedures and maintain changes already made. In addition, the dialysis clinics may face challenges related to decreased staffing, if staff members are affected by COVID-19. Changes to safety procedures and/or staffing issues may impede the clinics' ability to make additional protocol changes that are required for Triferic.

In addition, our clinical trials and our partners' clinical trials have been and may continue to be affected by the COVID-19 pandemic. For example, Wanbang is our commercialization partner for both Triferic (dialysate) and Triferic AVNU in China and has initiated clinical studies but these studies may experience slower than normal patient enrollment as a result of the COVID-19 pandemic. Such delays may result in a delay in Wanbang's submission to the Chinese regulatory authorities for approval. In addition, meetings between Sun Pharma and the regulatory authorities in India related to our Triferic products have been postponed due to government restrictions in India. Lastly, meetings between Jeil Pharma and the regulatory authorities in South Korea could be postponed due to potential government restrictions in South Korea. If COVID-19 continues to spread in the United States and elsewhere, we or our partners may experience additional disruptions that could severely impact our business and clinical trials, including:

- delays in receiving authorization from local regulatory authorities to initiate our planned clinical trials;

- delays in receiving legalization documents from foreign embassies, which are required to allow our partners to direct activities on behalf of the Company in local markets;
- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials, including interruption in global shipping that may affect the transport of clinical trial materials;
- changes in local regulations as part of a response to the COVID-19 pandemic which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring and data entry and verification, due to limitations on travel imposed or recommended by federal or state governments, employers and others, or interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the completeness and integrity of clinical trial data and, as a result, determine the outcomes of the trial;
- risk that participants enrolled in our clinical trials will acquire COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events;
- risk that participants enrolled in our clinical trials will not be able to travel to our clinical trial sites as a result of quarantines or other restrictions resulting from COVID-19;
- risk that participants enrolled in our clinical trials will not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services;
- interruptions or delays in preclinical studies due to restricted or limited operations at our contracted research and development laboratory facilities;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees;
- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- refusal of the FDA to accept data from clinical trials in affected geographies; and
- interruption or delays to our clinical activities.

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by COVID-19, and the duration of such impact, may be difficult to assess or predict, the widespread pandemic has resulted in significant disruption of global financial markets, which could reduce our ability to access capital and negatively affect our future liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 and related government orders and restrictions could materially affect our business and the value of our common stock.

The COVID-19 pandemic continues to evolve rapidly. The ultimate impact of the COVID-19 pandemic or a similar public health emergency is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, healthcare systems, or the global economy as a whole. However, any one or a combination of these events could have an adverse effect on the operation of and results from our clinical trials and on our other business operations, which could negatively impact our business, operating results and financial condition.

Our ability to market Triferic (dialysate) and Triferic AVNU 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. Triferic (dialysate) and Triferic AVNU are 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. We are not able to promote Triferic (dialysate) and Triferic AVNU or encourage our customers to use Triferic (dialysate) and Triferic AVNU 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 Triferic (dialysate) or secure an expanded product label, our ability to fully market Triferic (dialysate) on the basis of cost savings or improved patient outcomes may be limited, which would limit our ability to take full advantage of the market opportunity for Triferic (dialysate).

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-matter 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 Triferic (dialysate) 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 Triferic (dialysate) and Triferic AVNU, 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, labor strike at a supplier of COVID-caused halt or slowdown of supply of raw materials or production of components;
- 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.

We may not be successful in obtaining foreign regulatory approvals or in arranging out-licensing partners capable of obtaining the approvals needed to effectively commercialize Triferic (dialysate), Triferic AVNU 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 Triferic (dialysate) and Triferic AVNU, 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. We have encountered and may continue to encounter delays in the foreign approval process, which could delay the initiation of marketing of our products. 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 Triferic (dialysate), Triferic AVNU 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 Triferic (dialysate), Triferic AVNU or any other drug product candidates are approved and marketed outside of the United States, including:

- reduced protection for intellectual property rights;
- additional risk of litigation;
- 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, if we would seek 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 ESKD 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.

Federal and state healthcare reform measures could be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, or change the methods used by Medicare and Medicaid to reimburse providers, including the "bundled" payment model and the availability of transitional separate reimbursement. Any such reforms 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.

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 from an affiliate of Dr. Ajay Gupta, our former Chief Scientific Officer. These in-licensed patent rights cover Triferic AVNU 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 Triferic and Triferic AVNU, and could potentially subject us to expensive and protracted litigation. Any of these occurrences could significantly harm our results of operations and future prospects.

New classes of drugs, such as HIF-PHIs, may limit the need for iron to be administered to ESKD 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 HDD-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. It is also possible that it is not medically appropriate to use a HIF-PHI in conjunction with Triferic.

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 macromolecular IV iron or Triferic. Significant utilization of oral agents would diminish the commercial opportunity of Triferic within ESKD dialysis patients receiving hemodialysis.

RISKS RELATED TO CLINICAL TRIALS

Clinical drug development involves a lengthy and expensive process with uncertain timelines and uncertain outcomes, and the results of prior preclinical or clinical trials are not necessarily predictive of our future results.

Future FPC pipeline product candidates will be subject to rigorous and extensive clinical trials and extensive regulatory approval processes implemented by the FDA and comparable foreign regulatory authorities before obtaining marketing approval from these regulatory authorities. The drug development and approval process is lengthy and expensive, and approval is never certain. Investigational new drugs may not prove to be safe and effective in clinical trials. We have no direct experience as a company in conducting later stage clinical trials required to obtain regulatory approval in the disease states that we are currently investigating FPC pipeline product candidates in. We may be unable to conduct clinical trials at preferred sites, enlist clinical investigators, enroll sufficient numbers of participants or begin or successfully complete clinical trials in a timely fashion, if at all. In addition, the design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We may be unable to design and execute a clinical trial to support regulatory approval. Even if a current clinical trial is successful, it may be insufficient to demonstrate that our product candidates are safe or effective for registration purposes.

There is a high failure rate for drugs and biologic products proceeding through clinical trials. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of FPC pipeline product candidates may not be predictive of the results of later-stage clinical studies or trials and the results of studies or trials in one set of patients or line of treatment may not be predictive of those obtained in another. In fact, many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late stage clinical trials even after achieving promising results in preclinical studies and earlier stage clinical trials. In addition, data obtained from preclinical and clinical activities is subject to varying interpretations, which may delay, limit or prevent regulatory approval. It is impossible to predict when or if our future product candidates will prove effective or safe in humans in the disease states that we will be conducting the clinical trials or that they will receive regulatory approval. FPC pipeline product candidates may not demonstrate in patients the biochemical and pharmacological properties we anticipate based on laboratory studies or earlier stage clinical trials, and they may interact with human biological systems or other drugs in unforeseen, ineffective or harmful ways. The number of patients exposed to product candidates and the average exposure time in the clinical development programs may be inadequate to detect rare adverse events or findings that may only be detected once a product candidate is administered to more patients and for greater periods of time. If we are unable to successfully demonstrate the safety and efficacy of FPC pipeline product candidates in these disease states and are unable to receive the necessary regulatory approvals, our business will be materially harmed.

If we experience delays in clinical testing, our commercial prospects will be adversely affected, our costs may increase and our business may be harmed.

We cannot guarantee that we will be able to initiate and complete clinical trials and successfully accomplish all required regulatory activities or other activities necessary to gain approval and commercialize our future product candidates. In the future, we may file INDs for any future indications or future product candidates. If any such future IND is not approved by the FDA, our clinical development timeline may be negatively impacted and any future clinical programs may be delayed or terminated. As a result, we may be unable to obtain regulatory approvals or successfully commercialize our products. We do not know whether any other clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Our product development costs will increase if we experience delays in clinical testing. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our future product candidates or allow our competitors to bring products to market before we do, which would impair our ability to successfully commercialize our future product candidates and may harm our business, results of operations and prospects. Our or our future collaborators' inability to timely complete clinical development could result in additional costs to us as well as impair our ability to generate product revenue, continue development, commercialize our future product candidates, reach sales milestone payments and receive royalties on product sales. In addition, if we make changes to a product candidate including, for example, a new formulation, we may need to conduct additional nonclinical studies or clinical trials to bridge or demonstrate the comparability of our modified product candidate to earlier versions, which could delay our clinical development plan or marketing approval for our current product candidate and any future product candidates.

If we encounter difficulties in enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

The timely completion of clinical trials largely depends on patient enrollment. We may encounter delays in enrolling, or be unable to enroll, a sufficient number of patients to complete any of our future clinical trials, and even once enrolled, we may be unable to retain a sufficient number of patients to complete any of our trials. Some of the disease states in which we are investigating FPC, specifically the home setting, present logistical challenges for patient enrollment in clinical trials. In addition, our competitors, some of whom have significantly greater resources than we do, may conduct clinical trials for the same indications or in the same therapeutic areas and seek to enroll patients in their studies that may otherwise be eligible for

our clinical studies or trials. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which could further reduce the number of patients who are available for our clinical trials in these sites. Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Even if we are able to enroll a sufficient number of patients in our clinical studies or trials, delays in patient enrollment may result in increased costs or may affect the timing or outcome of our clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our future product candidates.

FPC may cause undesirable side effects or have other properties in the new disease states we are investigating that could delay or prevent their regulatory approval or limit the commercial profile of an approved label.

Undesirable side effects caused by our future product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities. Additional clinical studies may be required to evaluate the safety profile of our future product candidates.

Lack of efficacy, adverse events, administration challenges or limitations, or undesirable side effects may emerge in clinical trials conducted by third parties developing treatment candidates in the disease states that we are investigating, which could adversely affect our stock price, our ability to attract additional capital and our development program.

Lack of efficacy, adverse events or undesirable side effects may emerge in clinical trials conducted by third parties developing product candidates like ours. We have no control over their clinical trials or development program, and lack of efficacy, adverse events or undesirable side effects experienced by subjects in their clinical trials could adversely affect our stock price, our ability to attract additional capital and our clinical development plans for our future product candidates or even the viability of our future product candidates, including by creating a negative perception of FPC pipeline product candidates by healthcare providers or patients.

Interim, topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or topline data from our clinical trials, which are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical trials. In addition, we may report interim analyses of only certain endpoints rather than all endpoints. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available.

RISKS RELATED TO REGULATORY APPROVALS

Our FPC pipeline product candidates have not received regulatory approval in the disease state we are investigating. If we are unable to obtain regulatory approvals to market such product candidates, our business will be adversely affected.

We do not expect our FPC pipeline product candidates to be commercially available for several years, if at all. Our future product candidates will be subject to strict regulation by regulatory authorities in the United States and in other countries. We cannot market any product candidate until we have completed all necessary preclinical studies and clinical trials and have obtained the necessary regulatory approvals. We do not know whether regulatory agencies will grant approval for our future product candidates. Even if we complete preclinical studies and clinical trials successfully, we may not be able to obtain regulatory approvals or we may not receive approvals to make claims about our products that we believe to be necessary to effectively market our products. Data obtained from preclinical studies and clinical trials is subject to varying interpretations that could delay, limit or prevent regulatory approval, and failure to comply with regulatory requirements or inadequate manufacturing processes are examples of other problems that could prevent approval.

