2021 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, 2021

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 Capital 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, 2021 (computed by reference to the closing sales price of the registrant's Common Stock as reported on The Nasdaq Capital Market on such date) was $29,007,276.

Number of shares outstanding of the registrant's Common Stock, par value $0.0001, as of April 6, 2022: 93,986,470 shares.

Documents Incorporated by Reference

Portions of the registrant's definitive Proxy Statement pertaining to the 2022 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, 2021, 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 ability to continue as a going concern; 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:

- any further increases in raw material, labor, fuel or other input costs, particularly if we are unable to pass these cost increases along to our customers;
- the duration over which our cash balances will fund our operations;
- our ability to continue as a going concern;
- our ability to obtain additional financing and raise capital as necessary to fund operations or pursue business opportunities;
- our expectations regarding our ability to enter into marketing and other partnership agreements, including amendments to our existing agreements;
- our ability to comply with affirmative and negative covenants under our secured loan with Innovatus;
- 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 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 comply with the covenants included in the Products Purchase Agreement, as amended; 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 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 2022 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.

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.

OVERVIEW OF 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, 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 market both products to kidney dialysis centers for their patients receiving dialysis. In late 2021, we filed an IND with the United Stated Food and Drug Administration ("FDA") with the goal to advance our FPC platform strategy by conducting 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 infused medications 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.

At Rockwell Medical, we are dedicated to enhancing the currently sub-optimal 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 bioavailable 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 in clinical trials.

Iron deficiency can develop into a serious medical condition that is often overlooked and undertreated in several illnesses. 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.

We are the second largest supplier of hemodialysis concentrates in the United States, with a reputation for excellent service, quality, and reliability. We believe this reputation, which is based on over 25 years of service to kidney dialysis centers, combined with approximately $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.

STRATEGY

Dialysis Business:

We are one of the two major suppliers of hemodialysis concentrates in the United States. Over the past 25 years we 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.

We believe that the Company 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 supply chain disruptions due to recent natural disasters, in which our team has been challenged by hurricanes, flooding and freezing, while still meeting production demands. During the recent shortage in dialysis concentrates, the Company was able to fill the supply gaps for many clinics because they had not received deliveries of certain products from other suppliers.

We believe that our dialysis business in concentrates and our opportunities with FPC technology are synergistic. We scaled back our commercial organization in 2021, but we are working to maintain our current customer base in the United States while we seek a commercialization partner. We are also seeking to partner with established local and regional pharmaceutical companies for regulatory approval and commercialization in markets outside of the United States.

Despite our market position, we believe that our growth opportunities for our concentrates business and Triferic in the US dialysis market are challenged by the consolidated ownership of dialysis clinics, a capitated reimbursement model and the demographics of the dialysis patient population. The two largest dialysis organizations treat approximately 72% of the patients in the United States. One manufactures its own concentrates and IV iron, and we have an existing agreement to supply concentrates to the other. Through our partnership with Baxter Healthcare Corporation, a subsidiary of Baxter International, Inc. ("Baxter"),we currently supply concentrates to a significant percentage of the small and medium sized independent dialysis organizations. In a sector like 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 for dialysis treatment, market adoption became more dependent on the generation of these data, which were not required for the drug's approval by the FDA.

Notwithstanding the growth limitations mentioned above, we continue to believe that Triferic has the potential to be an important option for the maintenance of hemoglobin in dialysis patients. To this end, we have continued 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 are seeking a partner to help us further commercialize Triferic.

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 and to fully recoup manufacturing and shipping expenses so that this business has the potential to be profitable. To date, our concentrates business has operated at a loss, with the loss accelerating recently as inflationary pressures have increased our manufacturing and operating costs, while we have limited ability to pass these costs along to certain customers. We have undertaken discussions with our largest customers to renegotiate our existing supply contracts in an effort to improve the profitability of this business line. On April 6, 2022, we entered into a strategic arrangement with our long-time partner, DaVita, Inc. ("DaVita"), a leading provider of kidney care, to

allow the Company to stabilize its concentrates business. The strategic intent of this agreement is to make sure Rockwell Medical is on stable financial footing because it is one of the two major suppliers of dialysis concentrates in the U.S. The amended agreement provides a stronger financial arrangement, encompassing pricing, cost sharing and joint efforts in supply chain improvement and cost cutting, with the goal of having the Company's concentrates business operate profitably in the future. In addition to the amended agreement, DaVita entered into an agreement pursuant to which it will invest up to $15 million in preferred stock in two equal tranches. The first tranche of $7.5 million was funded on April 7, 2022. The second $7.5 million tranche is to be funded subject to the Company raising $15 million additional capital by June 30, 2022. We are also in discussions with our other major customer to renegotiate certain terms of that agreement. In addition, 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 strategy is to go beyond our foundational business in dialysis by leveraging the efficacy and safety data from Triferic in new therapeutic settings. Subject to having sufficient capital resources, we are planning to develop an FPC-based therapeutic for iron deficiency to be delivered in the home infusion setting. The number of patients served by home infusion therapy grew 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 accelerated by 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. We believe, based on our data from 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 further feedback received in December 2021 from the FDA, we have made plans to initiate a Phase 2 clinical study in home infusion patients with iron deficient anemia to confirm the dose and duration of FPC treatment. We expect to commence this study in 2022, subject to having sufficient working capital to fund this study, and would expect to have top-line data from the trial approximately 12-18 months following commencement of the study (see Clinical Pipeline below).

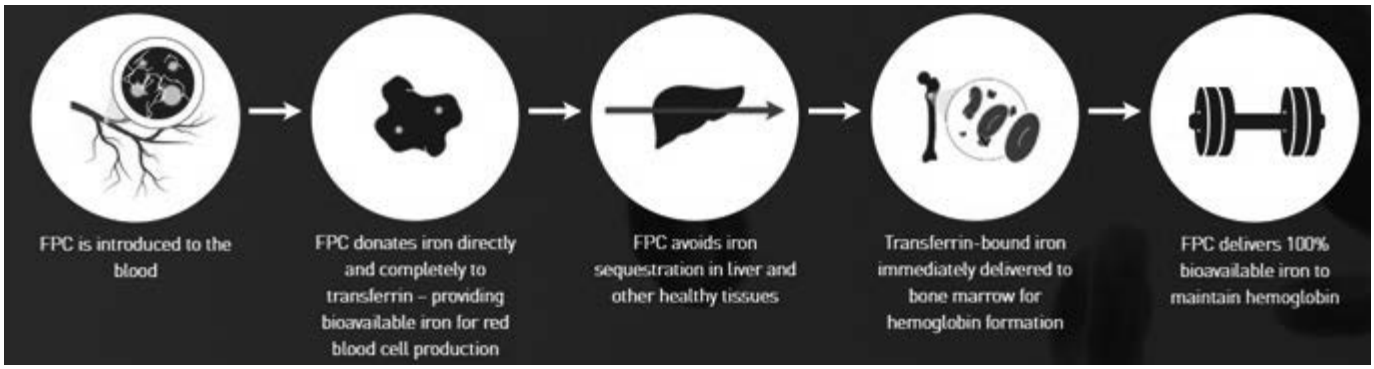
Pipeline Development

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.

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 1.6 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.

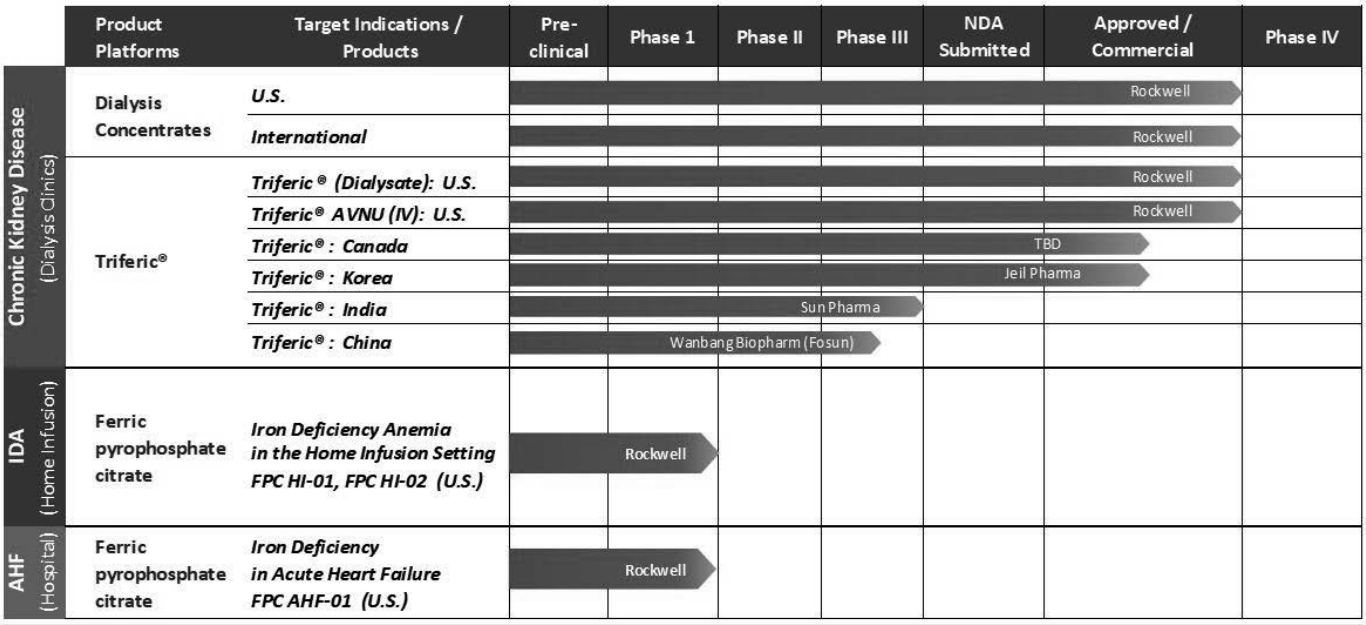
FPC has demonstrated an excellent safety profile. No reported instances of anaphylaxis or hypersensitivity events have been received during more than 1.2 million doses administered. Triferic may be administered even to patients with history of allergic reactions to IV iron.

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

PRODUCTS

Pipeline

We currently sell Triferic, Triferic AVNU and our dialysis concentrates portfolio of products. We partner with 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 2021, we estimate that we supplied approximately 27% of the United States domestic market with dialysis concentrates, with the majority of our sales in the United States. We also supply dialysis concentrates to distributors serving a number of foreign countries, primarily in the Americas and the Pacific Rim.

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 acid descale, filtration salts and other supplies used by hemodialysis providers.

Our Triferic Portfolio

Triferic

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 medical 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 facilitate 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 routinely occurring 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 we believe that 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. We scaled back our commercial organization in 2021, but we are working to maintain our current customer base in the United States while we seek a commercialization partner.

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)

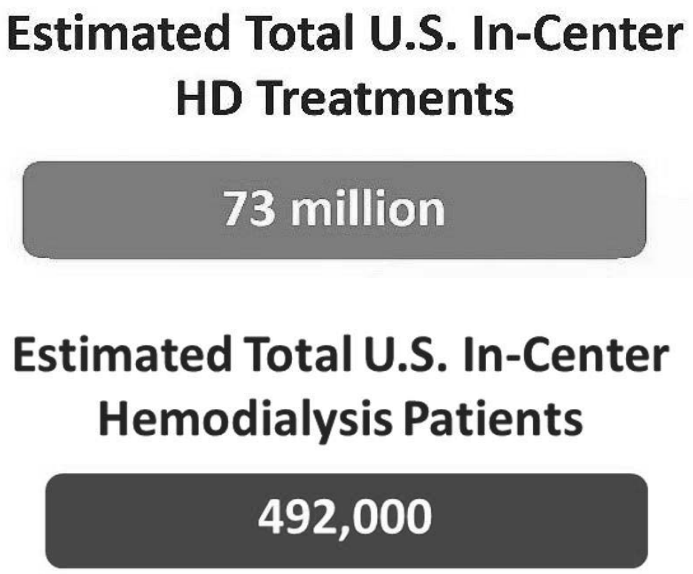
We also developed Triferic AVNU, an IV formulation of Triferic, for use by hemodialysis patients in the United States as well as international markets. Triferic AVNU was approved by the FDA on March 27, 2020. Triferic AVNU can be administered to any hemodialysis patient regardless of the type of bicarbonate 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. Triferic AVNU is not eligible for add-on reimbursement and is reimbursed within the "bundle," as with Triferic (dialysate).

