2022 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, 2022

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, 2022 (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 $11,096,662.

Number of shares outstanding of the registrant's Common Stock, par value $0.0001, as of March 29, 2023: 12,552,673 shares.

Documents Incorporated by Reference

Portions of the registrant's definitive Proxy Statement pertaining to the 2023 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, 2022, are herein incorporated by reference in Part III of this Annual Report on Form 10-K.

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Triferic®, CitraPure®, Dri-Sate®, 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;
- our ability to negotiate favorable agreements with major customers and obtain and/or retain major customers and distributors;
- the duration over which our cash balances will fund our operations;
- our ability to continue as a going concern;
- our ability to grow our revenue generating business;
- our expectations for generating revenue or becoming profitable on a sustained basis;
- 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 Loan Agreement with Innovatus;
- the effects of the COVID-19 pandemic on patients, our customers and distributors, and our business, including manufacturing operations and suppliers;
- the acceptance of our products by doctors, patients or payors;
- the availability of adequate reimbursement for our products from insurance companies and the government;
- our ability to use existing inventory before shelf life expiration;
- the safety and efficacy of our products;
- our expectations regarding the timing of submissions to, and decisions made by, the U.S. Food and Drug Administration ("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 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 manufacturing and research and development capabilities;
- 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 the profitability of such agreement; 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.

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 2023 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.

Triferic®, CitraPure®, Dri-Sate®, 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.

BUSINESS OVERVIEW

Rockwell Medical is a healthcare company that develops, manufactures, commercializes, and distributes a portfolio of hemodialysis products for dialysis providers worldwide.

Rockwell is a revenue-generating business and the second largest supplier of acid and bicarbonate concentrates for dialysis patients in the United States. Hemodialysis is the most common form of end-stage kidney disease treatment and is usually performed at freestanding outpatient dialysis centers, at hospital-based outpatient centers, at skilled nursing facilities, or in a patient's home. This represents a large market opportunity for which Rockwell's products are well-positioned to meet the needs of patients.

Rockwell manufactures hemodialysis concentrates under Current Good Manufacturing Practices ("cGMP") regulations at its three facilities in Michigan, Texas, and South Carolina totaling approximately 175,000 square feet, and manufactures dry acid concentrate mixers at its facility in Iowa. Rockwell delivers the majority of its hemodialysis concentrates products and mixers to dialysis clinics throughout the United States and internationally utilizing its own delivery trucks and third-party carriers. Rockwell has developed a core expertise in manufacturing and delivering hemodialysis concentrates, and has built a longstanding reputation for reliability, quality, and excellent customer service.

In addition to its primary focus on hemodialysis concentrates, Rockwell also has a proprietary parenteral iron product, Triferic® (ferric pyrophosphate citrate ("FPC")), which is indicated to maintain hemoglobin in adult patients with hemodialysis-dependent chronic kidney disease. While Rockwell has discontinued commercialization of Triferic in the United States, the Company has established several international partnerships with companies seeking to develop and commercialize Triferic outside the United States and is working closely with these international partners to develop and commercialize Triferic in their respective regions. Additionally, Rockwell continues to evaluate the viability of its FPC platform and FPC's potential to treat iron deficiency, iron deficiency anemia, and in different therapeutic settings.

Rockwell was 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 https://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.

SIGNIFICANT 2022 HIGHLIGHTS

Rockwell Medical's key developments from 2022 include:

- In January 2022, we announced regulatory approval of Triferic (dialysate) and Triferic AVNU in South Korea.
- In April 2022, we expanded our partnership with DaVita, Inc. ("DaVita") through an amended supply agreement.