Even if we are able to obtain regulatory approvals for our future product candidates, if they exhibit harmful side effects after approval, our regulatory approvals could be revoked or otherwise negatively impacted, and we could be subject to costly and damaging product liability claims.

Even if we receive regulatory approval for our FPC pipeline product candidates, we will have tested them in only a small number of patients during our clinical trials. If our applications for marketing are approved and more patients begin to use our product, new risks and side effects associated with our products may be discovered. As a result, regulatory authorities may revoke their approvals. We might have to withdraw or recall our products from the marketplace. We may also experience a significant drop in the potential sales of our product if and when regulatory approvals for such product are revoked. As a result, we may experience harm to our reputation in the marketplace or become subject to lawsuits, including class actions. Any of these results could decrease or prevent any sales of our approved product or substantially increase the costs and expenses of commercializing and marketing our product.

The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable. Our inability to obtain regulatory approval for our future FPC pipeline product candidates would substantially harm our business.

The time required to obtain approval from the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's development and may vary among jurisdictions. It is possible that none of our FPC pipeline product candidates will ever obtain regulatory approval. Our future product candidates could fail to receive regulatory approval from the FDA or comparable foreign regulatory authorities for many reasons. If we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may grant approval contingent on the performance of costly post-marketing clinical trials or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of the product candidate.

Even if our FPC pipeline product candidates receive regulatory approval, it may still face future development and regulatory difficulties.

Even if we obtained regulatory approval for a product candidate, it would be subject to ongoing requirements by the FDA and comparable foreign regulatory authorities governing the manufacture, quality control, further development, labeling, packaging, storage, distribution, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-market information. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP, regulations and standards. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, or undesirable side effects caused by such products are identified, a regulatory agency may: issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings about such product; mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners; require that we conduct post-marketing studies; require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance; seek an injunction or impose civil or criminal penalties or monetary fines; suspend marketing of, withdraw regulatory approval of or recall such product; suspend any ongoing clinical studies; refuse to approve pending applications or supplements to applications filed by us; suspend or impose restrictions on operations, including costly new manufacturing requirements; or seize or detain products, refuse to permit the import or export of products or require us to initiate a product recall. The occurrence of any event or penalty described above may inhibit our ability to commercialize our products and generate product revenue.

Even if our FPC pipeline product candidates receive regulatory approval, it may still face future reimbursement challenges.

Reimbursements of a our FPC pipeline product candidates, if approved, is integral to their ability to be a commercial success. While we have incorporated to the best of our ability factors such as marketing strategy and payer reimbursement into our clinical trial decision making, these decisions must be balanced against the time and resources required to demonstrate a benefit, the increased complexity of development and manufacturing and the potential delays to approval of the lead indication.

While, we try to plan clinical trials appropriately to foresee such challenges, but there is no guarantee that unexpected or unforeseen issues will not arise.

Furthermore, pricing and reimbursement of pharmaceutical products is subject to intense political scrutiny and the reimbursement understandings that we currently have now may be modified or rendered moot by the time the FPC pipeline product candidate could potentially receive regulatory approval. Such modifications could change the commercial viability of marketing the FPC pipeline product candidate which would have an effect upon the long term growth of Rockwell.

RISKS RELATED TO OUR CONCENTRATE BUSINESS

The ongoing COVID-19 pandemic has resulted in, and may continue to result in significant disruptions to our concentrates business operations, which could have a material adverse effect on our business.

Our business and its operations have been and are expected to continue to be adversely affected by the COVID-19 pandemic. To date, our manufacturing has been viewed as an essential activity and we have not been required to pause operations based upon executive or similar governmental directives. However, we have had, and anticipate continuing to have, instances where employees of our manufacturing plants test positive for COVID-19, resulting in a disruption to our manufacturing operations. These disruptions in our operations have had and could continue to have a negative impact our business, operating results and financial condition. Furthermore, it is possible that the outbreak of COVID-19 could be significant enough to force us to close the entirety of the manufacturing plant or transportation services for an extended period of time, which could result in a failure to deliver product.

In addition, we may face decreased demand for both our concentrates portfolio if dialysis patients are unable to travel to dialysis clinics or if dialysis patients are found to be disproportionally affected by COVID-19 due to their heightened risk associated with their disease. We have had an increase in costs associated with COVID-19 including costs associated with hazard pay, costs for PPE and costs for cleaning. These increased costs have impacted the profitability of our concentrates divisions. Given the uncertainty surrounding COVID-19, we may continue to incur these additional costs which in turn can have an impact upon our profitability. The COVID-19 pandemic continues to evolve rapidly. The ultimate impact of the COVID-19 pandemic or a similar public health emergency is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, healthcare systems, or the global economy as a whole. However, any one or a combination of these events could have an adverse effect on the operation of and results from our clinical trials and on our other business operations, which could negatively impact our business, operating results and financial condition.

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. In addition to Fresenius, we are aware of other large manufacturers potentially looking to increase their market share of the domestic concentrates market, which, if successful, could have an impact upon Rockwell's profitability.

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, the Second Amendment to our Distribution Agreement with Baxter, established a cap on the percentage amount that we receive in reimbursement for transportation expenses. This reimbursement cap could result in Rockwell not being able to obtain the full amount of our transportation costs. We have also 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, the costs of raw materials, or increases in transportation costs that are not reimbursed due to the cap on expenses with Baxter could negatively impact our profit margins, as we may be limited in our ability to pass these costs along to our customers.

In addition, one of the most expensive components of our dialysis solutions is pharmacopeia grade salt. Pharmacopeia grade salt is primarily manufactured domestically by two suppliers. It was announced in September 2020 that our primary supplier of pharmacopeia, one of our largest suppliers of pharmacopeia grade salt, is merging with the other primary manufacturer of pharmacopeia grade salt which could have an effect of our costs of raw material.

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 $337.4 million since inception and we expect to incur further losses for the foreseeable future. As of December 31, 2020, we had approximately $58.7 million of cash, cash equivalents and investments available-for-sale, and working capital of $56.7 million. Net cash used in operating activities for the year ended December 31, 2020 was approximately $29.6 million.

During the year ended December 31, 2020, the Company sold 1,128,608 shares of its common stock as part of its sales agreement with Cantor Fitzgerald & Co. for proceeds of $2.3 million, net of issuance costs. Approximately $32.3 million remains available for sale under this facility. See Note 11 for further detail.

In February 2020, the Company raised capital in an underwritten public offering for proceeds of $8 million, net of estimated issuance costs. In September 2020, the Company sold 23,178,809 shares of its common stock for proceeds of $32.7 million, net of issuance costs (see Note 11 in Part III for further detail).

In March 2020, the Company entered into a Loan and Security Agreement (the "Loan Agreement") with Innovatus Life Sciences Lending Fund I, LP, ("Innovatus") to make certain term loans to the Company in the aggregate principal amount of up to $35.0 million. Net draw down proceeds at closing were approximately $21 million, net of estimated fees and expenses (See Note 15 in Part III for further detail).

The Loan Agreement, noted above, is secured by all assets of the Company and Rockwell Transportation, Inc. and contains customary representations and warranties and covenants, subject to customary carve outs, and includes financial covenants related to liquidity and trailing twelve months sales of Triferic, with the latter beginning with the period ending

December 31, 2020. We cannot assure you that we can maintain compliance with the covenants under our Loan Agreement, which may result in an event of default. Our ability to comply with these covenants may be adversely affected by events beyond our control. For example, the Loan Agreement contains certain financial covenants relating to sales and, as a result of the ongoing COVID-19 pandemic and its effect on our sales activities, among other factors, we were not be able to satisfy such covenants as of December 31, 2020. As such, the Company utilized the cure options which were accepted by Innovatus to regain compliance. As of December 31, 2020, the Company was in compliance with all reporting and financial covenants.

Based on the equity offerings and Loan Agreement described 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.

Our ability to fund our activities in the long term will be dependent upon our ability to successfully execute on the development of the FPC platform in new indications and our ability to successfully commercialize and increase adoption of Triferic (dialysate) and Triferic AVNU. Both of these factors are subject to significant risks and uncertainties and there can be no assurance that we will be successful in achieving approval of FPC in new indications or that we will successfully expanding our Triferic franchise. If our planned clinical program is delayed or experiences failures, or if our commercialization of Triferic fails to achieve targeted levels of success, we may be forced to implement cost-saving measures that may potentially have a negative impact on our activities and we may have increased difficulty raising capital to fund our operations. If we are unable to raise required capital, we may be forced to curtail 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.

Our Loan Agreement with Innovatus contains certain covenants that could adversely affect our operations and, if an event of default were to occur, we could be forced to repay the outstanding indebtedness sooner than planned and possibly at a time when we do not have sufficient capital to meet this obligation. The occurrence of any of these events could cause a significant adverse impact on our business, prospects and share price.

Pursuant to the Loan Agreement, we have pledged substantially all of our assets and the assets of our subsidiary, Rockwell Transportation, Inc., and have agreed that we may not sell or assign rights to our patents and other intellectual property without the prior consent of Innovatus. Additionally, the Loan Agreement contains affirmative, including financial covenants related to liquidity and trailing twelve months sales of Triferic, and negative covenants that, among other things, restrict our ability to:

- incur additional indebtedness;
- grant liens;
- make distributions, including dividends;
- enter into a merger or consolidation;
- alter the business of the Company; or
- sell all or a portion of the Company's property, business or assets.

These terms of the Loan Agreement could prevent us from taking certain actions without the consent of our lenders, which may limit our flexibility in operating our business and our ability to take actions that might be advantageous to us and our stockholders, placing us at a competitive disadvantage compared to our competitors who have less leverage and who therefore may be able to take advantage of opportunities that our leverage prevents us from exploiting. These covenants could also limit our ability to make needed capital expenditures or otherwise conduct necessary or desirable business activities.

We cannot assure you that we can maintain compliance with the covenants under our Loan Agreement, which may result in an event of default. Our ability to comply with these covenants may be adversely affected by events beyond our control. For example, the Loan Agreement contains certain financial covenants relating to sales and, as a result of the ongoing COVID-19 pandemic and its effect on our sales activities, among other factors, we may not be able to satisfy such covenants in the future. Based on our Triferic sales, we were not able satisfy this covenant as of December 31, 2020. As such, the Company utilized the cure options which were accepted by Innovatus to regain compliance.

The Loan Agreement also includes customary events of default, including, among other things, a change of control or a failure to comply with certain of the covenants in the Loan Agreement. Upon the occurrence and continuation of an event of default, all amounts due under the Loan Agreement become (in the case of a bankruptcy event), or may become (in the case of all other events of default and at the option of Innovatus), immediately due and payable.

If an event of default under the Loan Agreement should occur, we could be required to immediately repay the outstanding indebtedness. If we are unable to repay this debt, the lenders would be able to foreclose on the secured collateral,

including our cash accounts, and take other remedies permitted under the Loan Agreement. Even if we are able to repay the indebtedness on an event of default, the repayment of these sums may significantly reduce our working capital and impair our ability to operate as planned. The occurrence of any of these events could cause a significant adverse impact on our business and financial condition.