MARKETING, SALES AND INTERNATIONAL

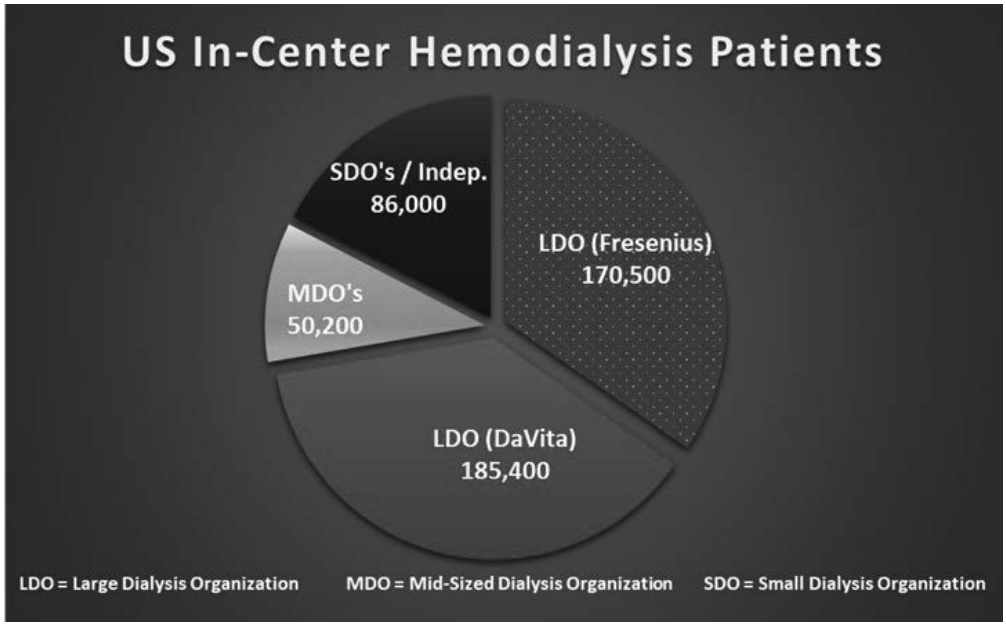
Market Opportunity

Hemodialysis

The United States dialysis market is currently the largest market in the world for dialysis products. As of the end of 2019, there were an estimated 566,600 patients treated with some form of dialysis.



Hemodialysis is the primary treatment modality for ESKD employed in the United States, with approximately 87% of all dialysis patients receiving in-center hemodialysis. There were an estimated 492,000 in-center hemodialysis patients in the United States in 2019, representing approximately 74 million treatments annually. We do not currently compete in the other two segments, peritoneal dialysis, representing approximately 11% 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.



According to international data collected by the United States Renal Data System ("USRDS"), the global ESKD population receiving some form of treatment was estimated to be approximately 2.7 million patients at the end of 2019 with an average yearly growth rate over the previous 10 years of 7.4%. 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 prevalent ESKD patient population in the United States has grown steadily over the past several decades, with an average yearly growth rate of >3% from 2009 - 2019. Growth rates slowed in 2020 and 2021 due to an increase in deaths associated with the COVID-19 pandemic, however we expect a more typical growth rate of approximately 3% per year to resume in 2022 and persist over the next several years. The Asia-Pacific region 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 majority of hemodialysis patients receive dialysis treatment three times per week, or approximately 153 times per year. Most patients who have their dialysis treatment performed at a free-standing clinic have permanent loss of kidney function. These are commonly referred to as “chronic” dialysis patients. Patients that undergo dialysis in hospitals for temporary loss of kidney function are typically referred to as “acute” dialysis patients. The small percentage of chronic dialysis 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 iron overload in tissues caused by high doses of macromolecular IV iron over time may lead to complications and introduce risk to a dialysis patient's long-term health. Furthermore, the carbohydrate moiety in IV iron complexes is thought to be responsible for anaphylactic reactions occasionally seen with clinical use.

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 (food or supplements delivered through a “feeding tube” or via intravenous delivery). 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 Foundation ("NHIF") report 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.

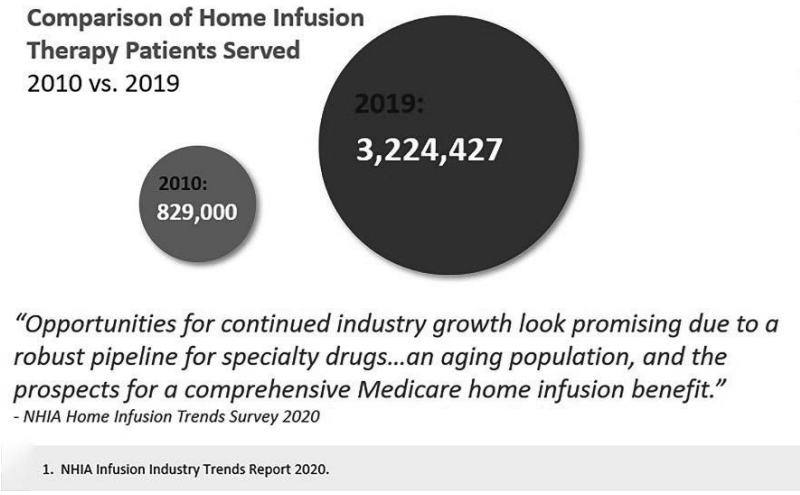
The technological advances that enabled safe and effective administration of infusion therapies in the home, the desire of patients to resume normal lifestyles and work activities while recovering from illness, and the cost-effectiveness of home care are important. Consequently, home infusion therapy 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 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, driven by: (1) high rates of patient demand, and satisfaction with services, (2) site of care optimization programs driven 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.

The following home infusion therapies are provided to patients for the treatment of diseases that may be associated with a risk of iron deficiency anemia. Applicability of FPC will depend on length of therapy, prevalence of iron deficiency, and acceptability of alternative therapies such as traditional IV iron loading or oral iron.

Home Infusion Therapy	Total # of Patients Treated Annually[1]	Estimated % Iron Deficient / FPC Eligible
Home parenteral nutrition	113,000	~50%[2]
Hydration therapy	160,000	at increased risk
Inotropes	86,000	~50%[4,6]
Chemotherapy	111,000	~17%[3]
Anti-infectives	1,400,000	at increased risk
Biologics	160,000	~10%[5]

1. NHIA Infusion Industry Trends Report 2020.
2. Hwa YL, Rashtak S, Kelly DG, and Murray JA. Iron deficiency in long-term parenteral nutrition therapy. JPEN 2015.
3. Busti E, et al. Anemia and iron deficiency in cancer patients. Role of iron replacement therapy. Pharmaceuticals 2018, 11, 94
4. Beale A, et al. Iron Deficiency in Acute Decompensated Heart Failure. J. Clin. Med. 2019, 8, 1569.
5. Kaitha S, et al. Iron deficiency anemia in inflammatory bowel disease. World J Gastrointest Pathophysiol. 2015. 6(3):62-72.
6. von Haehling S, et al. Iron Deficiency in Heart Failure. JACC. 2019. 7(1):36-46.

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. The NHIF estimates 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 36% 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 or unwanted side effects. We believe that the inadequacy and burden of current treatments presents an opportunity for our FPC pipeline.

We believe FPC may be 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 in hemodialysis patients.

- 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. 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.

The Products Purchase Agreement with DaVita provided for an increase in the product sale prices relative to the prices charged for products under the previous agreement with DaVita. On April 6, 2022, we entered into an amendment to the Products Purchase Agreement under which we agreed to a price increase, effective May 1, 2022, as well as the pass-through of certain costs, determined on a quarterly basis. Certain costs are subject to a cap. The Amendment will provide us with the potential to operate the concentrates business profitably in the future, subject to cost containment activities to be undertaken by the Company.

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 Distribution Agreement.

Dialysate concentrates accounted for approximately 98.3% of our 2021 revenue. Approximately 89.4% of our 2021 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 and are currently searching for a commercial partner within the United States to continue the commercialization these products into the market.

Triferic (dialysate). We significantly scaled back our field-based sales team that supported the commercialization of Triferic (dialysate) in the United States in August 2021.

Our initial target customers included selected medium and small sized dialysis chains and independent dialysis centers. The launch of Triferic (dialysate) 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 approximately 74% of the patients. The dialysis procedure, including all inputs, is reimbursed under capitated reimbursement model at a fixed rate. 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 an important option for the maintenance of hemoglobin in dialysis patients. To this end, we have increased our efforts in generating real world data in clinics with current protocols, which we believe can help with the adoption of Triferic as these results are created and disseminated over time. We are also seeking a commercialization partner that can help us market Triferic on a larger scale.

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 increase sales of our products throughout the world. To date, we have established partnerships in China, India, Korea, Turkey, 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 is currently 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) in India 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, continues to 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. In January 2022, Jeil received approval by the Ministry of Food and Drug Safety (MFDS) of the Republic of Korea for formulations: Triferic Injection (AVNU) and Triferic Dialysate with the goal of being able to commercially launch Triferic AVNU in 2022.

Turkey:

In 2021 Drogsan Pharmaceuticals, a leading pharmaceutical company in Turkey, entered into an exclusive license agreement with Rockwell Medical for the rights to commercialize Triferic AVNU in Turkey. The agreement also allows for Drogsan to negotiate further geographic expansion into the surrounding region. Drogsan submitted their application for Triferic AVNU in January 2022.

Canada:

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. In 2021 we terminated our distribution agreement with our commercial partner in Canada. We are now seeking a new commercialization partner in that market.

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 Latin American region; however, we also sell through distributors and directly to dialysis clinics.

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 47% of our concentrate sales in 2021 and 50% of our concentrate sales in 2020. Our accounts receivable from this customer were $1.0 million and $1.1 million as of December 31, 2021 and 2020, respectively. In August 2019, we signed a new Products Purchase Agreement with DaVita, with an initial term expiring on December 31, 2023. On April 6, 2022, we entered into an amendment to the Products Purchase Agreement under which we agreed to a price increase, effective May 1, 2022, as well as the pass-through of certain costs, determined on a quarterly basis. Certain costs are subject to a cap. The Amendment will provide us with the potential to operate the concentrates business profitably in the future, subject to cost containment activities to be undertaken by the Company.

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 were assigned to Baxter. As a result, for 2021 and 2020, our direct sales to Baxter aggregated approximately 26% and 25% of sales, respectively, and we had accounts receivable from Baxter of $3.5 million and $1.6 million as of December 31, 2021 and 2020, respectively.

Another customer, Nipro Medical Corporation, accounted for 8% and 7% of our sales in 2021 and 2020, 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 10% and 9% of our overall sales in 2021 and 2020, 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 we do. 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 products have been used to treat iron deficiency anemia, and currently, the drug Venofer® has a 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 Injectafer® 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®. Macromolecular IV iron products are indicated for repletion therapy and not explicitly for iron maintenance therapy. 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 is intended to be administered only to treat excessively low (or absolute) iron deficiency. Accordingly, if 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

Home Infusion

The FDA has provided 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 have incorporated feedback provided by FDA from our pre-IND meeting and initial IND submission 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.

Dialysis

Triferic portfolio

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 an annual pharmacy 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 of greater than 95% while anemia targets were met. This clinic determined that the reduction of these agents resulted in a net pharmacy 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. Recruitment in this study is ongoing.

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.

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 is uniquely suited for hospitalized acute heart failure – 200mg of immediately bioavailable iron can be delivered during an average 5-day hospital stay (approximately equivalent to over 1 gram of currently available traditional macromolecular IV iron).

We expect to request advice from the FDA in second half of 2022 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. The Grapevine, TX facility is certified to ISO 13485:2016. 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 which meet or exceed the requirements of United States Pharmacopeia ("USP"). Key raw materials used in our hemodialysis concentrates include USP grade sodium chloride, calcium chloride, magnesium chloride, potassium chloride, dextrose, citric acid, glacial acetic acid, and sodium bicarbonate. Key packaging components include bottles, caps, bags, boxes, and labels. 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 operates 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 manage customer service, transportation and certain other functions. 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 would 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.

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. In addition, the Company is required to 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 Cosmetic Act (the "FD&C 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 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 selling 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.

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.

Our hemodialysis concentrate products and other ancillary devices are subject the FDA 510(k) requirements.

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, 2021, we owned or had the rights to 27 issued patents (3 U.S. and 24 foreign) and 53 pending applications (7 U.S. and 46 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	2027 - 2029 (1)	1	4 (2)	2028 (1)	26 (3)
Triferic (ESA Sparing)	—	2034	1	11 (4)	2034	20
Triferic (TPN)	1	2030	—	9 (5)	2026	—
Other	—	—	4	—	—	—
Total	3		6	24		46

1. 2029 expiration date in U.S. and 2028 expiration date in 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. Granted patents validated in 28 European states (not included in total).
3. Pending patents for solid particulate formulation for preparing dialysate, if issued, will expire in 2036.
4. One European patent validated in 3 European states (not included in total).
5. 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, 2021, 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 a performance-based merit increase and 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, mandatory mask wearing in our manufacturing plants 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.