- In April 2022, we entered into a stock purchase agreement with DaVita and closed the initial $7.5 million tranche.
- In April 2022, we announced that our partner in China, Wanbang Biopharmaceuticals, a subsidiary of Shanghai Fosun Pharmaceutical, completed enrollment with over 400 patients for its pivotal phase 3 clinical trial of Triferic in China.
- In May 2022, we announced a 1-for-11 reverse stock split, which became effective at 12:01 a.m. Eastern Time on May 13, 2022. The new CUSIP number following the reverse stock split is 774374300.
- In May 2022, we regained compliance with the minimum bid price requirement under Nasdaq Listing Rule 5550(a)(2) for continued listing on The Nasdaq Capital Market.
- In June 2022, we closed a $15 million financing with Armistice Master Fund Ltd., which consisted of a $12 million registered direct offering, and a $3 million private placement, both priced at-market.
- In June 2022, we closed the second $7.5 million tranche of the DaVita stock purchase agreement.
- In July 2022, Jeil Pharmaceutical commercially launched Triferic in South Korea.
- In July 2022, Mark Strobeck, Ph.D. joined Rockwell as President and Chief Executive Officer and as a member of the Company's Board of Directors.
- In August 2022, Heather Hunter joined the Company as SVP, Chief Corporate Affairs Officer.
- In November 2022, we announced that we reacquired our distribution rights for our hemodialysis concentrates business from Baxter Healthcare Corporation, a subsidiary of Baxter International, Inc. ("Baxter").
- In November 2022, we announced that we discontinued our New Drug Applications ("NDAs") for Triferic and Triferic AVNU in the United States.
- In November 2022, we announced a new business strategy focusing on growing our revenue-generating businesses, which include hemodialysis concentrates and international partnerships for Triferic.
- In November 2022, we announced that we put development work associated with FPC for home infusion on hold. Preliminary results from the microbiology and short-term stability study indicated that the program would likely not meet the FDA's requirements to support the Investigational New Drug ("IND") application and would require significant capital expenditure and resources to conduct additional re-formulation work and a Phase 2 study.
- In November 2022, we announced that we will determine the path forward for FPC in acute heart failure as the Company works towards profitability.
- In November 2022, we announced that we undertook workforce reductions as part of our business restructuring.
- In December 2022, we expanded our hemodialysis concentrates distribution capabilities westward into Minnesota with DaVita.

OUR STRATEGY

Rockwell Medical is focused on innovative, long-term growth strategies that enhance its products, its processes, and its people, enabling the Company to deliver exceptional value to the healthcare system and provide a positive impact on the lives of hemodialysis patients.

Rockwell’s strategy is focused on growing the Company's revenue-generating business, which currently includes its hemodialysis concentrates and international partnerships for Triferic, pausing further investment in capital-intensive pharmaceutical development programs, and achieving profitability to put the Company in a stronger and more stable financial position.

Once the Company achieves profitability and sustains cash flow from its revenue-generating businesses, it will then consider investments in higher-value, longer-term products to develop a broader kidney care products portfolio.

HEMODIALYSIS CONCENTRATES

Rockwell's mission is to provide dialysis clinics and the patients they serve with the highest quality products supported by the best customer service in the industry.

Hemodialysis is the most common form of end-stage kidney disease treatment and is usually performed at freestanding outpatient dialysis centers, at hospital-based outpatient centers, at skilled nursing facilities, or in a patient's home. Our hemodialysis concentrates products are used to sustain a patient's life by removing toxins and balancing electrolytes in a dialysis patient's bloodstream.

Rockwell's products are vital to vulnerable patients with end-stage kidney disease. 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. All of our concentrate products are manufactured according to Association for the Advancement of Medical Instrumentation ("AAMI") 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.

A key element of our dialysis business strategy going forward is to improve the strength of our concentrates business. We believe we can achieve this by growing our business through the addition of new customers, expanding our territory coverage, increasing the efficiency by which Rockwell produces its products, and pricing our products appropriately to drive profitability.

Our Products:

Most hemodialysis patients receive dialysis treatment three times per week, or approximately 156 times per year. Most patients who have their dialysis treatment performed at a free-standing clinic have significant and irreversible loss of kidney function. These are commonly referred to as "chronic" dialysis patients. Patients who 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 who 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.

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 has been shown to 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 acid concentrate in 55 gallon drums and one-gallon jugs sold in cases of four, and as a dry powder acid concentrate for use with our Dry Acid Concentrate Mixer in 25 gallon cases.

Dri-Sate Dry Acid Concentrate

Our Dri-Sate Concentrate is our acetic acid-based product. Dri-Sate is packaged as a dry powder acid concentrate for use with our Dry Acid Concentrate Mixer in 25 gallon cases.

RenalPure Liquid Acid Concentrate

Our RenalPure Liquid Concentrate is our acetic acid-based product and is packaged in 55 gallon drums and cases of four one gallon jugs.

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 cases of four one-gallon jugs 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.

Market Opportunity:

Rockwell's vision is to become the leading global supplier of hemodialysis concentrates.

Today, Rockwell is the second largest supplier of acid and bicarbonate concentrates for dialysis patients in the United States. According to an independent research report that Rockwell commissioned from L.E.K. Consulting LLC in 2022, the hemodialysis concentrates market in the United States alone is currently valued at $380 million and is anticipated to grow to approximately $500 million by 2026. This is driven primarily by an increasing number of patients suffering from end-stage kidney disease. Hemodialysis concentrates represents a large market opportunity for which we believe Rockwell's products are well-positioned to meet the needs of patients. Rockwell is one of only two suppliers that has the manufacturing scalability and transportation infrastructure to service the over 7,200 dialysis clinics in the United States along with select international markets.