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

Our forecast of the period of time through which our existing capital resources will be adequate to support our current operations is a forward-looking statement that involves risks and uncertainties. The actual amount of funds we will need to operate is subject to many factors, some of which are beyond our control. These factors include, but are not limited to:

- the timing and expenditures associated with the commercialization of Triferic (dialysate) and Triferic AVNU 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 Triferic in dialysis, conduct planned clinical studies and pursue business opportunities, our business, results of operations, financial position and cash flows could be materially adversely affected.

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 the incurrence of substantial costs. 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 2020 and have hired additional executive-level employees who are leading the commercialization of 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.

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 proceedings described in Note 14 "Commitments and Contingencies" in the accompanying consolidated financial statements for the year ended December 31, 2020, 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 14 "Commitments and Contingencies – Litigation" in the accompanying consolidated financial statements for the year ended December 31, 2020.

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 weather or other geological event 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 LEGAL AND REGULATORY

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

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.

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.

RISKS RELATED TO OUR COMMON STOCK

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, 2020, there were 6,481,095 shares issuable upon the exercise of the then-outstanding and exercisable stock options, 1,728,929 shares issuable upon the exercise of then-outstanding stock options that were not yet exercisable, and 23,178,509 shares issuable upon the exercise of then-outstanding and exercisable warrants. 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.

GENERAL RISK FACTORS

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 2025, 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 under a lease 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. As a result of the ongoing COVID-19 pandemic, we consolidated the office space in Hackensack, New Jersey since employees are required to work from home based upon state law and stay-at-home orders. We are re-assessing our commercial footprint and need for office space given our experience of working from home during the COVID-19 pandemic. We expect that we may need additional 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 14, 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 is listed on The Nasdaq Global Market under the trading symbol "RMTI".

As of February 28, 2021, there were 48 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, 2020.

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

Rockwell Medical is a commercial-stage, biopharmaceutical company developing and commercializing our next-generation parenteral iron technology platform, ferric pyrophosphate citrate ("FPC"), which we believe has significant potential to lead to transformative treatments for iron deficiency in multiple disease states, that we believe could reduce healthcare costs and improve patients' lives. We are also one of the two major suppliers of life saving hemodialysis concentrate products to kidney dialysis clinics in the United States.

Rockwell Medical has evolved its strategy over the past year to develop into a more medically-, scientifically- and data-driven company. We believe future clinical, regulatory and commercial success requires us to generate compelling clinical data in each of our programs. Our strategy is to accelerate Rockwell's growth by creating and developing pharmaceutical products based on our FPC technology for disease states where patients can benefit the most from an effective treatment for iron deficiency, while concurrently refining our dialysis business to drive incremental growth and efficiencies. We plan to leverage and build on the foundation provided by our current dialysis business serving kidney dialysis centers by developing a pipeline of additional potential drug therapies in multiple disease states.

We have two novel, FDA approved therapies, Triferic and Triferic AVNU, which are the first two products developed from our FPC platform. We are marketing both products to kidney dialysis centers for their patients receiving dialysis. In 2021, we intend to advance our FPC platform strategy by starting a Phase II trial for the treatment of iron deficiency anemia in patients outside of dialysis, who are receiving intravenous medications in the home infusion setting. In our R&D pipeline, we

are also exploring FPC's impact in the treatment of hospitalized patients with acute heart failure, with the potential to begin another Phase II program in these patients in 2022.

Results of Operations

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

	For the Year Ended December 31,				
	2020	% of Revenue	2019	% of Revenue	% Change
Net Sales	**$ 62,197**		**$ 61,303**		**1.5 %**
Cost of Sales	59,472	95.6 %	58,464	95.4 %	1.7
Gross Profit	2,725	4.4	2,839	4.6	(4.0)
Research and Product Development	7,092	11.4	6,886	11.2	3.0
Selling and Marketing	7,871	12.7	9,050	14.8	(13.0)
General and Administrative	16,182	26.0	20,998	34.3	(22.9)
Settlement Expense, net of Reimbursement	—	—	430	0.7	(100.0)
Operating Loss	**$ (28,420)**	**(45.7)%**	**$ (34,525)**	**(56.3)%**	**(17.7)%**

Net Sales

During the year ended December 31, 2020, our net sales were $62.2 million compared to net sales of $61.3 million during the year ended December 31, 2019. Net sales of hemodialysis concentrates to dialysis providers and distributors in the United States and abroad were $61.1 million for the year ended December 31, 2020 compared to $60.8 million for the year ended December 31, 2019. The increase of $0.3 million was primarily due to increase in sales to our domestic customers offset by a decrease in international sales. Net sales of Triferic (dialysate) were approximately $1.1 million for the year ended December 31, 2020 compared to $0.5 million for the year ended December 31, 2019. For each year ended December 31, 2020 and 2019, Triferic net sales included approximately $0.2 million of deferred revenue recognized under the Company's license in the People's Republic of China with Wanbang.

Cost of Sales and Gross Profit

Cost of sales during the year ended December 31, 2020 was $59.5 million, resulting in gross profit of $2.7 million during the year ended December 31, 2020, compared to cost of sales of $58.5 million and a gross profit of $2.8 million during the year ended December 31, 2019. Gross profit decreased by $0.1 million during the year ended December 31, 2020 compared to the year ended December 31, 2019, due primarily to an increase in labor and material costs of $0.3 million to address protocols put in place from the ongoing COVID-19 pandemic. Gross profits are primarily related to our concentrates business at this time. The Company anticipates that potential future sales of Triferic will positively impact future gross profits.

Research and Product Development Expense

Research and product development expenses were $7.1 million for the year ended December 31, 2020 compared with $6.9 million during the year ended December 31, 2019. The increase of $0.2 million is related to clinical trials and other product development expenses for Triferic. The Company is continuing to invest in its medical and scientific programs to support the continued data and phase 4 clinical programs for Triferic in dialysis and the advancement of our FPC technology platform.

Selling and Marketing Expense

Selling and marketing expenses were $7.9 million during the year ended December 31, 2020 compared with $9.1 million during the year ended December 31, 2019. The decrease of $1.2 million is due primarily to the decrease in marketing costs of $2.3 million, partially offset by an increase in costs associated with hiring, training and educating new employees of

$1.1 million. The fluctuation in these costs are mainly due to the timing of the Triferic (dialysate) launch in the third quarter of 2019. We expect lower quarter-to-quarter fluctuations in sales and marketing costs going forward.

General and Administrative Expense

General and administrative expenses were $16.2 million during the year ended December 31, 2020 compared with $21.0 million during the year ended December 31, 2019. The $4.8 million decrease was driven primarily by decreases to stock compensation, legal, recruiting and consulting fees, partially offset by an increase in labor costs. The decrease in stock compensation primarily relate to the resignation of our former President and Chief Executive Officer, Stuart Paul, in April 2020 and former Chief Financial Officer effective July 2020.

Settlement Expense

Settlement expense was $0 for the year ended December 31, 2020, compared to $0.4 million in for the year ended December 31, 2019. Settlement expense for the year ended December 31, 2019 reflected the terms of the confidential settlement agreement and mutual release entered into in August 2018 relating to the Company's former Chief Executive Officer, and Director, Robert Chioini, former Chief Financial Officer, Thomas Klema, and a former and then current director.

Other Income (Expense)

Other income for the year ended December 31, 2020 was $246,000, consisting of interest income of $238,000 and $8,000 of realized gains on investments. Other income for the year ended December 31, 2019 was $422,000, consisting of $392,000 of interest income and $30,000 of realized gains on investments. Other expense for the year ended December 31, 2020 was $2.7 million, consisting of warrant modification expense of $0.8 million and interest expense of $1.9 million related to our debt facility (see Note 15 for more information on our debt facility). Other expense for the year ended December 31, 2019 was $25,000 of interest expense.

Liquidity and Capital Resources

Since inception, we have incurred significant net losses and have funded our operations primarily through revenue from commercial products, proceeds from the issuance of debt and equity securities and payments from partnerships. At December 31, 2020, we had an accumulated deficit of approximately $337.4 million and shareholders' equity of $34.2 million. As of December 31, 2020, we had approximately $58.7 million of cash, cash equivalents and investments available-for-sale, and working capital of $56.7 million. Net cash used in operating activities for the year ended December 31, 2020 was approximately $29.6 million. 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.

In February 2020, the Company sold 3,670,212 shares of its common stock for proceeds of $8 million, net of issuance costs. On March 16, 2020, the Company closed a debt financing transaction with net proceeds at closing of approximately $21.2 million, net of fees and expenses (See Note 15 for further detail). On September 23, 2020, the Company sold 23,178,809 shares of its common stock for proceeds of $32.7 million, net of issuance costs (see Note 11 for further detail).

During the year ended December 31, 2020, the Company sold 1,128,608 shares of its common stock as part of its sales agreement with Cantor Fitzgerald & Co. for proceeds of $2.3 million, net of issuance costs. Approximately $32.3 million remains available for sale under this facility. See Note 11 for further detail.

The Company expects it will require additional capital to sustain its operations and make the investments it needs to execute its strategic plan, including the commercialization of Triferic (dialysate) and Triferic AVNU in dialysis, generating additional data for Triferic in dialysis, developing FPC for iron deficiency anemia in patients undergoing home infusion and for progressing our pipeline development program of new indications for our FPC platform. If the Company is unable to generate sufficient revenue from sales of its commercial products and from partnerships, 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.

In addition, the Company is subject to certain covenants and cure provisions under our Loan Agreement with Innovatus. As of the date of this report, the Company believes that it will either be able to satisfy such covenants or, in the event of a breached covenant, exercise cure provisions to avoid an event of default. If we are unable to avoid an event of default, any required repayments could have an adverse effect on our liquidity (See Note 16 for further detail).

The COVID-19 pandemic and resulting domestic and global disruptions have adversely affected our business and operations, including, but not limited to, our sales and marketing efforts and our research and development activities, and the operations of third parties upon whom we rely. Quarantines, shelter-in-place, executive and similar government orders and the recent surge in infections domestically have negatively impact our sales and marketing activities, particularly as our sales representatives are unable to interact with current and potential customers to the same extent as before onset of the COVID-19 pandemic. Our international business development activities have also be negatively impacted by COVID-19, especially with the recent surge in infections and resulting quarantines or shelter-in-place orders. Depending on the severity of the impact on our sales and marketing efforts, the success of our commercial launch of Triferic AVNU could be delayed.

The COVID-19 pandemic, the recent domestic and international surge in infections and resulting global disruptions have caused significant volatility in financial and credit markets. We have utilized a range of financing methods to fund our operations in the past; however, current conditions in the financial and credit markets may limit the availability of funding, refinancing or increase the cost of funding. Due to the rapidly evolving nature of the global situation, it is not possible to predict the extent to which these conditions could adversely affect our liquidity and capital resources in the future.