- We have limited capital resources and will 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 been and may continue to be affected materially and adversely by increases in raw material and transportation costs and may be unable to recover certain costs due to provisions in our material contracts.
- The ongoing COVID-19 pandemic has resulted in significant disruptions to our business operations, including shortages or disruptions in labor and raw materials in our concentrates business, disruptions to the supply chain for pharmaceutical products in our clinical development programs and impacts on the commercialization of our Triferic products and our clinical trials, which could have a material adverse effect on our 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.
- Clinical drug development is a lengthy and expensive process with timelines and uncertain outcomes that may be beyond the control of the Company. Results of preclinical studies or previous clinical trials are not necessarily predictive of 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.

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 $370.1 million since inception and we expect to incur further losses for the foreseeable future. As of December 31, 2021, we had approximately $22.4 million of cash, cash equivalents and investments available-for-sale, and working capital of $14.3 million. Net cash used in operating activities for the year ended December 31, 2021 was approximately $33.5 million.

In March 2020, we 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.

Our ability to fund our activities will be dependent upon our ability to raise additional funds in a defined timeline, restructure the contract with the other major customer in our concentrates business, successfully execute on the development of the FPC platform in new indications and find a partner that can successfully commercialize and increase adoption of Triferic (dialysate) and Triferic AVNU in the United States. All of these factors are subject to significant risks and uncertainties and there can be no assurance that we will be successful in raising additional capital, restructuring our contracts, achieving approval of FPC in new indications or finding a partner to expand our Triferic franchise. If we are unable to achieve one or all of these items, we may be forced to implement cost-saving measures that may potentially have a negative impact on our activities. 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 customary representations and warranties and affirmative 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. The Loan Agreement also contains 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.

If we cannot maintain compliance with the covenants under our Loan Agreement, we may trigger 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 able to satisfy such covenants as of December 31, 2020.As such, we utilized the cure options which were accepted by Innovatus to regain compliance. In September 2021, we entered into an amendment to the Loan Agreement in which the Company, in exchange for Innovatus lowering the sales covenants, agreed to (i) prepay an aggregate principal amount of $7,500,000 in ten installments commencing on December 1, 2021; (ii) pay an additional prepayment premium of 5% on prepaid amounts if the Company elects to prepay all outstanding term loans on or before September 24, 2023 and (iii) maintain minimum liquidity of no less than $5,000,000 if the aggregate principal amount of term loans is greater than $15,000,000 pursuant to the liquidity covenant in the Loan Agreement. As of December 31, 2021, the Company was in compliance with all reporting and financial covenants, but there can be no assurance that we will be able to maintain compliance in the future.

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 of any restructuring of any of the other major contract for our concentrates business;
- the timing of securing a partner to help us commercialize Triferic in the United States;
- 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.

Because our cash is currently insufficient to meet our future operating requirements, we will have to raise additional funds and are required to do so to maintain compliance with the Products Purchase Agreement. 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. Any debt financing is limited by the terms of our Securities Purchase Agreement with DaVita, dated as of April 6, 2022, pursuant to which they invested in our convertible preferred stock. Specifically, until DaVita owns less than 50% of its investment, the Company may only incur additional debt in the form of a purchase money loan, a working capital line of up to $5 million or to refinance existing debt, unless DaVita consents.

Debt financing, if available, may involve significant cash payment obligations and covenants that restrict our ability to operate as a business. If our operations or 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 run our concentrates business, conduct planned clinical studies and pursue business opportunities, our business, results of operations, financial position and cash flows could be materially adversely affected.

Unfavorable weather or 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 U.S. and 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 or persistent inflation have and could continue to result in a variety of risks to our business, including our ability to recover our costs or to raise additional capital when needed on acceptable terms, if at all. 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.

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. We have hired executive-level employees who are leading Company initiatives, including clinical efforts. 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 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, monetary loss, 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 may become the target of litigation, which is costly and time-consuming to defend.

We have in the past been subject to litigation and it is possible that legal proceedings could be brought against us in the future. Litigation can be costly and time-consuming and 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.

Our business could be impacted as a result of actions by activist stockholders, 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 Stockholders, 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 stockholders. 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 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 stockholders or the ultimate impact on our business, results of operations, financial position and cash flows.

RISKS RELATED TO OUR CONCENTRATE BUSINESS

We have been and may continue to be affected materially and adversely by increases in raw material and transportation costs and may be unable to recover certain costs due to provisions in our material contracts.

A significant portion of our costs relates to chemicals and other raw materials and transportation, which such costs are out of our control, and we may not be able to recover a portion of such costs due to provisions in our material contracts with Baxter and DaVita.

The costs of chemicals and other raw materials 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. In the past year, raw materials costs have increased significantly. Under the Distribution Agreement with Baxter, such cost inflation may result in increases in the prices we charge Baxter, subject to specified levels. If these increases exceed the levels specified in the Distribution Agreement, Baxter has the option to terminate the Distribution Agreement. Any such termination could have a material and adverse effect on our business, results of operations, financial position and cash flows.

Transportation also comprises a significant portion of our costs. We have been adversely affected by a general shortage in commercial truckers in the United States and significant increases in labor and fuel costs. The Second Amendment to our Distribution Agreement with Baxter established a cap on the percentage amount that we receive in reimbursement for transportation expenses under such agreement. This reimbursement cap has in the past and may in the future result in Rockwell not being able to recover the full amount of our transportation costs, including labor and fuel costs, which are subject to the cap on transportation costs. Increases in transportation costs and reimbursement caps have materially and adversely impacted and may continue to materially and adversely impact our profit margins as we pay higher costs to ship products to our customers.

In addition, our Product Purchase Agreement ("Product Agreement") with DaVita provides for a fixed price to DaVita, with limited increases from year to year, regardless of the increases in raw materials costs. As a result, we have been unable to fully recover our costs for the products we sell to DaVita (including transportation costs) and are in a significant negative financial position with regard to the Product Agreement. This has had a material and adverse impact on our financial position.

On April 6, 2022, we entered into an amendment to the Products Purchase Agreement under which we agreed to a price increase, effective May 1, 2022, as well as the pass-through of certain costs, determined on a quarterly basis. Certain costs are subject to a cap. If our costs exceed those caps, we may be unable to fully recover our costs or if costs increase in excess of an overall cap, the Products Purchase Agreement may be subject to termination by DaVita.

We expect that if we continue to be subject to the limitations in the agreements with our largest customers, the increasing costs may continue to negatively impact our profit margins and materially and adversely affect our financial position.

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. While we were not required to pause operations based upon executive or similar governmental directives, we have had, and anticipate continuing to have, instances where, notwithstanding the existence of a vaccine, employees of our manufacturing plants test positive for COVID-19, resulting in a disruption to our manufacturing operations. In addition, the imposition of vaccine or testing mandates on vaccine hesitant workers could result in certain workers opting to resign. 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 an 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. Such a closure or failure to deliver product could cause us to be in breach of requirements to maintain safety stock and maintain transportation and other services under our Exclusive Distribution Agreement with Baxter and/or our Products Purchase Agreement with DaVita, which would allow them to exercise various remedies under those agreements.

In addition, we have and may continue to face decreased demand for our concentrates portfolio if dialysis patients are unable to travel to dialysis clinics or because dialysis patients have been 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 for PPE, costs for cleaning and increased labor costs due to the reluctance of workers to return to work and hazard pay, as well as general labor shortages. These increased costs have impacted the profitability of our concentrates portfolio. Given the uncertainty surrounding COVID-19, including future variants, we may continue to incur these additional costs which in turn may have an impact upon our profitability. The ultimate impact of the COVID-19 pandemic or a similar public health emergency on our business is highly uncertain and subject to change. We do not know whether we will face additional delays or further 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.

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. On April 6, 2022, we entered into an amendment to the Products Purchase Agreement with DaVita to change the cost structure of that agreement. In addition, the amendment provides that the Company must raise an additional $15 million through the sale of equity securities by June 30, 2022 and maintain a minimum cash balance of $10 million, or we will be in default under the Products Purchase Agreement. An event of default could result in termination of that agreement.

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.

If we are unable to locate and construct a new manufacturing facility on a timely basis, we could fail to achieve efficiencies in our business.

The lease for our highest volume manufacturing facility is scheduled to expire in early 2023. Although the lease could be renewed, we are seeking a new manufacturing site that will offer us the greatest opportunity to maximize our manufacturing efficiency and the efficiency related to the transportation of our products to end customers. However, the process of locating such a facility can be time intensive and costly. There can be no assurance that we will be able to locate a facility that maximizes our manufacturing and transportation efficiency.

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 FPC pipeline 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.

We expect that only a small number of patients will be enrolled in our clinical trials for our FPC pipeline product candidates relative to the total disease population. 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 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, which may, among other things, interpret data differently. 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. For example, although we have filed an IND for FPC in the home infusion setting and we have an FPC product that has been approved in other settings, if the FDA were to impose additional requirements in the home infusion setting that would result in significant additional expense or a significant administrative burden, we may have to forgo our pursuit of that indication. 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 one of our FPC pipeline product candidates, 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, they may still face future reimbursement challenges.

If approved, reimbursement of our FPC pipeline product candidates by Medicare and commercial payers will be 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, 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 obsolete 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.

There is also a risk our FPC pipeline product candidates, even if successfully developed, approved and reimbursed, will not be acceptable to or adopted by the market. Factors that may impact market adoption may include competition, health economic value of FPC versus alternative therapeutic approaches, usability, or suitability of the product for providers.

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 in which we are currently investigating FPC pipeline product candidates. 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 development, 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 current and future product candidates. We have filed an IND for a home infusion indication for FPC and in the future, we may file INDs for future indications or future product candidates. The IND for the home infusion indication is currently on clinical hold while we perform required studies. If any IND is not approved by the FDA, our clinical development timeline may be negatively impacted and any 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 patient populations 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 current and 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 current and 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 OUR DRUG BUSINESS

The long-term success of our pharmaceutical 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 successful commercialization of Triferic (dialysate) and Triferic AVNU in the United States depends upon our ability to find a partner to assist us with commercialization. If we are unable to identify and establish a relationship with a commercialization partner, or if the 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 Triferic AVNU was approved by the FDA in March 2020 and made commercially available in February 2021. We have recorded sales of Triferic of $1.1 million through December 31, 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. In August 2021, we significantly scaled back our commercialization efforts related to Triferic and are seeking a commercialization partner to assist us. There is no assurance that we will be successful in finding a partner to assist with the ongoing commercialization of these products or that Triferic will gain broad market acceptance.

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 have worked 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 Triferic depends, in part, on our ability to continue to generate data on the positive healthcare economic impact of Triferic and the extent to which such data is compelling enough to drive market adoption.

To gain broad market acceptance, we expect that any commercialization partner 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 a commercialization partner to be able to successfully penetrate a large portion of the total addressable market in the United States without adoption by 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:

- our ability to find a partner who will help us to commercialize Triferic in the United States;
- our competitors' activities, including aggressive marketing, pricing, and contracting practices and other tactics to retain their market share;
- 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 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.

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 us engaging with a commercialization partner and the effectiveness of our partner's marketing, sales and distribution strategies and operations for commercialization and our ability to execute our marketing strategy without significant additional expenditures. We scaled back our commercial organization in August 2021 and have been working to maintain the clinics that have adopted Triferic.

We cannot assure you that we or any commercialization partner 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 able to find a partner that is 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 provider organizations.

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

Our business and operations, including but not limited to our sales and marketing efforts, our efforts to maintain clinics that use Triferic after we scaled back our commercial organization, and our research and development activities, have been and are expected to continue to be adversely affected by the COVID-19 pandemic. The effects of executive and similar government orders, shelter-in-place orders and our work-from-home policies 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 and may continue to delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of limitations on our ability to conduct our business in the ordinary course. As the COVID-19 pandemic continues to evolve, these disruptions and any additional disruptions in our operations, or those of our suppliers and partners, we may face could materially and adversely 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 or other suppliers 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. The COVID-19 pandemic has negatively affected and may continue to negatively affect our manufacturing facilities, which has resulted in an increase in the costs related to such manufacturing and the decrease in the productivity of our facilities. Furthermore, some of our manufacturers and suppliers are in Canada and Europe and may be impacted by border and 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. Our sales representatives were unable to interact with current and potential customers to the same extent as before the onset of the COVID-19 pandemic due to restrictions put in place and change in prospective customer practices in response to the COVID-19 pandemic. Any commercialization partner for Triferic may continue to experience these obstacles and market acceptance of Triferic could be further hampered and commercial uptick may be slower than normal.