Sales and Marketing:

Prior to the second quarter of 2022, Rockwell's concentrates business operated at a loss. This loss was accelerated due to inflation, which has increased our manufacturing and operating costs. We undertook discussions with our largest customers to renegotiate our existing supply contracts to improve the profitability of this business line. On April 6, 2022, we amended our agreement with our long-time partner, DaVita, a leading provider of kidney care, to enable us to stabilize our concentrates business. The amended agreement provides for changes to pricing, cost share, cost cutting, and joint efforts to improve supply chain. In addition to the amended agreement, DaVita invested $15 million in preferred stock in two equal tranches. The first tranche of $7.5 million was funded on April 7, 2022. The second tranche of $7.5 million was funded on June 16, 2022. We continue to review our entire supply chain to identify opportunities for improvement, prioritizing initiatives that will have the largest impact on long-term efficiency, profitability, and growth.

On November 9, 2022, Rockwell reacquired its distribution rights to its hemodialysis concentrates products from Baxter and agreed to terminate the exclusive distribution agreement dated October 2, 2014. Exclusivity and other provisions associated with the distribution agreement terminated November 9, 2022 and the remaining operational elements of the agreement terminated December 31, 2022. Rockwell agreed to provide certain services to a group of Baxter customers until March 31, 2023. Under the exclusive distribution agreement, Baxter distributed and commercialized Rockwell’s hemodialysis concentrates products in the United States and certain other countries. Rockwell manufactured all hemodialysis concentrates products and provided customer service and order delivery to nearly all U.S. customers. Following the reacquisition of these rights, Rockwell is now able to sell its hemodialysis concentrates products directly to dialysis clinics throughout the United States and around the world. Additionally, Rockwell is now able to independently price its products, eliminate costs associated with manufacturing covenants, improve manufacturing efficiencies and realize the full benefits from those improvements, and develop, in-license, or acquire new products to develop a broader kidney care products portfolio. This is expected to improve Rockwell's overall profitability and set the Company on a positive growth trajectory.

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 the primary distributor of our dialysis concentrates in certain countries in Latin America that were not covered under the Distribution Agreement.

Dialysate concentrates accounted for approximately 98.4% of our revenue for the year ended December 31, 2022. Approximately 91.1% of our sales for the year ended December 31, 2022 were to distributors and customers for use in the United States.

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, accounted for 46% of our concentrate sales in 2022 and 47% of our concentrate sales in 2021. Our accounts receivable from this customer were $1.9 million and $1.0 million as of December 31, 2022 and 2021, respectively. In August 2019, we entered into the 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. Also on April 6, 2022, the Company and DaVita entered into a Securities Purchase Agreement (the "SPA"), which provided for the issuance by the Company of up to $15 million of preferred stock to DaVita (see "Preferred Stock" section in Note 12 below).

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 2022 and 2021, our direct sales to Baxter aggregated approximately 29% and 26% of sales, respectively, and we had accounts receivable from Baxter of $2.3 million and $3.5 million as of December 31, 2022 and 2021, respectively. As noted above, Rockwell reacquired its distribution rights to its hemodialysis concentrates products from Baxter and terminated the Distribution Agreement.

No other customers accounted for more than 10% of our sales in any of the last three years. Nipro Medical Corporation, accounted for 7% and 8% of our sales in 2022 and 2021, respectively.

DaVita, the former Baxter customers, and Nipro Medical Corporation are important to our business, financial condition and results of operations. The loss of any significant accounts could have a material adverse effect on our business, financial condition and results of operations.

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

The majority of our international sales in each of the last two years were sales to domestic distributors that were resold to end users outside the United States. Our total international sales, including sales made through domestic distributors for resale outside the United States, aggregated 9% and 10% of our overall sales in 2022 and 2021, respectively.

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

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 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.

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.

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, Texas 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 properties and microbial limits of each product lot comply 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.

The raw materials and packaging materials for our hemodialysis concentrates, the components for our hemodialysis kits and the ancillary hemodialysis products we distribute 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.

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 operated under the Distribution Agreement on behalf of Baxter for domestic business. On November 9, 2022, Rockwell reacquired its distribution rights to its hemodialysis concentrates products from Baxter and agreed to terminate the exclusive distribution agreement dated October 2, 2014. Exclusivity and other provisions associated with the distribution agreement terminated November 9, 2022 and the remaining operational elements of the agreement terminated December 31, 2022. Rockwell agreed to provide certain services to a subgroup of Baxter's customers until March 31, 2023.

Triferic®

Our first two branded products from our FPC platform, Triferic® (dialysate) and Triferic® AVNU, are indicated to maintain hemoglobin in patients undergoing hemodialysis. We began commercializing Triferic and Triferic AVNU in the United States in the second half of 2019 and in early 2021, respectively. In addition, Rockwell established six international partnerships to develop and commercialize Triferic in China, India, Korea, Turkey, Peru and Chile.