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 operations in the United States and internationally (with partners); the timing and magnitude of cash received from drug product sales; the timing and expenditures associated with the development programs including our FPC technology for home infusion and potentially acute heart failure; and the costs associated with our manufacturing and transportation operations related to our concentrate business.

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 1) our ability to execute on the development of the FPC platform for new therapies, and 2) our ability to commercialize and increase adaptation of Triferic (dialysate) and Triferic AVNU. Both of these strategies is subject to significant risks and uncertainties such that there can be no assurance that we will be successful is achieving approval of FPC in a new therapeutic area or that we will be able to have sustained commercial success with Triferic (dialysate) and Triferic AVNU. If our planned clinical program is delayed or fails or if our commercialization of Triferic (dialysate) and/or Triferic AVNU should fail to increase sales, 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 Triferic (dialysate) and Triferic AVNU 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 $29.6 million for the year ended December 31, 2020. The net loss for this period was higher than net cash used in operating activities by $1.3 million, which was primarily attributable to non-cash expenses of $4.2 million, consisting primarily of $1.5 million of amortization of the right to use assets, $0.8 million of depreciation and amortization, $0.8 million of warrant modification expense, $0.5 million of stock-based compensation, $0.3 million of inventory reserves, $0.3 million of debt financing cost amortization and accretion of discount , and a $3.0 million net change in assets and liabilities.

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.

Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities was $3.2 million during the year ended December 31, 2020. The net cash provided was primarily due to the purchase of investments available-for-sale of $29.3 million, offset by $33.6 million sale of our available-for-sale investments and $1.0 million for the purchase of equipment.

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.

Cash Provided by Financing Activities

Net cash provided by financing activities was $63.3 million during the year ended December 31, 2020. The net cash provided was primarily due to net proceeds of $40.7 million and $2.3 million from the sale of our common stock, related to our public offerings and our at-the market offerings, respectively, net proceeds of $21.2 million from the term loan, partially offset by payment of $0.8 million related to a short term note payable.

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.

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, 2020 and 2019, 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 for each of the years ended December 31, 2020 and 2019, respectively.

In 2016, the Company entered into a distribution and license agreement with Wanbang (the "Wanbang Agreement") 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 $0.2 million and $0.3 million for the years ended December 31, 2020 and 2019, respectively. Deferred revenue related to the Wanbang Agreement totaled $2.7 million and $2.9 million for the years ended December 31, 2020 and 2019, respectively.

On January 14, 2020, the Company entered into license and supply agreements with Sun Pharma (the "Sun Pharma Agreements"), for the rights to commercialize Triferic (dialysate) (ferric pyrophosphate citrate) in India. Under the terms of the Sun Pharma Agreements, Sun Pharma will be the exclusive development and commercialization partner for Triferic (dialysate) in India, and the Company will supply the product to Sun Pharma. In consideration for the license, the Company received an upfront fee of $0.1 million, 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 Triferic (dialysate) in India. Sun Pharma will be responsible for all clinical and regulatory approval, as well as commercialization activities. 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 $10,000 during the year ended December 31, 2020. Deferred revenue related to the Sun Pharma Agreement totaled $90,000 as of December 31, 2020.

On September 7, 2020, the Company entered into a license and supply agreements with Jeil Pharma (the "Jeil Pharma Agreements"), for the rights to commercialize Triferic (dialysate) (ferric pyrophosphate citrate) in South Korea. Under the terms of the Jeil Pharma Agreements, Jeil Pharma will be the exclusive development and commercialization partner for Triferic (dialysate) in South Korea, and the Company will supply the product to Jeil Pharma. In consideration for the license, the Company received an upfront fee of $0.2 million, and will be eligible for milestone payments and royalties on net sales. A Joint Alliance Committee, comprised of members from the Company and Jeil Pharma, will guide the development and execution for Triferic (dialysate) in South Korea. Jeil Pharma will be responsible for all clinical and regulatory approval, as well as commercialization activities. The upfront fee was recorded as deferred revenue and is being recognized as revenue based on the agreement term. The Company recognized revenue of $2,500 during the year ended December 31, 2020. Deferred revenue related to the Jeil Pharma Agreement totaled $197,500 as of December 31, 2020.

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, 2020 and 2019, 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, 2020. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2020. Additionally, 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, 2020. 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 the remediation of all the material weaknesses as described in our Annual Report filed on Form 10-K for the year ended December 31, 2019 relating to change management and third-party management controls, user access security and segregation of duties as it relates to user access controls in our Information Technology General Controls ("ITGC"), and the pervasive effect on other ITGC dependent business activity level internal control cycles, we concluded that we maintained effective control over financial reporting at a reasonable assurance level as of December 31, 2020.

Changes in Internal Controls

During the quarter ended June 30, 2020, the Company remediated the ITGC control deficiencies in connection with change management and third-party management and enhanced evidentiary review and documentation of key ITGC controls and implemented new programs and policies to provide improved control over change management and third-party management controls to the ERP system. During the quarter ended September 30, 2020, we continued our improvements by remediating the ITGC control deficiencies in connection with user access security and segregation of duties as it relates to user access controls. During the quarter ended December 31, 2020, we finalized our remediation efforts by evaluating and testing the design, implementation and operating effectiveness of the pervasive effect from the ITGC material weakness on other ITGC dependent business activity level internal control cycles. As of December 31, 2020, our management has remediated all material weaknesses described in our Annual Report filed on Form 10-K for the year ended December 31, 2019 and has deemed internal controls over financial reporting, our disclosure controls and procedures were effective as of December 31, 2020.

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 2021 Annual Meeting of Stockholders (the "2021 Proxy Statement"), which we expect to be filed with the SEC within 120 days of the end of our fiscal year ended December 31, 2020, including under headings "Election of Directors," "Executive Officers," "Corporate Governance" and, as applicable, "Delinquent Section 16(a) Reports."

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*. To the extent required, 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 2021 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 2021 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, 2020:

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)	5,621,500	$ 4.80	1,894,496
Equity compensation plans not approved by security holders (2)	1,258,750	$ 2.13	—
Total	6,880,250	$ 4.02	1,894,496

(1) Consists of 5,209,206 stock options with a weighted average exercise price of $4.80, 265,494 restricted stock units and 146,800 restricted stock awards.
(2) Consists of 1,258,750 stock options with a weighted average exercise price of $2.13.

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 2021 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 2021 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.

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 November 5, 2020).
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. (Company's Form 10-K filed March 17, 2020)
4.3	Form of Warrant (Company's Form 8-K filed on September 25, 2020).
4.4	Form of Pre-Funded Warrant (Company's Form 8-K filed on September 25, 2020).
4.5	For of Warrant to Purchase Common Stock for Innovatus (Company's Form 8-K filed March 20, 2020).
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).
*10.31	Russell Skibsted Employment Agreement, dated September 15, 2020 (Company's Form 8-K filed on September 16, 2020).
10.32	Securities Purchase Agreement dated September 23, 2020 (Company's Form 8-K filed on September 25, 2020).
*10.33	Russell Ellison Employment Agreement, dated April 17, 2020 (Company's Form 8-K filed on April 20, 2020).
*10.34	Rockwell Medical, Inc. Amended and Restated 2018 Long Term Incentive plan (Company's Form 8-K filed on May 21, 2020).
10.35	Loan and Security Agreement, dated March 16, 2020, by and among the Company, Innovatus Life Sciences Lending Fund I, LP and the lenders party thereto (Company's Form 10-Q filed on May 11, 2020).
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
104	The cover page from the Company's Annual Report on Form 10-K for the year ended December 31, 2020, formatted in Inline XBRL (included as Exhibit 101)

* 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/ Russell Ellison

Russell Ellison

President and Chief Executive Officer

Date: March 31, 2021

POWER OF ATTORNEY

KNOW BY ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Russell Ellison and Russell Skibsted, 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/ Russell Ellison Russell Ellison	President, Chief Executive Officer and Director (Principal Executive Officer)	March 31, 2021
/s/ Russell Skibsted Russell Skibsted	Chief Financial Officer (Principal Financial Officer)	March 31, 2021
/s/ Paul E. McGarry Paul E. McGarry	Principal Accounting Officer	March 31, 2021
/s/ John P. McLaughlin John P. McLaughlin	Director	March 31, 2021
/s/ John G. Cooper John G. Cooper	Director	March 31, 2021
/s/ Robert S. Radie Robert S. Radie	Director	March 31, 2021
/s/ Allen Nissenson Allen Nissenson	Director	March 31, 2021
/s/ Andrea Heslin Smiley Andrea Heslin Smiley	Director	March 31, 2021
/s/ Mark H. Ravich Mark H. Ravich	Director	March 31, 2021

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet**s** of Rockwell Medical Inc. and Subsidiaries (the "Company") as of December 31, 2020 and 2019, 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, 2020, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2020 and 2019, and the consolidated results of its operations and its cash flows for each of the two years in the period ended December 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("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 financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ Marcum LLP
Marcum LLP

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

Chicago, IL
March 31, 2021

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(Dollars in Thousands)

	December 31, 2020	December 31, 2019
ASSETS		
Cash and Cash Equivalents	$ 48,682	$ 11,795
Investments Available-for -Sale	9,997	14,250
Accounts Receivable, net of a reserve of $9 for both 2020 and 2019	4,171	4,203
Inventory	3,913	3,647
Prepaid and Other Current Assets	2,706	2,979
Total Current Assets	**69,469**	**36,874**
Property and Equipment, net	2,642	2,433
Inventory, Non-Current	1,176	441
Right of Use Assets, net	2,911	3,213
Goodwill	921	921
Other Non-current Assets	629	435
Total Assets	**$ 77,748**	**$ 44,317**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts Payable	$ 4,155	$ 3,018
Accrued Liabilities	5,013	4,518
Settlement Payable	—	104
Lease Liability - Current	1,167	1,493
Deferred License Revenue	2,175	2,234
Insurance Financing Note Payable	—	763
Customer Deposits	152	55
Other Current Liability - Related Party	131	189
Total Current Liabilities	**12,793**	**12,374**
Lease Liability - Long-Term	1,821	1,781
Term Loan, Net of Issuance Costs	20,949	—
Deferred License Revenue - Long-Term	8,015	9,842
Total Liabilities	**43,578**	**23,997**
Commitments and Contingencies (See Note 14)		
Stockholders' Equity:		
Preferred Stock, $0.0001 par value, 2,000,000 shares authorized, no shares issued and outstanding at December 31, 2020 and 2019	—	—
Common Stock, $0.0001 par value, 170,000,000 shares authorized, 93,573,165 and 65,378,890 shares issued and outstanding at December 31, 2020 and 2019, respectively	9	7
Additional Paid-in Capital	371,510	326,777
Accumulated Deficit	(337,406)	(306,516)
Accumulated Other Comprehensive Income	57	52
Total Stockholders' Equity	**34,170**	**20,320**
Total Liabilities And Stockholders' Equity	**$ 77,748**	**$ 44,317**

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, 2020 and 2019
(Dollars in thousands, except per share amounts)