Historically, there has been growth in the U.S. population of dialysis dependent ESRD patients; however, more recently, an overall decline in the U.S. dialysis population has been reported. This decline has reduced our overall market opportunity for Triferic. In addition, we may continue to face decreased demand for Triferic due to the inability of dialysis patients to travel to dialysis clinics or if dialysis patients continue to be disproportionally affected by COVID-19 due to their

heightened risk status, or if dialysis clinics are unable to make additional protocol changes that are required for Triferic. Dialysis clinics have faced challenges related to decreased staffing, due to the COVID-19 pandemic and other factors. Staffing issues may impede the clinics' interest and 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. If COVID-19 continues to exist 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 obtaining the supplies, including pharmaceutical products and medical devises, we need to run our clinical trials;
- 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 to sustain our operations and support our clinical trials and may 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. The ultimate impact of the COVID-19 pandemic or a similar public health emergency on our business is highly uncertain and subject to change. We do not know whether we will face additional delays or further 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 and any future partner's 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 or any future commercialization partner are not able to promote Triferic (dialysate) and Triferic AVNU or encourage 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 or any future partner's 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 2028 in Europe and Japan and 2029 in the United States. 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 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-related halt or slowdown of supply of raw materials or production of components;
- global supply chain delays or disruptions;
- 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 or our inability to comply with the minimums in such an agreement;
- 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. If those suppliers were unable to supply us for any reason, including the reasons mentioned above, we could experience cost increases or supply interruptions. For example, we have had disputes with our API supplier for Triferic. In January 2022, we received an invoice for a penalty payment because we failed to meet certain minimum order requirements under our agreement with them. Any dispute that may arise could result in the termination of the supply agreement or loss of API that is stored at our supplier. 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 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 or cost-effective 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 or any potential partner's 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 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 and may result in the violation of our license agreements.

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:

- increased cost or resource requirements associated with measures required to support the registration and/or sale of the product or products, such as labeling changes, product changes, testing, provision of documents or production requirements;
- 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.

If we do not successfully manage these risks, our business could suffer.

We may not be successful in expanding our drug product portfolio or in our business development efforts related to in-licensing, acquisitions or other business collaborations. Even if we are able to enter into business development arrangements, they could have a negative impact on our business and our profitability.

As part of our business strategy to expand our drug product portfolio, we may 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, complex and expensive process and there can be no assurance that any such negotiations will be completed on a timely basis or at all, or result in an arrangement that will enable us to effectively integrate, develop and launch such products or product candidates effectively.

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

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

Medicare and Medicaid fund the majority of dialysis costs in the United States. Many dialysis providers receive the majority of their funding from the government and are supplemented by payments from private health care insurers. These providers depend on Medicare and Medicaid funding to be viable businesses. Changes to health insurance and reimbursement by Congress may have a negative impact on Medicare and Medicaid funding and on reimbursement protocols. If Medicare and Medicaid funding were to be materially decreased, dialysis providers would be severely impacted, increasing our risk of not being paid in full. An increase in our exposure to uncollectible accounts could have a material adverse effect on our business, results of operations, financial position and cash flows.

Since 2011, CMS has continued to modify reimbursement policies for dialysis under the ESRD prospective payment system generally resulting in lower payment to dialysis providers. We anticipate that dialysis providers will continue to seek ways to reduce their costs per treatment due to this change in reimbursement practice, which could reduce our sales and profitability and have a material adverse effect on our business, results of operations, financial position and cash flows.

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 patents, if granted, would 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 ESRD patients.

A new class of drugs, known as HIF-PHIs, is currently in development for a variety of indications, including the treatment of anemia for patients with chronic kidney disease. HIF-PHIs are designed to stimulate erythropoiesis and manage iron utilization and can be administered orally. Certain HIF-PHI compounds, including roxadustat and vadadustat, have reached or completed Phase 3 development in the United States, and an NDA for roxadustat was submitted in the United States in December 2019. The PDUFA date for vadadustat, which may be the first FDA approved HIF-PHI agent, is currently set for March 29, 2022. Further, HIF-PHIs are approved in other countries where we have licensing partners, including China and Korea. If successfully developed and approved in the United States, 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 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, sale and delivery 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, including, with respect to our transportation operations, the U.S. Department of Transportation. 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.

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.

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.

Our business operations may subject us to numerous commercial disputes, claims, lawsuits and/or investigations.

Operating in the pharmaceutical industry involves numerous commercial relationships, complex contractual arrangements, uncertain intellectual property rights, potential product liability and other aspects that create heightened risks of disputes, claims, lawsuits and investigations. In particular, we may face claims related to the safety of our products, intellectual property matters, employment matters, tax matters, commercial disputes, competition, sales and marketing practices, environmental matters, personal injury, insurance coverage and acquisition or divestiture-related matters. A counterparty may assert claims that we do not believe are meritorious, but we nonetheless need to defend. For example, Baxter sent us a letter in December 2021 reserving its right to assert that it could claim a refund of a portion of its upfront payment if it terminates the Distribution Agreement as a result of certain price increases. While we believe the claims in Baxter's letter are without merit and that Baxter cannot recoup any portion of its upfront payment, we cannot assure you what a mediator or arbitrator may decide if it pursues such claim. We intend to vigorously defend against and such claim. In addition, any commercial dispute, claim, lawsuit or investigation may divert our management's attention away from our business, we may incur significant expenses in addressing or defending any commercial dispute, claim or lawsuit or responding to any investigation, and we may be required to pay damage awards or settlements or become subject to equitable remedies that could adversely affect our operations and financial results.

RISKS RELATED TO OUR COMMON STOCK

We may fail to qualify for continued listing on Nasdaq, which could make it more difficult for our stockholders to sell their shares.

We are required to satisfy the continued listing requirements of Nasdaq to maintain such listing, including, among other things, the maintenance of a minimum closing bid price of $1.00 per share. On June 11, 2021, we received a notice from Nasdaq that we were not in compliance with the minimum bid price requirements set forth in Nasdaq Listing Rule 5450(a)(1) for continued listing on The Nasdaq Global Market. Nasdaq Listing Rule 5450(a)(1) requires listed securities maintain a minimum closing bid price of $1.00 per share, and Listing Rule 5810(c)(3)(A) provides that a failure to meet the minimum closing bid price requirement exists if the deficiency continues for a period of 30 consecutive business days. In order to regain compliance, the closing bid price of the Company's common stock must be at least $1.00 per share for a minimum of 10 consecutive business days. We did not regain compliance by our initial deadline of December 8, 2021. We have moved our listing to The Nasdaq Capital Market and on December 9, 2021, we received written notice that Nasdaq has determined we are eligible for an additional 180-day extension, or until June 6, 2022, to regain compliance with the minimum bid price requirements set forth in Nasdaq Listing Rule 5550(a)(2) for continued listing on The Nasdaq Capital Market.

There can be no assurance that we will be able to regain compliance with the minimum bid price requirement. In the event that we do not regain compliance with the Nasdaq Listing Rules prior to the expiration of the extension period, we expect to receive

written notification that our common stock is subject to delisting. If our common stock is delisted by Nasdaq, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our common stock;
- reduced liquidity with respect to our common stock;
- a determination that our shares are "penny stock," which will require brokers trading in our shares to adhere to more stringent shares, and which may limit demand for our common stock among certain investors;
- a limited amount of news and analyst coverage for our company; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

The market price of our common stock has fluctuated in the past, and is likely to continue to be volatile, which could subject us to litigation.

The market price of our common stock has fluctuated and is likely to be subject to further wide fluctuations in response to numerous factors, many of which are beyond our control, such as those in this "Risk Factors" section and others including:

- 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 or device 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.

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, 2021, there were 2,612,079 shares issuable upon the exercise of then-outstanding and exercisable stock options, 3,202,427 shares issuable upon the exercise of then-outstanding stock options that were not yet exercisable, and 26,426,863 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.

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 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 2024. 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 October 31, 2024. This lease is currently under a sublease expiring on October 31, 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 were 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.

Market Information

Our common stock is listed on The Nasdaq Capital Market under the trading symbol "RMTI".

Holders

As of February 28, 2022, there were 51 holders of record of our common stock.

Dividends Policy

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.

Item 6. Reserved.

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 the potential to lead to transformative treatments for iron deficiency in multiple disease states, 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 market both products to kidney dialysis centers for their patients receiving dialysis. In late 2021, we filed an IND with the United Stated Food and Drug Administration ("FDA") with the goal to advance our FPC platform strategy by starting a Phase II trial in the second half of 2022 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 infused medications, 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.

At Rockwell Medical, we are dedicated to enhancing the currently sub-optimal 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 bioavailable 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 in clinical trials.

Results of Operations

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

	For the Year Ended December 31,				
	2021	% of Revenue	2020	% of Revenue	% Change
Net Sales	**$ 61,931**		**$ 62,197**		**(0.4)%**
Cost of Sales	64,351	103.9 %	59,472	95.6 %	8.2
Gross (Loss) Profit	(2,420)	(3.9)	2,725	4.4	(188.8)
Research and Product Development	6,835	11.0	7,092	11.4	(3.6)
Selling and Marketing	5,733	9.3	7,871	12.7	(27.2)
General and Administrative	15,348	24.8	16,182	26.0	(5.2)
Operating Loss	**$ (30,336)**	**(49.0)%**	**$ (28,420)**	**(45.7)%**	**6.7 %**

Net Sales

During the year ended December 31, 2021, our net sales were $61.9 million compared to net sales of $62.2 million during the year ended December 31, 2020. Net sales of hemodialysis concentrates to dialysis providers and distributors in the United States and abroad were $60.8 million for the year ended December 31, 2021 compared to $61.1 million for the year ended December 31, 2020. Net sales of Triferic (dialysate) remained flat at approximately $1.1 million for the years ended December 31, 2021 and 2020. On April 6, 2022, the Company and DaVita entered into an amendment (the "DaVita Amendment") to the Products Purchase Agreement, dated July 1, 2019 under which the Company supplies DaVita with certain dialysis concentrates. Under the DaVita Amendment, the Company and DaVita agreed to a price increase, effective May 1, 2022. Based the DaVita Amendment and assuming steady sales volumes, the Company expects a double digit increase in concentrates revenue year-over-year.

Cost of Sales and Gross Profit

Cost of sales during the year ended December 31, 2021 was $64.4 million, resulting in gross loss of $2.4 million, compared to cost of sales of $59.5 million and a gross profit of $2.7 million during the year ended December 31, 2020. Gross profit decreased by $5.1 million during the year ended December 31, 2021 compared to the year ended December 31, 2020 due to significant inflationary pressures related to the concentrates segment. The Company has sought to mitigate these inflationary pressures by increasing product costs and by renegotiating certain terms of its supply contract with DaVita in the DaVita Amendment, one of the Company's largest customers, to be able to pass through a significant portion of inflationary costs. As a result of these changes, the Company expects an improvement in margins in 2022

Research and Product Development Expense

Research and product development expenses were $6.8 million for the year ended December 31, 2021 compared with $7.1 million during the year ended December 31, 2020. The decrease of $0.3 million is related to timing of costs for clinical trials and other product development expenses for our FPC platform. We are continuing to invest in our medical and scientific programs to support the advancement of our FPC technology platform.

Selling and Marketing Expense

Selling and marketing expenses were $5.7 million during the year ended December 31, 2021 compared with $7.9 million during the year ended December 31, 2020. The decrease of $2.1 million is due a decrease in marketing spend for our Triferic products and a headcount reduction.

General and Administrative Expense

General and administrative expenses were $15.3 million during the year ended December 31, 2021 compared with $16.2 million during the year ended December 31, 2020. The $0.9 million decrease was driven primarily by a decrease in labor of $0.8 million, recruiting of $0.3 million and legal costs of $0.4 million, partially offset by increases to D&O insurance premiums of $0.3 million, FDA fees of $0.2 million, and investor relation costs of $0.1 million.

Other Income (Expense)

Other income for the year ended December 31, 2021 consisted of $22,000 of interest income. 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 expense for the year ended December 31, 2021 was $2.4 million, consisting of interest expense related to our debt facility (see Note 15 to the financial statements for more information on our debt facility). 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 to the financial statements for more information on our debt facility).

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, 2021, we had an accumulated deficit of approximately $370.1 million and shareholders' equity of $2.5 million. As of December 31, 2021, we had approximately $22.4 million of cash, cash equivalents and investments available-for-sale, and working capital of $14.3 million. Net cash used in operating activities for the year ended December 31, 2021 was approximately $33.5 million.

Prior to filing our Form 10-K for the year ended December 31, 2021, the Company had experienced significant inflationary pressures in its dialysis concentrates business, particularly in recent months, which has resulted in an accelerated operating loss associated with this business line. As a result of these inflationary pressures, and in light of the fact that the Company's concentrates business continued to operate at a loss in 2021, the Company sought to renegotiate certain terms of its supply contracts with the Company's two largest customers in an effort to allow the Company to stabilize its concentrates business.

These factors raised substantial doubt about the Company's ability to continue as a going concern and depended, in part, on the degree of success in addressing inflationary pressures affecting the Company's concentrates business, as well as the Company's ability to contain costs, raise additional working capital and remain in compliance with financial and operating covenants under the Company's secured loan.