	2020	2019
Net Sales	**$ 62,197**	**$ 61,303**
Cost of Sales	59,472	58,464
Gross Profit	2,725	2,839
Research and Product Development	7,092	6,886
Selling and Marketing	7,871	9,050
General and Administrative	16,182	20,998
Settlement Expense, net of Reimbursement	—	430
Operating Loss	**(28,420)**	**(34,525)**
Other Income (Expense)		
Realized Gain (Loss) on Investments	8	30
Warrant Modification Expense	(837)	—
Interest Expense	(1,879)	(25)
Interest Income	238	392
Total Other Income (Expense)	**(2,470)**	**397**
Net Loss	**$ (30,890)**	**$ (34,128)**
Basic and Diluted Net Loss per Share	**$ (0.41)**	**$ (0.56)**
Basic and Diluted Weighted Average Shares Outstanding	**75,621,674**	**60,918,544**

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, 2020 and 2019

(Dollars in Thousands)

	2020	2019
Net Loss	**$ (30,890)**	**$ (34,128)**
Unrealized Loss on Available-for-Sale Investments	(3)	(10)
Foreign Currency Translation Adjustments	8	(1)
Comprehensive Loss	**$ (30,885)**	**$ (34,139)**

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, 2020 and 2019

(Dollars in Thousand)

	COMMON STOCK					
	SHARES	AMOUNT	ADDITIONAL PAID-IN CAPITAL	ACCUMULATED DEFICIT	ACCUMULATED OTHER COMPREHENSIVE INCOME / (LOSS)	TOTAL STOCKHOLDERS' EQUITY
Balance as of January 1, 2019	**57,034,154**	**$ 6**	**$ 299,596**	**$ (272,388)**	**$ 63**	**$ 27,277**
Net Loss	—	—	—	(34,128)	—	(34,128)
Unrealized Loss on Available-for-Sale Investments	—	—	—	—	(10)	(10)
Foreign Currency Translation Adjustments	—	—	—	—	(1)	(1)
Issuance of Common Stock	30,000	—	148	—	—	148
Vesting of Restricted Stock Units Issued, net of taxes withheld	215,079	—	(279)	—	—	(279)
Issuance of Common Stock, net of Issuance Costs/Public offering	6,259,214	1	17,287	—	—	17,288
Issuance of Common Stock, net of Issuance Costs / At-the-market	1,840,443	—	5,073	—	—	5,073
Stock-based Compensation	—	—	4,952	—	—	4,952
Balance as of December 31, 2019	**65,378,890**	**$ 7**	**$ 326,777**	**$ (306,516)**	**$ 52**	**$ 20,320**
Net Loss	—	—	—	(30,890)	—	(30,890)
Unrealized Loss on Available-for-Sale Investments	—	—	—	—	(3)	(3)
Foreign Currency Translation Adjustments	—	—	—	—	8	8
Vesting of Restricted Stock Units Issued, net of taxes withheld	216,646	—	(19)	—	—	(19)
Issuance of Common Stock, net of Issuance Costs / Public offering	26,849,021	2	40,677	—	—	40,679
Issuance of Common Stock, net of Issuance Costs / At-the-market offerings	1,128,608	—	2,262	—	—	2,262
Issuance of Warrants related to Debt Financing	—	—	501	—	—	501
Warrant Modification Expense	—	—	837	—	—	837
Stock-based Compensation	—	—	475	—	—	475
Balance as of December 31, 2020	**93,573,165**	**$ 9**	**$ 371,510**	**$ (337,406)**	**$ 57**	**$ 34,170**

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, 2020 and 2019
(Dollars in Thousands)

	2020	2019
Cash Flows From Operating Activities:		
Net Loss	**$ (30,890)**	**$ (34,128)**
Adjustments To Reconcile Net Loss To Net Cash Used In Operating Activities:		
Depreciation and Amortization	834	788
Stock-based Compensation	475	4,952
Warrant Modification Expense	837	—
Increase in Inventory Reserves	305	1,271
Amortization of Right of Use Asset	1,455	1,865
Amortization of Debt Financing Costs and Accretion of Debt Discount	294	—
Loss on Disposal of Assets	7	5
Realized Loss on Sale of Investments Available-for-Sale	(8)	(30)
Foreign Currency Translation Adjustment	8	(1)
Changes in Assets and Liabilities:		
Decrease in Insurance Receivable	—	371
Decrease in Accounts Receivable, net	32	2,777
(Increase) Decrease in Inventory	(1,306)	317
Decrease in Other Assets	76	934
Increase (Decrease) in Accounts Payable	1,136	(1,474)
Decrease in Settlement Payable	(104)	(313)
Decrease in Lease Liability	(1,439)	(1,803)
Increase (Decrease) in Other Liabilities	534	(532)
Decrease in Deferred License Revenue	(1,887)	(2,253)
Changes in Assets and Liabilities	(2,958)	(1,976)
Cash Used In Operating Activities	**(29,641)**	**(27,254)**
Cash Flows From Investing Activities:		
Purchase of Investments Available-for-Sale	(29,307)	(41,678)
Sale of Investments Available-for-Sale	33,565	38,266
Purchase of Equipment	(1,046)	(588)
Purchase of Research and Development Licenses (Related Party)	—	(750)
Cash Provided By (Used in) Provided By Investing Activities	**3,212**	**(4,750)**
Cash Flows From Financing Activities:		
Proceeds from Term Loan	22,500	—
Debt Issuance Costs	(1,343)	—
Payments on Short Term Note Payable	(763)	(1,145)
Proceeds from the Issuance of Common Stock / Public Offering	43,148	18,778
Offering Costs from the Issuance of Common Stock / Public Offering	(2,469)	(1,490)
Proceeds from the Issuance of Common Stock / At-the Market Offerings	2,325	5,383
Offering Costs from the Issuance of Common Stock / At-the Market Offerings	(63)	(310)
Proceeds from the Exercise of Employee Stock Options, Net of Tax	—	148
Repurchase of Common Stock to Pay Employee Withholding Taxes	(19)	(279)
Cash Provided By Financing Activities	**63,316**	**21,085**
Increase (Decrease) In Cash and Cash Equivalents	36,887	(10,919)
Cash and Cash Equivalents At Beginning Of Period	11,795	22,714
Cash and Cash Equivalents At End Of Period	**$ 48,682**	**$ 11,795**
Supplemental Disclosure of Cash Flow Information:		
Cash Paid for Interest	$ 1,558	$ —
Supplemental Disclosure of Noncash Investing Activities:		
Change in Unrealized Loss on Marketable Securities Available-for-Sale	$ (3)	$ (10)
Insurance Financing Note Payable	$ —	$ 763
Fair Value of Warrants issued related to Debt Financing	$ 501	$ —

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

Note 1. Description of Business

Rockwell Medical, Inc. ("Rockwell Medical," "Rockwell" or the "Company") is a commercial-stage, biopharmaceutical company developing and commercializing our next-generation parenteral iron technology platform, ferric pyrophosphate citrate ("FPC"), which we believe has significant potential to lead to transformative treatments for iron deficiency in multiple disease states, that we believe could reduce healthcare costs and improve patients' lives. We are also one of the two major suppliers of life saving hemodialysis concentrate products to kidney dialysis clinics in the United States.

We have two novel, FDA approved therapies, Triferic and Triferic AVNU, which are the first two products developed from our FPC platform. We are marketing both products to kidney dialysis centers for their patients receiving dialysis. In 2021, we intend to advance our FPC platform strategy by starting a Phase II trial for the treatment of iron deficiency anemia in patients outside of dialysis, who are receiving intravenous medications in the home infusion setting. In our R&D pipeline, we are also exploring FPC's impact in the treatment of hospitalized patients with acute heart failure, with the potential to begin another Phase II program in these patients in 2022.

We are the second largest supplier of hemodialysis concentrates in the United States, with a reputation for excellent service, quality, and reliability. We believe that this reputation, which is based on over 25 years of service to the kidney dialysis centers, combined with about $60 million in annual revenue, approximately 300 dedicated employees, expertise in manufacturing and logistics and the added expertise in pharmaceutical development and commercialization brought to the Company by recent additions to our management team, gives us a solid foundation on which to grow.

Note 2. Liquidity and Capital Resources

Since inception, Rockwell has incurred significant net losses and have funded its operations primarily through revenue from commercial products, proceeds from the issuance of debt and equity securities and payments from partnerships. At December 31, 2020, Rockwell had an accumulated deficit of approximately $337.4 million and stockholders' equity of $34.2 million. As of December 31, 2020, Rockwell had approximately $58.7 million of cash, cash equivalents and investments available-for-sale, and working capital of $56.7 million. Net cash used in operating activities for the year ended December 31, 2020 was approximately $29.6 million. 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.

In February 2020, the Company sold 3,670,212 shares of its common stock for proceeds of $8.0 million, net of issuance costs. On March 16, 2020, the Company closed a debt financing transaction with net proceeds at closing of approximately $21.2 million, net of fees and expenses (See Note 15 for further detail). On September 23, 2020, the Company sold 23,178,809 shares of its common stock for proceeds of $32.7 million, net of issuance costs (see Note 11 for further detail).

During the year ended December 31, 2020, the Company sold 1,128,608 shares of its common stock as part of its At-the-Market ("ATM") sales agreement with Cantor Fitzgerald & Co. for proceeds of $2.3 million, net of issuance costs. Approximately $32.3 million remains available for sale under this facility. See Note 11 for further detail.

The Company expects it will require additional capital to sustain its operations and make the investments it needs to execute its strategic plan, including the commercialization of Triferic (dialysate) and Triferic AVNU in dialysis, generating additional data for Triferic in dialysis, developing FPC for iron deficiency anemia in patients undergoing home infusion and for progressing our pipeline development program of new indications for its FPC platform. If the Company is unable to generate sufficient revenue from sales of its commercial products and from partnerships, 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.

In addition, the Company is subject to certain covenants and cure provisions under its Loan Agreement with Innovatus. As of the date of this report, the Company believes that it will either be able to satisfy such covenants or, in the event of a breached covenant, exercise cure provisions to avoid an event of default. If Rockwell is unable to avoid an event of default, any required repayments could have an adverse effect on its liquidity (See Note 15 for further detail).

The COVID-19 pandemic and resulting domestic and global disruptions have adversely affected Rockwell's business and operations, including, but not limited to, its sales and marketing efforts and our research and development activities, and the operations of third parties upon whom the Company relies. Quarantines, shelter-in-place, executive and similar government orders and the recent surge in infections domestically may negatively impact Rockwell's sales and marketing activities, particularly if its sales representatives are unable to interact with current and potential customers to the same extent as before onset of the COVID-19 pandemic. The Company's international business development activities may also be negatively impacted by COVID-19, especially with the recent surge in infections and resulting quarantines or shelter-in-place orders.

The COVID-19 pandemic, the domestic and international surge in infections and resulting global disruptions have caused significant volatility in financial and credit markets. Rockwell has utilized a range of financing methods to fund its operations in the past; however, current conditions in the financial and credit markets may limit the availability of funding, refinancing or increase the cost of funding. Due to the rapidly evolving nature of the global situation, it is not possible to predict the extent to which these conditions could adversely affect the Company's liquidity and capital resources in the future.