On April 6, 2022, the Company entered into the DaVita Amendment, which restructures the supply relationship with DaVita, which management expects to result in improved financial performance of the Company's concentrates business. The Company also entered into a securities purchase agreement with DaVita, which provides for an investment of up to $15 million in two tranches of $7.5 million each. The first tranche of $7.5 million was funded on April 7, 2022. The second $7.5 million tranche to be funded subject to the Company raising $15 million in additional capital by June 30, 2022. The Company's existing liquidity, taking into account the two executed agreements described above and implementing increases to product pricing, containing certain costs, and reducing expenses, management believes that the Company has sufficient capital to fund its operations and is sufficient to fund its operations and anticipated capital expenditures for the next 12 months.

The Company expects it will require additional capital to sustain its operations and make the investments it needs to execute its strategic plan in 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 cash flows from operations as described above, the Company will need to obtain additional equity or debt financing. In particular, the DaVita Amendment provides that the Company must raise an additional $15 million equity investment by June 30, 2022 and maintain a minimum cash balance of $10 million, or we will be in default under the Products Purchase Agreement. An event of default could result in termination of that agreement. The Company cannot assume that any additional equity or debt financing will be available on favorable terms, if at all. In addition, any debt financing is limited by the terms of our Securities Purchase Agreement with DaVita. Specifically, until DaVita owns less than 50% of its investment, the Company may only incur additional debt in the form of a purchase money loan, a working capital line of up to $5 million or to refinance existing debt, unless DaVita consents.

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 to the financial statements for more information on our debt facility).

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. 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.

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.

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, 2) our ability to restructure our other significant commercial contract within our concentrate business, and 3) our ability to find a commercial partner to commercialize and increase adaptation of Triferic (dialysate) and Triferic AVNU. All of these strategies are 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, that we will be successful in restructuring our commercial agreements in our concentrate business or that we will be able to find a commercial partner and have sustained commercial success with Triferic (dialysate) and Triferic AVNU. If our planned clinical program is delayed or fails or our other significant commercial contract in the concentrate business cannot be restructured in way that is beneficial to Rockwell or our if ability to find a commercial partner for Triferic (dialysate) and/or Triferic AVNU should fail, 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. 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 $33.5 million for the year ended December 31, 2021. The net loss for this period was less than net cash used in operating activities by $0.9 million, which was primarily attributable to non-cash expenses of $4.0 million, consisting primarily of $1.8 million of amortization of the right to use assets, $0.7 million of depreciation and amortization, $0.9 million of stock-based compensation, $0.1 million of inventory reserves, $0.4 million of debt financing cost amortization and accretion of discount, and a $4.8 million net change in assets and liabilities.

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.

Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities was $0.3 million during the year ended December 31, 2021. The net cash provided was primarily due to the purchase of investments available-for-sale of $26.1 million, offset by $26.9 million sale of our available-for-sale investments and $0.5 million for the purchase of equipment.

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.

Cash (Used in) Provided by Financing Activities

Net cash used in financing activities was $2.2 million during the year ended December 31, 2021. The net cash used in was primarily due to payments on the Company's debt and short term note payable.

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 in our public offerings and our at-the market offerings, respectively, net proceeds of $21.2 million from our term loan, partially offset by payment of $0.8 million related to a short term note payable.

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, 2021 and 2020, 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 $1.9 million and $2.0 million related to the Baxter agreement for each of the years ended December 31, 2021 and 2020, 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 for both of the years ended December 31, 2021 and 2020. Deferred revenue related to the Wanbang Agreement totaled $2.5 million and $2.7 million for the years ended December 31, 2021 and 2020, 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 for both of the years ended December 31, 2021 and 2020. Deferred revenue related to the Sun Pharma Agreement totaled $80,000 and $90,000 as of December 31, 2021 and 2020, respectively.

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 $10,000 and $2,500 during the year ended December 31, 2021 and 2020, respectively. Deferred revenue related to the Jeil Pharma Agreement totaled $187,500 and $197,500 as of December 31, 2021 and 2020, respectively.

On June 2021, the Company entered into license and supply agreements with Drogsan Pharma (the "Drogsan Agreements"), for the rights to commercialize Triferic (dialysate) and Triferic AVNU in Turkey. Under the terms of the Drogsan Agreements, Drogsan Pharma will be the exclusive commercialization partner for Triferic (dialysate) and Triferic AVNU in Turkey. In consideration for the license, the Company received an upfront fee of $0.15 million, and will be eligible for milestone payment and royalties on net sales. A Joint Alliance Committee, comprised of members from the Company and Drogsan Pharma, will guide the execution for Triferic (dialysate) and Triferic AVNU in Turkey. Drogsan Pharma will be responsible for all regulatory approval and commercialization activities, and the Company will supply the product to Drogsan Pharma for Turkey. The upfront fee will be recorded as deferred revenue and will be recognized as revenue based on the agreement term. The Company recognized revenue of $7,500 during the year ended December 31, 2021. Deferred revenue related to the Drogsan Agreements totaled approximately $0.1 million as of December 31, 2021.

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, 2021 and 2020, 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, 2021. 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, 2021. 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, 2021. 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. Based on our evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2021.

Attestation Report of the Registered Public Accounting Firm

As a non-accelerated filer, we are not required to provide an attestation report on our internal control over financial reporting issued by the Company's independent registered public accounting firm.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) identified in management's evaluation pursuant to Rules 13a-15(d) or 15d-15(d) of the Exchange Act that occurred during the quarter ended December 31, 2021, that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable

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 2022 Annual Meeting of Stockholders (the "2022 Proxy Statement"), which we expect to be filed with the SEC within 120 days of the end of our fiscal year ended December 31, 2021, 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 2022 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 2022 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, 2021:

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)	5,364,988	$ 3.07	1,040,339
Equity compensation plans not approved by security holders (2)	850,000	$ 1.50	—
Total	6,214,988	$ 2.85	1,040,339

(1) Consists of 4,964,506 stock options with a weighted average exercise price of $3.15, 322,182 restricted stock units and 78,300 restricted stock awards.
(2) Consists of 850,000 stock options with a weighted average exercise price of $1.50.

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 2022 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 2022 Proxy Statement, including under heading "Independent Accountants."

PART IV

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	Certificate of Incorporation, dated 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
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	Form 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	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).
*10.6	Rockwell Medical, Inc. 2018 Long Term Incentive Plan (Company's Proxy Statement for the 2018 Annual Meeting of Shareholders filed on April 30, 2018).
*10.7	Form of Nonqualified Stock Option Agreement (2007 Long Term Incentive Plan) (Director Version) (Company's Form 8-K filed December 20, 2007).
*10.8	Form of Nonqualified Stock Option Agreement (2007 Long Term Incentive Plan) (Employee Version) (Company's Form 8-K filed December 20, 2007).
*10.9	Form of Restricted Stock Award Agreement (2007 Long Term Incentive Plan) (Director Version) (Company's Form 10-K filed February 29, 2016).
*10.10	Form of Restricted Stock Award Agreement (2007 Long Term Incentive Plan) (Executive Version) (Company's Form 10-Q filed May 12, 2014).
*10.11	Form of Performance Share Award Agreement March 2017 (Executive Version) (Company's Form 10-Q filed May 9, 2017).
*10.12	Form of Performance Share Award Agreement March 2017 (Director Version) (Company's Form 10-Q filed May 9, 2017).
*10.13	Form of Stock Option Agreement (2018 Long Term Incentive Plan) (Employee Version) (Company's Form 10-K filed March 15, 2019).
*10.14	Form of Contingent Option Agreement for Directors (2018 Long Term Incentive Plan) (Company's Form 8-K filed March 21, 2018).
10.15	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).
*10.16	Form of Indemnification Agreement (Company's Form 8-K filed August 30, 2019).
10.17	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).

*10.18	Approval of Independent Director Compensation (Company's Form 8-K filed March 21, 2018).
10.19	Registration Rights Agreement, dated October 17, 2018 (Company's Form 8-K filed October 19, 2018).
10.2	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).
10.21	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).
10.22	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).
10.23	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).
10.24+	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).
*10.25	Russell Skibsted Employment Agreement, dated September 15, 2020 (Company's Form 8-K filed on September 16, 2020).
*10.26	Russell Ellison Employment Agreement, dated April 17, 2020 (Company's Form 8-K filed on April 20, 2020).
*10.27	Rockwell Medical, Inc. Amended and Restated 2018 Long Term Incentive plan (Company's Form 8-K filed on May 21, 2020).
10.28	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).
10.29	Second Amendment to the Exclusive Distribution Agreement entered into as of March 16, 2020 between the Company and Baxter Healthcare Corporation (Company's Form 10-Q filed on November 15, 2021).
10.3	First Amendment to Loan and Security Agreement, dated September 24, 2021, by and among the Company, Innovatus Life Sciences Lending Fund I, LP and the lenders party thereto (Company's Form 8-K filed on September 30, 2021)
21.1	List of Subsidiaries (Company's Form 10-K filed on March 31, 2021).
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, 2021, 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: April 8, 2022

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)	April 8, 2022
/s/ Russell Skibsted Russell Skibsted	Chief Financial Officer (Principal Financial Officer)	April 8, 2022
/s/ Paul E. McGarry Paul E. McGarry	Principal Accounting Officer	April 8, 2022
/s/ John G. Cooper John G. Cooper	Director	April 8, 2022
/s/ Robert S. Radie Robert S. Radie	Director	April 8, 2022
/s/ Allen Nissenson Allen Nissenson	Director	April 8, 2022
/s/ Andrea Heslin Smiley Andrea Heslin Smiley	Director	April 8, 2022
/s/ Mark H. Ravich Mark H. Ravich	Director	April 8, 2022

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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 sheets of Rockwell Medical Inc. and Subsidiaries (the "Company") as of December 31, 2021 and 2020, 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, 2021, 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, 2021 and 2020, and the consolidated results of its operations and its cash flows for each of the two years in the period ended December 31, 2021, 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. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate. We determined that there was a critical audit matter as discussed below.

Evaluation of Going Concern

As disclosed in Note 2 to the consolidated financial statements, the Company has experienced significant net losses since inception, has an accumulated deficit and has used significant cash flows for operations during 2021, which caused management to evaluate if those factors raised substantial doubt about the Company's ability to continue as a going concern which could be mitigated through Management's plan. Management's plan as disclosed in Note 2 includes increasing prices with some of its customers and implementing certain cost cutting and containment measures, all of which are significant assumptions in the Company's projections used in its evaluation of going

concern. The Company's management has exercised significant judgment in their determination of how existing accounting principles generally accepted in the United States of America should be applied to the evaluation of going concern, the associated financial statement presentation and note disclosures relating to substantial doubt about the Company's ability to continue as a going concern.

We identified the evaluation of the Company's ability to continue as a going concern as a critical audit matter due to the nature and extent of audit effort required to obtain sufficient appropriate audit evidence to address the risks of material misstatement related to the disclosure of the Company's liquidity and ability to continue as a going concern for at least the next twelve months in the consolidated financial statements. The nature and extent of audit effort required to address the matter included significant involvement of more experienced engagement team members. The primary procedures we performed to address this critical audit matter included the following:

- Understand management's process and related internal controls in conducting the evaluation of going concern, including preparing projections.
- We examined the executed Amendment to the Products Purchase Agreement and the terms in the agreement compared to the significant assumptions in the projected financial information, including, but not limited to, the projected revenue, growth rates, margins, as well as to the historical performance of the concentrates business.
- We examined the executed Stock Purchase Agreement for the sale of preferred shares and traced the receipts of the proceeds to the bank account and the projected financial cash flow information.
- We evaluated and tested management's assumptions for projected price increases to subsequent customer invoices to validate the projected financial information, including, but not limited to, the projected revenue, gross margins, as well as to the historical performance of the concentrates business for cost assumptions.
- We examined and tested certain assumptions reasonableness to test the changes to the expected cash flows.
- We concluded on the probability of success of management's plan.