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 2019 financial statements and notes to conform to the 2020 presentation.

Revenue Recognition

The Company recognizes revenue under Accounting Standards Codification ("ASC") 606, *Revenue from Contracts with Customers.* The core principle of the 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 four distribution and license agreements that have been deferred as a contract liability. The amounts received from Wanbang Biopharmaceuticals Co., Ltd. ("Wanbang"), Sun Pharmaceutical Industries Ltd. ("Sun Pharma") and Jeil Pharmaceutical Co., Ltd. ("Jeil Pharma") are recognized as revenue over the estimated term of the applicable distribution and license agreement as regulatory approval was not received and the Company did not have sufficient experience in China, India and South Korea, respectively, 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, 2020		
Products By Geographic Area	Total	U.S.	Rest of World
Drug Revenues			
Product Sales - Point-in-time	$ 910	$ 910	$ —
License Fee – Over time	226	—	226
Total Drug Products	1,136	910	226
Concentrate Products			
Product Sales – Point-in-time	59,100	53,707	5,393
License Fee – Point-in-time	1,961	1,961	—
Total Concentrate Products	61,061	55,668	5,393
Net Revenue	$ 62,197	$ 56,578	$ 5,619

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

For the years ended December 31, 2020 and 2019, license fee revenue was $2.2 million and $2.3 million, respectively. For the years ended December 31, 2020 and 2019, product sales revenue was $60.0 million and $59.0 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, 2020	December 31, 2019
Receivables, which are included in "Trade and other receivables"	$ 4,171	$ 4,203
Contract liabilities	$ 10,190	$ 12,076

There were no impairment losses recognized related to any receivables arising from the Company's contracts with customers for the years ended December 31, 2020 and 2019.

For the years ended December 31, 2020 and 2019, the Company did not recognize material bad-debt expense and there were no material contract assets recorded on the consolidated balance sheets as of December 31, 2020 and 2019. 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, 2020 or December 31, 2019.

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, 2020, 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 $10.2 million and $12.1 million as of December 31, 2020 and 2019, respectively. 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. As of December 31, 2020 unfulfilled performance obligations related to the Baxter Agreement are product sales totaling $7.2 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 fair value and classification of warrants, 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 is 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, 2020 and 2019, 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.

Rockwell reviews 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 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 for the years ended December 31, 2020 and 2019, respectively. Deferred revenue related to the Baxter agreement totaled $7.2 million and $9.1 million as of December 31, 2020 and 2019, respectively.

If a “Refund Trigger Event” occurs prior to December 31, 2021, Rockwell would be obligated to repay 25% of the upfront fee.

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 $0.2 million and $0.3 million during the years ended December 31, 2020 and 2019, respectively. Deferred revenue related to the Wanbang agreement totaled $2.7 million and $2.9 million as of December 31, 2020 and 2019, respectively.

On January 14, 2020, the Company entered into license and supply agreements with Sun Pharma (the "Sun Pharma Agreements"), for the rights to commercialize Triferic (dialysate) (ferric pyrophosphate citrate) in India. Under the terms of the Sun Pharma Agreements, Sun Pharma will be the exclusive development and commercialization partner for Triferic (dialysate) in India, and the Company will supply the product to Sun Pharma. In consideration for the license, the Company received an upfront fee of $0.1 million, 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 Triferic (dialysate) in India. Sun Pharma will be responsible for all clinical and regulatory approval, as well as commercialization activities. 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 $10,000 during the year ended December 31, 2020. Deferred revenue related to the Sun Pharma Agreement totaled $90,000 as of December 31, 2020.

On September 7, 2020, the Company entered into a license and supply agreements with Jeil Pharma (the "Jeil Pharma Agreements"), for the rights to commercialize Triferic (dialysate) (ferric pyrophosphate citrate) in South Korea. Under the terms of the Jeil Pharma Agreements, Jeil Pharma will be the exclusive development and commercialization partner for Triferic (dialysate) in South Korea, and the Company will supply the product to Jeil Pharma. In consideration for the license, the Company received an upfront fee of $0.2 million, and will be eligible for milestone payments and royalties on net sales. A Joint Alliance Committee, comprised of members from the Company and Jeil Pharma, will guide the development and execution for Triferic (dialysate) in South Korea. Jeil Pharma will be responsible for all clinical and regulatory approval, as well as commercialization activities. The upfront fee was recorded as deferred revenue and is being recognized as revenue based on the

agreement term. The Company recognized revenue of $2,500 during the year ended December 31, 2020. Deferred revenue related to the Jeil Pharma Agreement totaled $0.2 million as of December 31, 2020.

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 $7.1 million and $6.9 million for the years ended December 31, 2020 and 2019, respectively.

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, 2020 and 2019, 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, 2020 and 2019 were as follows:

	As of December 31,	
	2020	2019
Options to purchase common stock	6,467,956	8,598,149
Unvested restricted stock awards	146,800	146,800
Unvested restricted stock units	265,494	1,452,744
Warrants to purchase common stock	26,426,863	2,770,781
	33,307,113	12,968,474

Accumulated Other Comprehensive Income

Accumulated other comprehensive income 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 refers to revenues, expenses, gains and losses that are included in comprehensive income, but excluded from net income as these amounts are recorded directly as an adjustment to stockholders' equity. Accumulated other comprehensive income 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.

Note 4. Investments - Available-for-Sale

Investments available-for-sale consisted of the following as of December 31, 2020 and 2019 (table in thousands):

	December 31, 2020				
	Amortized Cost	Unrealized Gain	Unrealized Loss	Accrued Interest Income	Fair Value
Available-for-Sale Securities					
Bonds	$ 9,987	$ 3	$ —	$ 7	$ 9,997

	December 31, 2019				
	Amortized Cost	Unrealized Gain	Unrealized Loss	Accrued Interest Income	Fair Value
Available-for-Sale Securities					
Bonds	$ 14,238	$ 13	$ (1)	$ —	$ 14,250

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, 2020 and 2019, 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 50% of our sales in 2020 and 49% of our sales in 2019. Our accounts receivable from this customer were $1.1 million and $1.2 million as of December 31, 2020 and 2019, respectively.

In October 2014, we entered into the Distribution Agreement with Baxter, which was amended in June 2017 and March 2020, pursuant to which Baxter received exclusive distribution rights for our concentrate products in the United States, a commitment by Rockwell to maintain a specified manufacturing capacity for Baxter, a cap upon the net amount of reimbursable transportation expenses and modified extension terms. 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 2020 and 2019, our direct sales to Baxter aggregated approximately 25% and 27% of sales, respectively, and we had a receivable from Baxter of $1.6 million and $2.0 million as of December 31, 2020 and 2019, 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 9% and 11% of our total sales in 2020 and 2019, respectively. One international customer, Nipro Medical Corporation, accounted for 7% and 9% of our sales for 2020 and 2019, respectively.

Note 6. Distribution Agreement

In October 2014, we entered into the Distribution Agreement with Baxter, pursuant to which Baxter became 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”). The Amendment provides for, among other things, reduced pricing on certain accounts and incentives to Baxter to pursue new customers and increase future sales. In March 2020, we entered into the Second Amendment to the Exclusive Distribution Agreement with Baxter (the “Second Amendment”). The

Second Amendment provides for, among other things, a commitment by Rockwell to maintain a specified manufacturing capacity for Baxter, a cap upon the net amount of reimbursable transportation expenses and modified extension terms.

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, as amended by the Second Amendment, also contains provisions regarding our obligations to maintain specified manufacturing capacity and quality levels. We continue to manage customer service, transportation and certain other functions for our current customers. For customer service, Baxter pays us an amount equal to our related costs plus a slight mark-up for these services. For transportation costs, Baxter pays us an amount equal to our related costs, subject to the defined caps contained within the Second Amendment, which are based upon defined percentages of liquid concentrate product being shipped.

The Distribution Agreement also provides that, upon the mutual determination of us and Baxter, Baxter will pay us up to $10 million to build a new manufacturing facility in the Pacific time-zone that would serve customers in the western United States. The fee payable in connection with construction of 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 in October 2014. If a "Refund Trigger Event" occurs prior to December 31, 2021, we would be obligated to repay 25% 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. 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 $2.0 million and $2.1 million for the years ended December 31, 2020, and 2019, respectively.

The Distribution Agreement may be extended for 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, 2020 and 2019 are as follows (table in thousands):

	December 31, 2020	December 31, 2019
Raw Materials	$ 3,112	$ 2,471
Work in Process	172	185
Finished Goods	1,805	1,432
Total	$ 5,089	$ 4,088

As of December 31, 2020 and 2019, we classified $1.2 million and $0.4 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, 2020 and 2019, we had total Triferic inventory aggregating $3.9 million and $3.5 million respectively, against which we had reserved $2.6 million and $2.8 million, respectively.

For the year ended December 31, 2020, the Company's inventory reserves and write-offs decreased overall by $0.1 million, which consisted primarily of an increase in inventory reserve of $0.3 million offset by a reduction to inventory reserve of $0.4 million related to destruction of Triferic inventory. For the year ended December 31, 2019, inventory reserves and write-offs increased by $1.3 million.

The $1.3 million net value of Triferic inventory consisted of $0.1 million of Triferic (dialysate) finished goods with expiration dates ranging from May 2021 to September 2021, $0.3 million of Triferic API with estimated useful lives extending through 2023, and $890,000 of Triferic raw material with an estimated useful live of 25 years.

Note 8. Property and Equipment

As of December 31, 2020 and 2019, the Company's property and equipment consisted of the following (table in thousands):

	2020	2019
Leasehold Improvements	$ 1,196	$ 1,162
Machinery and Equipment	5,475	4,673
Information Technology & Office Equipment	1,831	1,810
Laboratory Equipment	676	653
	9,178	8,298
Accumulated Depreciation	(6,536)	(5,865)
Net Property and Equipment	$ 2,642	$ 2,433

Depreciation expense during the years ended December 31, 2020 and 2019 is as follows (table in thousands):

	2020	2019
Depreciation expense	$ 834	$ 788

Note 9. Goodwill and Intangible Assets

Total goodwill was $0.9 million at December 31, 2020 and 2019. We completed our annual impairment tests as of December 31, 2020 and 2019, and determined that no adjustment for impairment of goodwill was required during the years ended December 31, 2020 and 2019.

Note 10. Accrued Liabilities

Accrued liabilities as of December 31, 2020 and 2019 consisted of the following (table in thousands):

	2020	2019
Accrued Research & Development Expense	$ 232	$ 283
Accrued Compensation and Benefits	2,500	1,108
Accrued Unvouchered Receipts	755	1,901
Accrued Workers Compensation	395	195
Other Accrued Liabilities	1,131	1,031
Total Accrued Liabilities	$ 5,013	$ 4,518

Note 11. Stockholders' Equity

Preferred Stock

As of December 31, 2020 and 2019, 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, 2020 and 2019, there were 170,000,000 shares of common stock, $0.0001 par value per share, authorized and 93,573,165 and 65,378,890 shares issued and outstanding, respectively.

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.