/s/ Marcum LLP
Marcum LLP
(PCAOB ID 688)

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

Chicago, Illinois
April 8, 2022

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(Dollars in Thousands)

	December 31, 2021	December 31, 2020
ASSETS		
Cash and Cash Equivalents	$ 13,280	$ 48,682
Investments Available-for-Sale	9,158	9,997
Accounts Receivable, net of a reserve of $16 for 2021 and $9 for 2020	5,913	4,171
Inventory	4,076	3,913
Prepaid and Other Current Assets	2,861	2,706
Total Current Assets	**35,288**	**69,469**
Property and Equipment, net	2,486	2,642
Inventory, Non-Current	1,523	1,176
Right of Use Assets, net	7,737	2,911
Goodwill	921	921
Other Non-Current Assets	619	629
Total Assets	**$ 48,574**	**$ 77,748**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts Payable	$ 3,739	$ 4,155
Accrued Liabilities	5,090	5,013
Lease Liability - Current	2,004	1,167
Deferred License Revenue	2,171	2,175
Term Loan - Net of Issuance Costs	7,381	—
Insurance Financing Note Payable	437	—
Customer Deposits	144	152
Other Current Liability - Related Party	—	131
Total Current Liabilities	**20,966**	**12,793**
Lease Liability - Long-Term	5,887	1,821
Term Loan, Net of Issuance Costs	13,186	20,949
Deferred License Revenue - Long-Term	5,986	8,015
Long Term Liability - Other	14	—
Total Liabilities	**46,039**	**43,578**
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, 2021 and 2020	—	—
Common Stock, $0.0001 par value, 170,000,000 shares authorized, 93,986,470 and 93,573,165 shares issued and outstanding at December 31, 2021 and 2020, respectively	9	9
Additional Paid-in Capital	372,554	371,510
Accumulated Deficit	(370,080)	(337,406)
Accumulated Other Comprehensive Income	52	57
Total Stockholders' Equity	**2,535**	**34,170**
Total Liabilities and Stockholders' Equity	**$ 48,574**	**$ 77,748**

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, 2021 and 2020
(Dollars in thousands, except per share amounts)

	2021	2020
Net Sales	**$ 61,931**	**$ 62,197**
Cost of Sales	64,351	59,472
Gross (Loss) Profit	(2,420)	2,725
Research and Product Development	6,835	7,092
Selling and Marketing	5,733	7,871
General and Administrative	15,348	16,182
Operating Loss	**(30,336)**	**(28,420)**
Other Expense		
Realized Gain on Investments	—	8
Warrant Modification Expense	—	(837)
Interest Expense	(2,360)	(1,879)
Interest Income	22	238
Total Other Expense	**(2,338)**	**(2,470)**
Net Loss	**$ (32,674)**	**$ (30,890)**
Basic and Diluted Net Loss per Share	**$ (0.35)**	**$ (0.41)**
Basic and Diluted Weighted Average Shares Outstanding	**93,788,050**	**75,621,674**

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, 2021 and 2020

(Dollars in Thousands)

	2021	2020
Net Loss	**$ (32,674)**	**$ (30,890)**
Unrealized Loss on Available-for-Sale Investments	(6)	(3)
Foreign Currency Translation Adjustments	1	8
Comprehensive Loss	**$ (32,679)**	**$ (30,885)**

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, 2021 and 2020

(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, 2020	**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
Issuance of Common Stock	—	—	—	—	—	—
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	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**
Net Loss	—	—	—	(32,674)	—	(32,674)
Unrealized Loss on Available-for-Sale Investments	—	—	—	—	(6)	(6)
Foreign Currency Translation Adjustments	—	—	—	—	1	1
Vesting of Restricted Stock Units Issued, net of taxes withheld	258,305	—	(6)	—	—	(6)
Issued shares for services	155,000	—	107	—	—	107
Stock-based Compensation	—	—	943	—	—	943
Balance as of December 31, 2021	**93,986,470**	**$ 9**	**$ 372,554**	**$ (370,080)**	**$ 52**	**$ 2,535**

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, 2021 and 2020
(Dollars in Thousands)

	2021	2020
Cash Flows From Operating Activities:		
Net Loss	**$ (32,674)**	**$ (30,890)**
Adjustments To Reconcile Net Loss To Net Cash Used In Operating Activities:		
Depreciation and Amortization	668	834
Stock-based Compensation	943	475
Warrant Modification Expense	—	837
Increase in Inventory Reserves	146	305
Amortization of Right of Use Asset	1,847	1,455
Amortization of Debt Financing Costs and Accretion of Debt Discount	369	294
Loss on Disposal of Assets	8	7
Realized Loss on Sale of Investments Available-for-Sale	—	(8)
Foreign Currency Translation Adjustment	2	8
Changes in Assets and Liabilities:		
(Increase) Decrease in Accounts Receivable, net	(1,742)	32
Increase in Inventory	(656)	(1,306)
Decrease in Other Assets	1,823	76
(Decrease) Increase in Accounts Payable	(416)	1,136
Decrease in Settlement Payable	—	(104)
Decrease in Lease Liability	(1,771)	(1,439)
(Decrease) Increase in Other Liabilities	(48)	534
Decrease in Deferred License Revenue	(2,033)	(1,887)
Changes in Assets and Liabilities	(4,843)	(2,958)
Cash Used In Operating Activities	**(33,534)**	**(29,641)**
Cash Flows From Investing Activities:		
Purchase of Investments Available-for-Sale	(26,058)	(29,307)
Sale of Investments Available-for-Sale	26,891	33,565
Purchase of Equipment	(522)	(1,046)
Cash Provided By Investing Activities	**311**	**3,212**
Cash Flows From Financing Activities:		
Proceeds from Term Loan	—	22,500
Debt Issuance Costs	—	(1,343)
Payments on Short Term Note Payable	(1,530)	(763)
Payments on Debt	(750)	—
Proceeds from the Issuance of Common Stock / Public Offering	—	43,148
Offering Costs from the Issuance of Common Stock / Public Offering	—	(2,469)
Proceeds from the Issuance of Common Stock / At-the Market Offerings	—	2,325
Offering Costs from the Issuance of Common Stock / At-the Market Offerings	—	(63)
Proceeds from issuance of Common Stock for payment related to services provided	107	—
Repurchase of Common Stock to Pay Employee Withholding Taxes	(6)	(19)
Cash (Used in) Provided By Financing Activities	**(2,179)**	**63,316**
(Decrease) Increase In Cash and Cash Equivalents	(35,402)	36,887
Cash and Cash Equivalents At Beginning Of Period	48,682	11,795
Cash and Cash Equivalents At End Of Period	**$ 13,280**	**$ 48,682**
Supplemental Disclosure of Cash Flow Information:		
Cash Paid for Interest	$ 1,827	$ 1,558
Supplemental Disclosure of Noncash Investing Activities:		
Change in Unrealized Loss on Marketable Securities Available-for-Sale	$ (6)	$ (3)
Insurance Financing Note Payable	$ 437	$ —
Fair Value of Warrants issued related to Debt Financing	$ 501	$ 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 market both products to kidney dialysis centers for their patients receiving dialysis. In late 2021, we filed an IND with the United Stated Food and Drug Administration ("FDA") with the goal to advance our FPC platform strategy by conducting 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 infused medications, 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.

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 Going Concern Considerations

Since inception, Rockwell has incurred significant net losses and has 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, 2021, Rockwell had an accumulated deficit of approximately $370.1 million and stockholders' equity of $2.5 million. As of December 31, 2021, Rockwell had approximately $22.4 million of cash, cash equivalents and investments available-for-sale, and working capital of $14.3 million. Net cash used in operating activities for the year ended December 31, 2021 was approximately $33.5 million.

Prior to filing our Form 10-K for the year ended December 31, 2021, the Company had experienced significant inflationary pressures in its dialysis concentrates business, particularly in recent months, which has resulted in an accelerated operating loss associated with this business line. As a result of these inflationary pressures, and in light of the fact that the Company's concentrates business continued to operate at a loss in 2021, the Company sought to renegotiate certain terms of its supply contracts with the Company's two largest customers in an effort to allow the Company to stabilize its concentrates business.

These factors raised substantial doubt about the Company's ability to continue as a going concern and depended, in part, on the degree of success in addressing inflationary pressures affecting the Company's concentrates business, as well as the Company's ability to contain costs, raise additional working capital and remain in compliance with financial and operating covenants under the Company's secured loan.

On April 6, 2022, the Company was able to execute an amendment to one of its supply agreements that restructures the supply relationship, which management expects to result in improved financial performance of the Company's concentrate business. The Company also entered into an equity investment agreement with one of the contracting parties for up to $15 million of investment in two tranches of $7.5 million each. The first tranche of $7.5 million was funded on April 7, 2022. The second $7.5 million tranche is to be funded subject to the Company raising $15 million in additional capital by June 30, 2022. The Company's existing liquidity, taking into account the two executed agreements described above and implementing increases to product pricing, containing certain costs, and reducing expenses, management believes that the Company has sufficient capital to fund its operations and is sufficient to fund its operations and anticipated capital expenditures for the next 12 months.

The Company expects it will require additional capital to sustain its operations and make the investments it needs to execute its strategic plan in 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 cash flows from operations as described above, 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.

Currently, because the Company's public float is less than $75 million, we are subject to the baby shelf limitations under our current registration statement on Form S-3, which limit the amount we may offer under our Form S-3. This could limit our ability to raise capital under this registration statement.

As previously reported, on June 11, 2021, the Company received written notice (the "Notification Letter") from the Nasdaq Stock Market ("Nasdaq") notifying the Company that it is not in compliance with the minimum bid price requirements set forth in Nasdaq Listing Rule 5450(a)(1) for continued listing on The Nasdaq Global Market. Nasdaq Listing Rule 5450(a)(1) requires listed securities maintain a minimum closing bid price of $1.00 per share, and Nasdaq Listing Rule 5810(c)(3)(A) provides that a failure to meet the minimum closing bid price requirement exists if the deficiency continues for a period of 30 consecutive business days. Based on the closing bid price of the Company's common stock for the 30 consecutive business days prior to the date of the Notification Letter, the Company did not meet the minimum closing bid price requirement. The Notification Letter provided for 180 calendar days, or until December 8, 2021, for the Company to regain compliance with Nasdaq Listing Rule 5450(a)(1). To regain compliance, the closing bid price of the Company's common stock must be at least $1.00 per share for a minimum of 10 consecutive business days at any time prior to December 8, 2021. The Company was not able to meet the minimum compliance requirements set forth by Nasdaq by December 8, 2021.

On December 9, 2021, the Company received a written notice from Nasdaq indicating that the Company's application to transfer its listing venue from The Nasdaq Global Market to The Nasdaq Capital Market for its common stock had been approved. The Company's common stock commenced trading on The Nasdaq Capital Market at the opening of business on December 10, 2021 under the symbol "RMTI."

Also on December 9, 2021, the Company received written notice that Nasdaq has determined the Company is eligible for an additional 180-day extension, or until June 6, 2022, to regain compliance with the minimum bid price requirements set forth in Nasdaq Listing Rule 5550(a)(2) for continued listing on The Nasdaq Capital Market. To regain compliance, the closing bid price of the Company's common stock must be at least $1.00 per share for a minimum of 10 consecutive business days at any time prior to June 6, 2022.

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 16 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 have negatively impact Rockwell's sales and marketing activities. 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 2018 for the purpose of conducting certain commercial activities in India. All intercompany balances and transactions have been eliminated in consolidation.

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 five 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"), Jeil Pharmaceutical Co., Ltd. ("Jeil Pharma") and Drogsan Pharmaceuticals ("Drogsan 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, South Korea and Turkey, 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, 2021		
Products By Geographic Area	Total	U.S.	Rest of World
Drug Revenues			
Product Sales - Point-in-time	$ 835	$ 835	$ —
License Fee – Over time	241	—	241
Total Drug Products	1,076	835	241
Concentrate Products			
Product Sales – Point-in-time	58,913	52,614	6,299
License Fee – Point-in-time	1,942	1,942	—
Total Concentrate Products	60,855	54,556	6,299
Net Revenue	$ 61,931	$ 55,391	$ 6,540

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

For each of the years ended December 31, 2021 and 2020, license fee revenue was $2.2 million. For the years ended December 31, 2021 and 2020, product sales revenue was $59.7 million and $60.0 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, 2021	December 31, 2020
Receivables, which are included in "Trade and other receivables"	$ 5,913	$ 4,171
Contract liabilities	$ 8,157	$ 10,190

There were no impairment losses recognized related to any receivables arising from the Company's contracts with customers for the years ended December 31, 2021 and 2020.

For the years ended December 31, 2021 and 2020, 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, 2021 and 2020. 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, 2021 or 2020.

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, 2021, 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 $8.2 million and $10.2 million as of December 31, 2021 and 2020, 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 ASC 606, 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, 2021 unfulfilled performance obligations related to the Baxter Agreement are product sales totaling $5.2 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 determines the appropriate classification of its investments in equity securities at the time of purchase and reevaluates such determination at each balance sheet date. Marketable securities that are bought and held principally for the purpose of selling them in the near term are reported at fair value, with unrealized gains and losses recognized in earnings.

Marketable debt securities classified as available for sale securities are carried at fair market value, with the unrealized gains and losses, net of tax, included in the determination of comprehensive income (loss) and reported in stockholders' equity.

All of the Company's investments available-for-sale are subject to periodic impairment review. The Company recognizes an impairment charge when a decline in the fair value of its 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. The Company reviews outstanding trade accounts receivable balances and based on its assessment of expected collections, the Company estimates 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. The Company's policy is to reserve for its drug product inventory that it determines is unlikely to be sold to, or if sold, unlikely to be utilized by its customers on or before its expiration date.

Property and Equipment

Property and equipment is recorded at cost and is 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, 2021 and 2020, 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 the Baxter Agreement, which has a term of 10 years 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 $1.9 million and $2.0 million for the years ended December 31, 2021 and 2020, respectively. Deferred revenue related to the Baxter agreement totaled $5.2 million and $7.2 million as of December 31, 2021 and 2020, respectively.

During the year ended December 31, 2016, the Company entered into a distribution agreement with Wanbang (the "Wangbang 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 during the years ended December 31, 2021 and 2020, respectively. Deferred revenue related to the Wanbang Agreement totaled $2.5 million and $2.7 million as of December 31, 2021 and 2020, respectively.

In January 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 for both of the years ended December 31, 2021 and 2020. Deferred revenue related to the Sun Pharma Agreement totaled $80,000 and $90,000 as of December 31, 2021and 2020, respectively.

In September 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 $10,000 and $2,500 during the year ended December 31, 2021 and 2020, respectively. Deferred revenue related to the Jeil Pharma Agreement totaled $187,500 and $197,500 as of December 31, 2021 and 2020, respectively.

In June 2021, the Company entered into license and supply agreements with Drogsan Pharma (the "Drogsan Agreements"), for the rights to commercialize Triferic (dialysate) and Triferic AVNU in Turkey. Under the terms of the Drogsan Agreements, Drogsan Pharma will be the exclusive commercialization partner for Triferic (dialysate) and Triferic AVNU in Turkey. In consideration for the license, the Company received an upfront fee of $0.15 million, and will be eligible for milestone payment and royalties on net sales. A Joint Alliance Committee, comprised of members from the Company and Drogsan Pharma, will guide the execution for Triferic (dialysate) and Triferic AVNU in Turkey. Drogsan Pharma will be responsible for all regulatory approval and commercialization activities, and the Company will supply the product to Drogsan Pharma for Turkey. The upfront fee will be recorded as deferred revenue and will be recognized as revenue based on the agreement term. The Company recognized revenue of $7,500 during the year ended December 31, 2021. Deferred revenue related to the Drogsan Agreements totaled approximately $0.1 million as of December 31, 2021.

Income Taxes

Rockwell accounts 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 the Company determine it to be more likely than not that the deferred tax asset will not be realized.

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

been incurred and the amount of the liability is reasonably estimable, or when it is probable that a tax benefit, such as a tax credit or loss carryforward, will be disallowed by a taxing authority. The amount of unrecognized tax benefits related to current tax positions is insignificant. The Company recognizes interest and penalties accrued related to unrecognized tax benefits as income tax expense.

Research and Product Development

The Company recognizes research and product development expenses as incurred. The Company incurred product development and research costs related to the commercial development, patent approval and regulatory approval of new products aggregating approximately $6.8 million and $7.1 million for the years ended December 31, 2021 and 2020, 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, 2021 and 2020, 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 12).

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, 2021 and 2020 were as follows:

	As of December 31,	
	2021	2020
Options to purchase common stock	5,814,506	6,467,956
Unvested restricted stock awards	78,300	146,800
Unvested restricted stock units	322,182	265,494
Warrants to purchase common stock	26,426,863	26,426,863
Total	32,641,851	33,307,113

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, 2021 and 2020 (table in thousands):

	December 31, 2021				
	Amortized Cost	Unrealized Gain	Unrealized Loss	Accrued Interest Income	Fair Value
Available-for-Sale Securities					
Bonds	$ 9,143	$ 1	$ —	$ 14	$ 9,158

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

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, 2021 and 2020, 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

Rockwell operates 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 47% of Rockwell's sales in 2021 and 50% of its sales in 2020. Rockwell's accounts receivable from this customer were $1.0 million and $1.1 million as of December 31, 2021 and 2020, respectively.

In October 2014, Rockwell entered into the Baxter Distribution Agreement, which was amended in June 2017 and March 2020, pursuant to which Baxter received exclusive distribution rights for the Company's 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. Rockwell's 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 2021 and 2020, Rockwell's direct sales to Baxter aggregated approximately 26% and 25% of sales, respectively, and the Company had a receivable from Baxter of $3.5 million and $1.6 million as of December 31, 2021 and 2020, respectively.

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

The majority of Rockwell's international sales in each of the last two years were sales to domestic distributors that were resold to end users outside the United States. Rockwell's sales to foreign customers and distributors accounted for approximately 10% and 9% of its total sales in 2021 and 2020, respectively. One international customer, Nipro Medical Corporation, accounted for 8% and 7% of its sales for 2021 and 2020, respectively.

Note 6. Distribution Agreement

In October 2014, Rockwell entered into the Baxter Distribution Agreement, pursuant to which Baxter became Rockwell's exclusive agent for commercializing its hemodialysis concentrate and ancillary products in the United States and various foreign countries for an initial term of 10 years ending October 2, 2024. Rockwell retains sales, marketing and distribution rights for its hemodialysis concentrate products for its international customers and in those countries in which its has an established commercial presence. During the term of the Distribution Agreement, Baxter has agreed not to manufacture or sell any competitive concentrate products in the United States hemodialysis market, other than specified products. The Distribution Agreement does not include any of the Company’s drug products. In June 2017, Rockwell 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, Rockwell 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 Rockwell 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 Rockwell's obligations to maintain specified manufacturing capacity and quality levels. Rockwell continues to manage customer service, transportation and certain other functions for its current customers. For customer service, Baxter pays Rockwell an amount equal to our related costs plus a slight mark-up for these services. For transportation costs, Baxter pays Rockwell an amount equal to its 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 Rockwell and Baxter, Baxter will pay Rockwell 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, Rockwell 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 Rockwell 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, Rockwell received an upfront fee of $20 million in October 2014. In December 2021, Baxter sent us a letter reserving its right to assert that it could claim a refund of a portion of its upfront payment if it terminates the Distribution Agreement as a result of certain price increases. While management believes that the claims in Baxter's letter are without merit and that Baxter cannot recoup any portion of its upfront payment, management cannot assure you what a mediator or arbitrator may decide if it pursues such claim. Rockwell intends to vigorously defend against any such claim.

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 $1.9 million and $2.0 million for the years ended December 31, 2021, and 2020, 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, 2021 and 2020 are as follows (table in thousands):

	December 31, 2021	December 31, 2020
Raw Materials	$ 3,434	$ 3,112
Work in Process	201	172
Finished Goods	1,964	1,805
Total	$ 5,599	$ 5,089

As of December 31, 2021 and 2020, the Company classified $1.5 million and $1.2 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, 2021 and 2020, Rockwell had total Triferic inventory aggregating $1.7 million and $3.9 million, respectively, against which Rockwell had reserved $0.1 million and $2.6 million, respectively.

The $1.6 million net value of Triferic inventory consisted of $0.3 million of Triferic (dialysate) finished goods with expiration dates ranging from July 2022 to December 2023, $0.4 million of Triferic API with estimated useful lives extending through 2023, and $0.9 million of Triferic raw material with an estimated useful live of 25 years.

Note 8. Property and Equipment

As of December 31, 2021 and 2020, the Company's property and equipment consisted of the following (table in thousands):

	2021	2020
Leasehold Improvements	$ 1,204	$ 1,196
Machinery and Equipment	5,864	5,475
Information Technology & Office Equipment	1,845	1,831
Laboratory Equipment	676	676
	9,589	9,178
Accumulated Depreciation	(7,103)	(6,536)
Net Property and Equipment	$ 2,486	$ 2,642

Depreciation expense during the years ended December 31, 2021 and 2020 is as follows (table in thousands):

	2021	2020
Depreciation expense	$ 668	$ 834

Note 9. Goodwill and Intangible Assets

Total goodwill was $0.9 million at December 31, 2021 and 2020. Rockwell completed its annual impairment tests as of December 31, 2021 and 2020, and determined that no adjustment for impairment of goodwill was required during the years ended December 31, 2021 and 2020.

Note 10. Accrued Liabilities

Accrued liabilities as of December 31, 2021 and 2020 consisted of the following (table in thousands):

	2021	2020
Accrued Research & Development Expense	$ 366	$ 232
Accrued Compensation and Benefits	1,791	2,500
Accrued Unvouchered Receipts	796	755
Accrued Workers Compensation	382	395
Other Accrued Liabilities	1,755	1,131
Total Accrued Liabilities	$ 5,090	$ 5,013

Note 11. Insurance Financing Note Payable

On July 3, 2021, the Company entered into a short-term note payable for $2.0 million, bearing interest at 3.93% per annum to finance various insurance policies. Principal and interest payments related to this note began on July 3, 2021 and are paid on a straight-line amortization over 9 month with the final payment due on March 3, 2022. As of December 31, 2021, the Company's insurance note payable balance was $0.4 million.

Note 12. Stockholders' Equity

Preferred Stock

As of December 31, 2021 and 2020, 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, 2021 and 2020, there were 170,000,000 shares of common stock, $0.0001 par value per share, authorized and 93,986,470 and 93,573,165 shares issued and outstanding, respectively.

During the years ended December 31, 2021 and 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. The registration statement on Form S-3 expired on October 1, 2021 and no further sales may be made under the Sales Agreement.

During the year ended December 31, 2021, the Company did not sell any shares of its common stock pursuant to the Sales Agreement.

Note 13. Stock-Based Compensation

The Board of Directors adopted the Rockwell Medical, Inc., 2007 Long Term Incentive Plan ("2007 LTIP") on April 11, 2007. The 2007 LTIP expired on April 11, 2017 and no equity awards were granted under the 2007 LTIP following its expiration. There were 11,500,000 shares of common stock reserved for issuance under the 2007 LTIP. The Board of Directors adopted the 2018 Long-Term Incentive Plan ("2018 LTIP") on January 29, 2018 as a replacement for the 2007 LTIP. Initially there were 3,300,000 shares of common stock reserved for issuance under the 2018 LTIP. On May 18, 2020, at the 2020 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.

The Company's 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 the Company, 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 the Company in this manner would be retired.

The Company recognized total stock-based compensation expense during the years ended December 31, 2021 and 2020 as follows (table in thousands):

	Year Ended December 31,	
	2021	2020
Service based awards:		
Restricted stock units	$ 344	$ 372
Stock option awards	1,354	1,491
	$ 1,697	$ 1,863
Performance based awards:		
Restricted stock awards	$ (390)	$ —
Restricted stock units	—	(1,148)
Stock option awards	(364)	(240)
	(754)	(1,388)
Total	$ 943	$ 475

Restricted Stock Awards

A summary of the Company's restricted stock awards during the years ended December 31, 2021 and 2020 is as follows:

	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested at January 1, 2020	146,800	$ 5.70
Unvested at December 31, 2020	146,800	5.70
Forfeited	(68,500)	5.70
Unvested at December 31, 2021	78,300	$ 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, 2021, unvested restricted stock awards of 78,300 were related to performance based awards. The forfeited performance-based restricted stock awards of 68,500 was due to the termination of the Company's former Chief Science Officer on January 19, 2021. These forfeited awards reduced stock-based compensation expense by $0.4 million. Stock-based compensation expense of nil was recognized for both the year ended December 31, 2021 and 2020, respectively. As of December 31, 2021, 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, 2021 and 2020 is as follows:

	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested at January 1, 2020	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
Granted	310,050	0.90
Forfeited	(11,799)	4.81
Vested	(241,563)	2.27
Unvested at December 31, 2021	322,182	$ 1.17

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 0.3 million and $0.4 million was recognized during the year ended December 31, 2021 and 2020, respectively. As of December 31, 2021, the unrecognized stock-based compensation expense was $0.1 million over the next 12 months.

Performance Based Restricted Stock Units

As of December 31, 2021, there were no outstanding performance-based restricted stock units

A summary of the Company’s performance based restricted stock units during the year ended December 31, 2020 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	—	$ —

Stock-based compensation expense recognized for performance based restricted stock units was nil and $(1.1) million for the year ended December 31, 2021 and 2020, respectively. As of December 31, 2021, there was no unrecognized stock-based compensation expense related to performance-based restricted stock units.

Service Based Stock Options

The fair value of the service based stock options granted for the years ended December 31, 2021 and 2020 were based on the following assumptions:

	December 31,	
	2021	**2020**
Exercise price	$0.54 - $0.54	$0.92 - $2.90
Expected stock price volatility	75.0% - 77.7%	68.2% - 75.8%
Risk-free interest rate	0.47% - 1.30%	1.70%
Term (years)	5.5 - 6.0	5.5 - 6.0

A summary of the Company's service based stock option activity for the years ended December 31, 2021 and 2020 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, 2020	8,210,024	$ 7.06	5.1	$ —
Granted	2,288,386	1.94	9.0	—
Expired	(4,249,596)	(8.07)		
Forfeited	(530,858)	(3.88)	—	
Outstanding at December 31, 2020	5,717,956	$ 4.55	6.6	$ —
Granted	1,947,162	0.88	—	—
Expired	(1,408,709)	(7.00)	—	
Forfeited	(441,903)	(2.22)	—	
Outstanding at December 31, 2021	5,814,506	$ 2.91	7.5	$ —
Exercisable at December 31, 2021	2,612,079	$ 4.81	5.7	$ —

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, 2021 and 2020, the service based stock options granted consisted of 1,947,162 and 2,288,386 options granted to employees, respectively. As of December 31, 2021, 2,612,079 vested options were exercisable at a weighted average price of $4.81 per share.