During the year ended December 31, 2020, no vested employee stock options were exercised.

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.

During the year ended 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. For the year ended December 31, 2020, the Company sold 1,128,608 of shares of its common stock pursuant to the Sales Agreement for gross proceeds of $2,325,478, at a weighted average selling price of approximately $2.06. The Company paid $63,000 in commissions and offering fees related to the sale of common stock. As of December 31, 2020, approximately $32.3 million remains available for sale 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 Offerings of Common Stock

On February 4, 2020, the Company entered into an underwriting agreement with Cantor Fitzgerald & Co., as underwriter, pursuant to which the Company agreed to issue and sell an aggregate of up to 3,670,212 shares of its common stock, which included 478,723 optional shares that may be sold pursuant to an over-allotment option granted to the underwriters. On February 6, 2020, the Company closed the sale of 3,191,489 shares of its common stock at the public offering price of $2.22 per share (the "Offering").

On February 19, 2020, the underwriter exercised its over-allotment option to purchase an additional 478,723 shares at a price of $2.22 per share, which closed on February 21, 2020. The Company raised a total of $8.0 million, net of issuance costs of $0.1 million, relating to the sale of the common stock in the Offering. 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 September 23, 2020, the Company entered into a Securities Purchase Agreement (the "2020 Purchase Agreement") with certain purchasers named therein, pursuant to which the Company agreed to issue and sell to several institutional and accredited investors in a registered direct offering, 21,818,544 shares of common stock and warrants to purchase up to 23,178,809 shares of common stock (the "Warrants") at a combined purchase price equal to $1.51 per share. Each Warrant is exercisable for one share of common stock at an exercise price of $1.80 per share. The Warrants are immediately exercisable and will expire on September 25, 2022.

The Company also offered to certain purchasers pre-funded warrants to purchase up to an aggregate of 1,360,265 shares of common stock (the "Pre-Funded Warrants"), in lieu of shares of common stock. The purchase price of each Pre-Funded Warrant is equal to the price at which a share of common stock is sold to the public in the offering, minus $0.001, and the exercise price of each Pre-Funded Warrant is $0.001 per share. The Pre-Funded Warrants were exercised in conjunction with the issuance of common stock under the Securities Purchase Agreement. The Company received gross proceeds of approximately $35.0 million in connection with the offering, before deducting placement agent fees and related offering expenses of approximately $2.3 million.

A holder (together with its affiliates) may not exercise any portion of the Warrant to the extent that the holder would own more than 9.99% (or, at the holder's option upon issuance, 4.99%) of the Company's outstanding common stock immediately after exercise, as such percentage ownership is determined in accordance with the terms of the Warrant or Pre-Funded Warrant.

The Company agreed to pay H.C. Wainwright & Co., LLC (the "Placement Agent") a cash fee of 6% of the aggregate gross proceeds raised in the offering, minus $0.4 million payable by the Company to a financial advisory firm for services related to the offering.

In addition, the Company agreed to pay the Placement Agent (i) 6% of the aggregate gross proceeds to be received, if any, from the cash exercise of any Warrants through December 25, 2021 and (ii) 4.0% of the aggregate gross proceeds to be received, if any, from the cash exercise of any Warrants subsequent to December 25, 2021. The Company also agreed to pay the Placement Agent non-accountable expenses of $50,000 as well as $12,900 for the clearing fees of the Placement Agent in connection with the offering.

The Company has accounted for the common stock for the 2020 Purchase Agreement as equity on the accompanying consolidated balance sheets as of December 31, 2020. The amount allocated to common stock was $26.1 million. This allocation is equal to the total proceeds of $35.0 million less the amount allocated to Warrants of $8.9 million and is also net of the direct and incremental costs associated with the 2020 Purchase Agreement of $2.3 million. The Black-Scholes pricing model was used to calculate the value of Warrants relating to the 2020 Purchase Agreement.

Restricted Common Stock

During the year ended December 31, 2020, 988,958 shares of performance-based restricted stock and 152,097 shares of time-based restricted stock were forfeited. Forfeitures of the performance-based and time-based restricted stock were related to the resignation of Stuart Paul, former CEO, and Angus Smith, former CFO.

During the year ended December 31, 2020, 224,994 shares of common stock related to fully vested restricted stock units were delivered to officers and employees of the Company. The Company withheld 8,348 of these shares of common stock at a fair value of $18,950 to cover the employees and officer's withholding taxes related to the vesting of restricted stock units.

Note 12. 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. Initially there were 3,300,000 shares of common stock reserved for issuance under the 2018 LTIP. On May 18, 2020, at the Annual Meeting, the Company's stockholders approved the amendment and restatement of the Rockwell Medical, Inc. 2018 Long Term Incentive Plan to increase the number of shares of common stock issuable thereunder by 2,900,000 shares bringing common stock reserve for issuance up to 6,200,000 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, 2020 and 2019 as follows (table in thousands):

	Year Ended	
	2020	2019
Service based awards:		
Restricted stock awards	$ —	$ (33)
Restricted stock units	372	1,600
Stock option awards	1,491	2,300
	$ 1,863	$ 3,867
Performance based awards:		
Restricted stock units	$ (1,148)	$ 642
Stock option awards	(240)	443
	(1,388)	1,085
Total	$ 475	$ 4,952

Restricted Stock Awards

A summary of the Company's restricted stock awards during the years ended December 31, 2020 and 2019 is as follows:

	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested at January 1, 2019	146,800	$ 5.70
Unvested at December 31, 2019	146,800	$ 5.70
Unvested at December 31, 2020	146,800	$ 5.70

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, 2020, unvested restricted stock awards of 146,800 were related to performance based awards. Stock-based compensation expense of nil was recognized for both the year ended December 31, 2020 and 2019, respectively. As of December 31, 2020, 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, 2020 and 2019 is as follows:

	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested at January 1, 2019	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
Granted	208,993	2.00
Forfeited	(159,724)	4.26
Vested	(247,561)	4.30
Unvested at December 31, 2020	265,494	$ 2.60

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 0.4 million and $1.6 million was recognized during the year ended December 31, 2020 and 2019, respectively. As of December 31, 2020, the unrecognized stock-based compensation expense was $0.2 million over the next 12 months.

Performance Based Restricted Stock Units

A summary of the Company's performance based restricted stock units during the year ended December 31, 2020 and 2019 is as follows:

	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested at January 1, 2020	988,958	$ 4.48
Forfeited	(988,958)	$ 4.48
Unvested at December 31, 2020	—	$ —

	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested at January 1, 2019	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 $(1.1) million and $0.6 million for the year ended December 31, 2020 and 2019, respectively. As of December 31, 2020, there was no unrecognized stock-based compensation expense related to performance-based restricted stock units. The forfeited performance-based restricted stock awards of 988,958 is due to the resignation of the Company's former President and Chief Executive Officer, Stuart Paul, on April 17, 2020 and the resignation of the Company's former Chief Financial Officer, Angus Smith, effective July 3, 2020. These forfeited awards reduced stock-based compensation expense for the year ended December 31, 2020 by $1.4 million.

Service Based Stock Options

The fair value of the service based stock options granted for the years ended December 31, 2020 and 2019 were based on the following assumptions:

	December 31,	
	2020	2019
Exercise price	$0.92 - $2.90	$1.91 - $6.55
Expected stock price volatility	68.2% - 75.8%	67.5% - 70.3%
Risk-free interest rate	0.31% - 1.70%	1.40% - 2.60%
Term (years)	5.5 - 6.0	3.4 - 6.5

A summary of the Company's service based stock option activity for the years ended December 31, 2020 and 2019 is as follows:

	Shares Underlying Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value *(in $1,000's)*
Outstanding at January 1, 2019	7,856,480	$ 7.50	5.2	$ —
Granted	1,103,938	$ 3.37	9.0	107
Exercised	(30,000)	$ 4.93	—	
Forfeited	(720,394)	$ (6.24)	—	
Outstanding at December 31, 2019	8,210,024	$ 7.06	5.1	$ 107
Granted	2,288,386	$ 1.94	9.0	—
Exercised	—	$ —	—	
Expired	(4,249,596)	$ (8.07)	—	
Forfeited	(530,858)	$ (3.88)	—	
Outstanding at December 31, 2020	5,717,956	$ 4.55	6.6	$ —
Exercisable at December 31, 2020	2,898,104	$ 6.85	3.9	$ —

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, 2020 and 2019, the service based stock options granted consisted of 2,288,386 and 1,103,938 options granted to employees, respectively. As of December 31, 2020, 2,898,104 vested options were exercisable at a weighted average price of 6.85 per share.

During the year ended December 31, 2020 and 2019, stock-based compensation expense of $1.5 million and $2.3 million was recognized, respectively. As of December 31, 2020, total stock-based compensation expense related to 2,819,582 unvested options not yet recognized totaled approximately $2.2 million over the next 2.2 years.

Performance Based Stock Options

A summary of the performance based stock options granted for the year ended December 31, 2020, is as follows:

	Number of Shares	Weighted Average Exercise Price
Outstanding at January 1, 2019	388,125	$ 4.70
Outstanding at December 31, 2019	388,125	$ 4.70
Granted	750,000	$ 2.20
Forfeited	(388,125)	$ (4.70)
Outstanding at December 31, 2020	750,000	$ 2.20
Exercisable at December 31, 2020	—	$ —

Stock-based compensation expense recognized for performance-based stock options was $(0.2) million and $0.4 million for the year ended December 31, 2020 and 2019. As of December 31, 2020, the unrecognized stock-based compensation expense related to unvested performance-based stock options was $0.2 million. The forfeited unvested performance-based stock options of 388,125 is due to the resignation of the Company's former President and Chief Executive Officer, Stuart Paul, on April 17, 2020. These forfeited options reduced stock-based compensation expense by $0.7 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.

The fair value of the performance-based stock options granted for the year ended December 31, 2020 were based on the following assumptions:

Expected stock price volatility	74.4%
Risk-free interest rate	0.4%
Dividend yield rate	—
Term (years)	5.7

Note 13. 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, a former Officer of the Company (see Note 18). 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 paid all four of the quarterly installments totaling $1.0 million and accrued $0.1 million for the reimbursement of certain legal expenses during the year ended December 31, 2019. As of December 31, 2020, the Company has fulfilled its reimbursement obligation of certain legal expenses and accrued $0.1 million relating to certain IP reimbursement expenses and certain sublicense royalty fees 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 potential milestone payments are not yet considered probable, and no milestone payments have been accrued at December 31, 2020.

Director Compensation

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, 2020 and 2019 was $225,000 and $202,500, respectively. The Advisory Committee disbanded in May 2020.

Note 14. 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 2025, and a 57,000 square foot facility in Greer, South Carolina under a lease expiring February 2023. In addition, we occupy 4,100 square feet of office space in Hackensack, New Jersey under a lease expiring on July 1, 2024. This lease is currently being offered for sublease.