During the year ended December 31, 2021 and 2020, stock-based compensation expense of $1.4 million and $1.5 million was recognized, respectively. As of December 31, 2021, total stock-based compensation expense related to 3,202,427 unvested options not yet recognized totaled approximately $1.3 million over the next 3.1 years.

Performance Based Stock Options

A summary of the performance based stock options granted for the year ended December 31, 2021, is as follows:

	Number of Shares	Weighted Average Exercise Price
Outstanding at January 1, 2020	388,125	$ 4.70
Granted	750,000	2.20
Forfeited	(388,125)	(4.70)
Outstanding at December 31, 2020	750,000	$ 2.20
Cancelled	(750,000)	2.20
Outstanding at December 31, 2021	—	$ —
Exercisable at December 31, 2021	—	$ —

Stock-based compensation expense recognized for performance-based stock options was $(0.4) million and $(0.2) million for the year ended December 31, 2021 and 2020. As of December 31, 2021, there were no performance based stock options outstanding. The canceled unvested performance-based stock options of 750,000 is due to management determining that the performance goal will not be achieved.

Note 14. License Agreements

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. 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). As of December 31, 2021 and 2020, the Company has accrued $86,400 and $100,700, respectively, relating to certain IP reimbursement expenses and certain sublicense royalty fees as an accrued liability 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, 2021.

Note 15. Commitments and Contingencies

Leases

Rockwell leases its production facilities and administrative offices as well as certain equipment used in its operations including leases on transportation equipment used in the delivery of its products. The lease terms range from monthly to seven years. Rockwell occupies a 51,000 square foot facility and a 17,500 square foot facility in Wixom, Michigan under a lease expiring in August 2024. Rockwell also occupies 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, Rockwell occupies 4,100 square feet of office space in Hackensack, New Jersey under a lease expiring on October 31, 2024. This lease was subleased on December 15, 2021 with an expiration date of October 31, 2024.

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

	For the year ended December 31, 2021	For the year ended December 31, 2020
Operating leases		
Operating lease cost	$ 1,793	$ 1,609
Variable lease cost	373	488
Operating lease expense	2,166	2,097
Finance leases		
Amortization of right-of-use assets	313	18
Interest on lease obligations	99	5
Finance lease expense	412	23
Short-term lease rent expense	17	17
Total rent expense	$ 2,595	$ 2,137
Other information		
Operating cash flows from operating leases	$ 1,772	$ 1,648
Operating cash flows from finance leases	$ 99	$ 5
Financing cash flows from finance leases	$ 255	$ 17
Right of use assets exchanged for operating lease liabilities	$ 4,217	$ 268
Right of use assets exchanged for finance lease liabilities	$ 2,431	$ 930
Weighted-average remaining lease term - operating leases	3.5	2.3
Weighted-average remaining lease term – finance leases	5.4	5.8
Weighted-average discount rate - operating leases	6.3 %	6.4 %
Weighted-average discount rate – finance leases	6.4 %	5.1 %

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

	Operating	Finance
Year ending December 31, 2022	$ 1,772	$ 660
Year ending December 31, 2023	1,455	668
Year ending December 31, 2024	1,114	671
Year ending December 31, 2025	637	676
Year Ended December 31, 2026	259	665
Remaining future payments	120	311
Total	5,357	3,651
Less present value discount	$ (555)	$ (562)
Operating and Finance lease liabilities.	$ 4,802	$ 3,089

Insurance

The Company evaluates various kinds of risk that it is exposed to in its business. In its evaluation of risk, the Company evaluates options and alternatives to mitigating such risks. For certain insurable risks, Rockwell may acquire insurance policies to protect against potential losses or to partially insure against certain risks. For the Company's subsidiary, Rockwell Transportation, Inc., Rockwell maintains a partially self-insured workers' compensation policy. Under the policy, its self-insurance retention is $350,000 per occurrence and $599,000 in aggregate coverage for the policy year ending July 1, 2022. The total amount at December 31, 2021 by which retention limits exceed the claims paid and accrued is approximately $431,000 for the policy year ending July 1, 2022. Estimated loss and additional future claims of approximately $382,000 have been reserved and accrued for the year ended December 31, 2021.

As of December 31, 2021, approximately $0.4 million was held in cash collateral and escrow by the insurance carrier for workers' compensation insurance. At December 31, 2021, amounts held in cash collateral and escrow are included in prepaid expenses and other non-current assets in the consolidated financial statements.

Purchase Obligations

Rockwell has contracts for anticipated future obligations through December 31, 2022 of approximately $32.6 million, which include $31.2 million for concentrate manufacturing and $1.4 million in ancillary supplies.

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 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. On January 31, 2022, the Company received a letter from the United States Securities and Exchange Commission (the "Commission") concluding it's investigation and stating that it does not intend to recommend an enforcement action by the Commission against the Company.

Note 16. Loan and Security Agreement

On March 16, 2020, Rockwell 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, 2021, interest expense amounted to $2.0 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, 2021. 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. If the Company is unable to comply with the covenants under the Loan Agreement, it would pursue all available cure options in order to regain compliance. The Company previously failed to satisfy a revenue covenant for the period ended December 31, 2020 and then subsequently agreed to an appropriate remedy during the applicable cure period. However, the Company may not be able to mutually agree with Innovatus on appropriate remedies to cure a future breach of a covenant, which could give rise to an event of default. If the Company is unable to avoid an event of default, any required repayments could have an adverse effect on its liquidity. The financial statements for December 31, 2021 have been prepared with the assumption that the Company will be able to agree to an appropriate remedy during the applicable cure period for any future breaches of operating 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.

In September 2021, the Company entered into an amendment to the Loan Agreement in which the Company, in exchange for Innovatus lowering the sales covenants, agreed to (i) prepay an aggregate principal amount of $7,500,000 in ten installments commencing on December 1, 2021; (ii) pay an additional prepayment premium of 5% on prepaid amounts if the Company elects to prepay all outstanding term loans on or before September 24, 2023 and (iii) maintain minimum liquidity of no less than $5,000,000 if the aggregate principal amount of term loans is greater than $15,000,000 pursuant to the liquidity covenant in the Loan Agreement. As of December 31, 2021, the Company was in compliance with its financial covenants and was not in compliance with its reporting covenant related to the delivery of the financial statements. As disclosed in Note 18, the Company and Innovatus entered into an agreement to waive this non-compliance.

As of December 31, 2021, the outstanding balance of the Term Loan was $20.6 million, net of unamortized issuance costs and discount of $1.2 million.

The following table reflects the schedule of principal payments on the Term Loan as of December 31, 2021 (in thousands):

Year	Principal Payments
2022	$ 7,750
2023	6,000
2024	6,000
2025	2,000
	$ 21,750

Note 17. Income Taxes

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

	2021	2020
Tax Expense (Benefit) Computed at 22.62% and 22.67% of Pretax Income (Loss)	$ (6,744)	$ (6,373)
Changes in Tax Laws	—	—
Foreign Income Tax Expense	—	—
Effect of Change in Valuation Allowance	6,744	6,373
Total Income Tax Expense	$ —	$ —

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

	December 31,	
	2021	2020
Deferred tax assets:		
Net Operating Loss Carryforward	$ 66,895	$ 59,586
Stock Based Compensation	7,726	7,582
Deferred Revenue	1,846	2,310
General Business Credit	6,872	6,872
Accrued Expenses	174	185
Inventories	88	666
Book over Tax Depreciation	6	25
Other Deferred Tax Assets	865	387
Total Deferred Tax Assets	84,472	77,613
Deferred Tax Liabilities:		
Goodwill & Intangible Assets	183	155
Prepaid Expenses	381	294
Total Deferred Tax Liabilities	564	449
Subtotal	83,908	77,164
Valuation Allowance	(83,908)	(77,164)
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 $294.8 million that expire between 2022 and 2038.

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. The Company recognized no income tax expense or benefit for the years ended December 31, 2021, and 2020. While the Company anticipates generating income within the next year or two, it expects to incur operating losses until its drug products are marketed and generating sufficient profits to offset its operating expenses. Considered together with the Company's limited history of operating income and its net losses in 2021 and 2020, management has placed a full valuation allowance against the net deferred tax assets as of December 31, 2021 and 2020. 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.

Rockwell accounts for its uncertain tax positions in accordance with ASC 740-10, *Income Taxes* and the amount of unrecognized tax benefits related to tax positions is not significant at December 31, 2021 and 2020. The Company has not been under tax examination in any jurisdiction for the years ended December 31, 2021 and 2020. Tax examination years of 2017 to 2020 remain open.

Note 18. Subsequent Events

On March 14, 2022, Raymond Pratt notified the Company of his decision to resign as the Company’s Chief Development Officer, effective as of March 25, 2022.

On March 20, 2022, John P. McLaughlin notified the board of directors (the “Board”) of the Company of his intent to resign as a member of the Board and as Chairman of the Board effective as of April 1, 2022. The size of the Board will be reduced to six directors effective upon Mr. McLaughlin’s resignation. The Board intends to appoint a replacement for Mr. McLaughlin on the Audit Committee of the Board prior to the effective date of his resignation. Mr. McLaughlin’s decision was

not the result of any dispute or disagreement with the Company on any matter relating to the Company's operations, policies or practices.

On March 31, 2022, the Company requested the Collateral Agent and Lenders to consent to the delivery to Collateral Agent and Lenders of its annual audited financial statements for the fiscal year 2021, as required pursuant to Debt Agreement, by April 15, 2022 as opposed to within 90 days of the December 31, 2021 and Collateral Agent and Lenders agreed to such request.

Amended Supply Agreement

The Company has been working to renegotiate certain terms of its supply contracts with the Company's two largest customers in an effort to allow the Company to stabilize its concentrates business. On April 6, 2022, the Company and DaVita Inc. ("DaVita") entered into an amendment (the "Amendment") to the Products Purchase Agreement, dated July 1, 2019 (the "Supply Agreement") under which the Company supplies DaVita with certain dialysis concentrates. Under the Amendment, the Company and DaVita agreed to a price increase, effective May 1, 2022, as well as the pass-through of certain inflationary costs, determined on a quarterly basis. Certain costs are subject to a cap. The Amendment also requires the Company to implement certain cost containment and cost-cutting measures.

The Amendment contains certain covenants with respect to the Company's ongoing operations, including a minimum cash covenant, and the requirement to raise $15 million in additional capital by June 30, 2022. The Amendment also establishes a joint committee that will oversee certain efficiency and cost-savings activities to be undertaken by the Company. Certain cost savings that are realized by the Company will be shared with DaVita in the manner set forth in the Amendment.

Securities Purchase Agreement

Also on April 6, 2022, the Company and DaVita entered into a Securities Purchase Agreement (the "SPA"), pursuant to which the Company will issue up to $15 million of preferred stock to DaVita. The Company initially issue 7,500 shares of a newly designated series of preferred stock, which is designated "Series X Convertible Preferred Stock" (the "Series X Preferred Stock") for gross proceeds of $7,500,000. The Company will issue to DaVita an additional 7,500 shares of Series X Preferred Stock in a second closing (the "Second Tranche") for an additional $7,500,000 if the Company raises $15 million in additional capital by June 30, 2022.

The Series X Preferred Stock will be issued for a price $1,000 per share (the "Face Amount"), subject to accretion at a rate of 1% per annum, compounded annually. If the Company's common stock trades above $2.00 for a period of 30 calendar days, the accretion will thereafter cease.

The Series X Convertible Preferred Stock is convertible to common stock at rate equal to the Face Amount, divided by a conversion price of $1.00 per share (subject to adjustment for stock splits, reverse stock splits and similar recapitalization events). As a result, each share of Series X Preferred Stock will initially convert into 1,000 shares of common stock. DaVita's right to convert to common stock is subject to a beneficial ownership limitation, which is initially set at 9.9% of the outstanding common stock, which limitation may be reset (not to exceed 19.9%) at DaVita's option and upon providing prior written notice to the Company. The shares issued in the Second Tranche will have a lower conversion price if the Company raises capital through the issuance of convertible preferred stock prior to the closing of the Second Tranche and the conversion price of the securities sold in such preferred stock offerings is below $1.00 per share. In addition, any debt financing is limited by the terms of our Securities Purchase Agreement with DaVita. Specifically, until DaVita owns less than 50% of its investment, the Company may only incur additional debt in the form of a purchase money loan, a working capital line of up to $5 million or to refinance existing debt, unless DaVita consents.

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ROCKWELL MEDICAL, INC.

Corporate Information

Annual Meeting

The Annual Meeting of the Stockholders will be held:

Monday May 9, 2022
At 10:00 am ET
Virtual Stockholder Meeting
www.virtualshareholdermeeting.com/RMTI2022

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, 2021 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".

2021 ANNUAL REPORT

www.rockwellmed.com