The following summarizes quantitative information about the Company's operating leases (dollars in thousands):

	For the year ended December 31, 2020	For the year ended December 31, 2019
Operating leases		
Operating lease cost	$ 1,609	$ 2,076
Variable lease cost	488	318
Operating lease expense	2,097	2,394
Finance leases		
Amortization of right-of-use assets	18	—
Interest on lease obligations	5	—
Finance lease expense	23	—
Short-term lease rent expense	17	17
Total rent expense	$ 2,137	$ 2,411
Other information		
Operating cash flows from operating leases	$ 1,648	$ 2,015
Operating cash flows from finance leases	$ 5	$ —
Financing cash flows from finance leases	$ 17	$ —
Right of use assets exchanged for operating lease liabilities	$ 268	$ 5,077
Right of use assets exchanged for finance lease liabilities	$ 930	$ —
Weighted-average remaining lease term - operating leases	2.3	1.9
Weighted-average remaining lease term – finance leases	5.8	0
Weighted-average discount rate - operating leases	6.4 %	6.8 %
Weighted-average discount rate – finance leases	5.1 %	— %

Future minimum rental payments under operating lease agreements are as follows (table in thousands):

	Operating	Finance
Year ending December 31, 2021	$ 1,131	$ 176
Year ending December 31, 2022	668	179
Year ending December 31, 2023	314	181
Year ending December 31, 2024	118	178
Year Ended December 31, 2025	6	176
Year Ended December 31, 2026	—	163
Total	2,237	1,053
Less present value discount	$ (162)	$ (140)
Operating and Finance lease liabilities.	$ 2,075	$ 913

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 $602,354 in aggregate coverage for the policy year ending July 1, 2021. The total amount at December 31, 2020 by which retention limits exceed the claims paid and accrued is approximately $479,000 for the policy year ending July 1, 2020. Estimated loss and additional future claims of approximately $395,000 have been reserved and accrued for the year ended December 31, 2020.

As of December 31, 2020, approximately $0.3 million was held in cash collateral and escrow by the insurance carrier for workers' compensation insurance. At December 31, 2020, 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, 2021 of approximately $25.5 million, which include $23.8 million for concentrate manufacturing and $1.7 million in ancillary supplies.

Demand Notice

In February 2020, the Company received a letter from a supplier relating to a supply agreement entered into with the Company in 2015. 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. While the Company believed it had several defenses to the supplier's claim, the Company and the supplier negotiated an amicable resolution of the dispute. On July 31, 2020, the Company and the supplier entered into a settlement agreement, which released the Company from any penalties relating to annual minimums under the 2015 agreement, established new minimums under an amended supply agreement and required the Company to pay for certain raw materials with 50% of the cost to be paid upon execution of the settlement agreement and the remaining 50% to be paid no later than December 31, 2020. As of December 31, 2020, the Company has performed all required obligations under the settlement agreement.

Litigation

SEC Investigation

As a follow up to certain prior inquiries, the Company received a subpoena from the SEC during the Company's quarter ended September 30, 2018 requesting, among other things, certain information and documents relating to the status of the Company's request to the Centers for Medicare & Medicaid Services (the "CMS") for separate reimbursement status for Triferic (dialysate), the Company's reserving methodology for expiring Triferic inventory, and the basis for the Board's termination of the former Chief Executive Officer, Robert Chioini, and former Chief Financial Officer, Thomas Klema, in 2018. 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 "Too Complaint"). The Too 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 Too 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 Too Complaint alleges that defendants filed reports with the SEC that contained purported inaccurate and misleading statements regarding the potential for the Company's drug, Triferic, to quality for separate reimbursement status by the CMS.

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"). 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 CMS 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.

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. This resulted in a settlement expense of approximately $0.4 million for the year ended December 31, 2019. Of the Settlement Amount, the Company contributed approximately $0.1 million, which represented the remaining retention amount under the Company’s director and officer liability insurance policy as of December 31, 2020. The remainder of the settlement amount was funded by the Company’s director and officer insurance carrier. 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 were consolidated.

The Company tendered the above shareholder derivative actions to its director and officer insurance carrier(s) for defense and indemnity under its applicable insurance policies. On May 18, 2020, the Company, the Individual Defendants and the Plaintiffs (the "Settling Parties") entered into a formal Stipulation of Settlement, which memorializes the terms of the Settling Parties' settlement of the Derivative Complaints. A hearing occurred before the court on August 10, 2020 and the court issued a final order approving the settlement. The Company's director and officer insurance carrier has funded the settlement on behalf of the Company.

Note 15. 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 ("Innovatus"), as collateral agent and the lenders party thereto, pursuant to which Innovatus, as a lender, agreed to make certain term loans to the Company in the aggregate principal amount of up to $35.0 million (the "Term Loans"). Funding of the first $22.5 million tranche was completed on March 16, 2020. The Company is no longer eligible to draw on a second tranche of $5.0 million, which was tied to the achievement of certain milestones by a specific date. The Company may be eligible to draw on a third tranche of $7.5 million upon the achievement of certain additional milestones, including the achievement of certain Triferic sales thresholds. Net draw down proceeds were $21.2 million with closing costs of $1.3 million.

The Company is entitled to make interest-only payments for thirty months, or up to thirty-six months if certain conditions are met. The Term Loans will mature on March 16, 2025, and will bear interest at the greater of (i) Prime Rate (as defined in the Loan Agreement) and (ii) 4.75%, plus 4.00% with an initial interest rate of 8.75% per annum and an effective interest rate of 10.90%. The Company has 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. For the year ended December 31, 2020, interest expense amounted to $1.6 million.

The Loan Agreement is secured by all assets of the Company and Rockwell Transportation, Inc. Proceeds will be used for working capital purposes. The Loan Agreement contains customary representations and warranties and covenants, subject to customary carve outs, and includes financial covenants related to liquidity and trailing twelve months sales of Triferic, with the latter beginning with the period ending December 31, 2020. We cannot assure you that we can maintain compliance with the covenants under our Loan Agreement, which may result in an event of default. Our ability to comply with these covenants may be adversely affected by events beyond our control. For example, the Loan Agreement contains certain financial covenants relating to sales and, as a result of the ongoing COVID-19 pandemic and its effect on our sales activities, among other factors, we may not be able to satisfy such covenants in the future. Based on our Triferic sales for the year ended December 31, 2020, we did not satisfy this covenant as of December 31, 2020. The Company utilized the cure provision to regain compliance,

which Innovatus accepted. As of December 31, 2020, the Company is in compliance with all the reporting and financial covenants.

In connection with each funding of the Term Loans, the Company is required to issue to Innovatus a warrant (the "Warrants") to purchase a number of shares of the Company's common stock equal to 3.5% of the principal amount of the relevant Term Loan funded divided by the exercise price, which will be based on the lower of (i) the volume weighted average closing price of the Company's stock for the 5-trading day period ending on the last trading day immediately preceding the execution of the Loan Agreement or (ii) the closing price on the last trading day immediately preceding the execution of the Loan Agreement (or for the second and third tranches only at the lower of (i) $1.65 per share or (ii) the volume weighted average closing price of the Company's stock for the 5-trading day period ending on the last trading day immediately preceding the relevant Term Loan funding). The Warrants may be exercised on a cashless basis and are immediately exercisable through the seventh anniversary of the applicable funding date. The number of shares of common stock for which each Warrant is exercisable and the associated exercise price are subject to certain proportional adjustments as set forth in such Warrant. In connection with the first tranche of the Term Loans, the Company issued a Warrant to Innovatus, exercisable for an aggregate of 477,273 shares of the Company's common stock at an exercise price of $1.65 per share. The Company evaluated the warrant under ASC 470, Debt, and recognized an additional debt discount of approximately $0.5 million based on the relative fair value of the base instruments and warrants. The Company calculated the fair value of the warrant using the Black-Scholes model.

As of December 31, 2020, the outstanding balance of the Term Loan was $20.9 million, net of unamortized issuance costs and unaccreted discount of $1.6 million.

The following table reflects the schedule of principal payments on the Term Loan as of December 31, 2020 (in thousands):

Year	Principal Payments
2021	$ —
2022	2,250
2023	9,000
2024	9,000
2025	2,250
	$ 22,500

Note 16. Income Taxes

A reconciliation of income tax expense at the statutory rate to income tax expense at our effective tax rate is as follows (dollars in thousands):

	2020	2019
Tax Expense (Benefit) Computed at 22.67% and 22.79% of Pretax Income (Loss)	$ (6,373)	$ (7,780)
Changes in Tax Laws	—	—
Foreign Income Tax Expense	—	—
Effect of Change in Valuation Allowance	6,373	7,780
Total Income Tax Expense	$ —	$ —

The details of the net deferred tax asset are as follows (dollars in thousands):

	December 31,	
	2020	2019
Deferred tax assets:		
Net Operating Loss Carryforward	$ 59,586	$ 52,935
Stock Based Compensation	7,582	7,514
Deferred Revenue	2,310	2,752
General Business Credit	6,872	6,872
Accrued Expenses	185	280
Inventories	666	866
Book over Tax Depreciation	25	18
Other Deferred Tax Assets	387	22
Total Deferred Tax Assets	77,613	71,259
Deferred Tax Liabilities:		
Goodwill & Intangible Assets	155	136
Prepaid Expenses	294	332
Total Deferred Tax Liabilities	449	468
Subtotal	77,164	70,791
Valuation Allowance	(77,164)	(70,791)
Net Deferred Tax Asset	$ —	$ —

The Tax Cuts and Jobs Act of 2017 ("TCJA") impacted how net operating losses are utilized. The Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") temporarily suspends the TCJA limitation, allowing a net operating loss carryforward to fully offset taxable income in tax years beginning before January 1, 2021. The CARES Act also temporarily reinstated a carryback period for all net operating losses generated in years beginning after December 31, 2017 and before January 1, 2021. The carryback period for those years is five years under the CARES Act.

Deferred tax assets result primarily from net operating loss carryforwards. For federal tax purposes, we have net operating loss carryforwards of approximately $262.9 million that expire between 2021 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, 2020, and 2019. While we anticipate generating income within the next year or two, we expect to incur operating losses until our drug products are marketed and generating sufficient profits to offset our operating expenses. Considered together with our limited history of operating income and our net losses in 2020 and 2019, management has placed a full valuation allowance against the net deferred tax assets as of December 31, 2020 and 2019. 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 $4.2 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, 2020 and 2019. We have not been under tax examination in any jurisdiction for the years ended December 31, 2020 and 2019. Tax examination years of 2016 to 2019 remain open.

Note 17. Subsequent Events

Effective January 19, 2021, as authorized by the Board of Directors of Rockwell Medical, Inc., the Company terminated the employment of Ajay Gupta, M.D. as the Company's Chief Scientific Officer.

ROCKWELL MEDICAL, INC.

Corporate Information

Annual Meeting

The Annual Meeting of the Stockholders will be held:

Thursday June 17, 2021
At 10:00 am ET
Virtual Stockholder Meeting
www.virtualshareholdermeeting.com/RMTI2021

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, 2020 is available upon written request to:

Investor Relations
Rockwell Medical, Inc.
30142 Wixom Road
Wixom, MI 48393

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".

2020 ANNUAL REPORT

www.rockwellmed.com