In 2022, Rockwell undertook a strategic review of Triferic's viability in the United States. Triferic was launched into a very competitive marketplace with well-entrenched products and a lack of consensus regarding unmet medical needs for dialysis patients with anemia. Due to its limited market adoption, unfavorable reimbursement, and absence of interest from other companies to license or acquire Triferic despite Rockwell's significant effort to partner the program, the Company discontinued its NDAs for Triferic and Triferic AVNU in the United States in the fourth quarter of 2022. Sustaining Triferic commercially in the United States resulted in a losses to Rockwell annually. The decision to discontinue the NDAs was not made lightly as the Company realizes the direct impact this action had on patients using the products. Triferic and its approved presentations were not discontinued for safety reasons.

International Partnerships:

Rockwell continues to support its partners outside the United States who have exclusive license agreements to develop and commercialize Triferic in China, India, Korea, Turkey, Peru and Chile. 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. We believe there is still potential opportunity for Triferic internationally and will work diligently to support our partners, which requires minimal financial commitment from Rockwell and provides us with potential for near- and long-term revenue. We continue to pursue international licensing opportunities in other countries and regions.

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.

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.

We have engaged CMOs for the manufacture and packaging of Triferic. We have one supplier for the active pharmaceutical ingredient ("API") utilized in Triferic 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.

RESEARCH AND DEVELOPMENT PIPELINE

FPC for home infusion is Rockwell's follow-up to Triferic and utilizes the FPC platform in the home infusion setting.

In late 2021, Rockwell filed an IND application with the FDA for the treatment of iron deficiency anemia in patients, who are receiving medications in the home infusion setting. During the second quarter 2022, Rockwell provided the FDA with supplemental data to be used in Rockwell's clinical studies and to clinically support the Company's IND application for home infusion. The FDA placed this program on Clinical Hold and requested that additional data related to the microbiology and short-term stability of this formulation be provided to support the application. During the third quarter of 2022, Rockwell conducted a microbial challenge and short-term stability study of FPC for Home Infusion, in accordance with FDA guidance, to support the Company's IND application. Preliminary results from the microbiology and short-term stability study indicated that the program would likely not meet the FDA's requirements to support the IND application and would require significant capital expenditure and resources to support additional re-formulation work and conduct a Phase 2 study. As a result, Rockwell has put development work associated with FPC for Home Infusion on hold.

Rockwell is also exploring FPC's impact on the treatment of hospitalized acute heart failure patients, which affects more than one million people in the United States annually. Rockwell conducted a pre-IND meeting with the FDA in 2022 and will determine the path forward for FPC in acute heart failure as the Company works toward profitability.

MATERIAL AGREEMENTS

Distribution Agreement with Baxter

Pursuant to the Exclusive Distribution Agreement dated October 2, 2014 (as amended, the "Distribution Agreement"), Baxter was 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 retained sales, marketing and distribution rights for our hemodialysis concentrate products for our international customers and in those countries in which we had an established commercial presence. In the fourth quarter of 2022, Rockwell reacquired its distribution rights to its hemodialysis concentrates products from Baxter and terminated the Distribution Agreement. Rockwell is required to pay Baxter a fee for the reacquisition of its distribution rights. This fee is payable in two equal installments on January 1, 2023 and April 1, 2023.

Following the reacquisition of the distribution rights, Rockwell is now able to sell its hemodialysis concentrates products to dialysis clinics throughout the United States and around the world. Baxter and Rockwell are working closely together to transition customers' purchases of Rockwell's hemodialysis concentrates from Baxter to Rockwell.

Products Purchase Agreement with DaVita

In August 2019, we signed a Products Purchase Agreement (the "Products Purchase Agreement") with DaVita. Pursuant to the Products Purchase Agreement, the Company supplies certain DaVita dialysis centers with dialysis acid concentrate (i.e., CitraPure (Liquid and Dry Acid), Dri-Sate Dry Acid or RenalPure Liquid Acid) and bicarbonate (i.e., RenalPure® Bicarbonate Powder or SteriLyte Liquid Bicarbonate) through December 31, 2023 (the "Initial Term"), subject to certain terms and conditions. The Products Purchase Agreement is a fixed price contract that allows for prices increases only under certain conditions and only after following procedures set forth in the Products Purchase Agreement. In addition, the

Products Purchase Agreement requires us to maintain twenty-one days of inventory for DaVita and contains penalties if we fail to supply DaVita. If, upon expiration of the Initial Term, the parties have not completed an extension or a new purchase agreement, the Purchase Agreement will continue in effect until terminated by either party with 90 days written notice or until the completion of an extension or new purchase agreement. 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.

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.

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 have developed and are developing drug 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 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. NDA applicants are required to submit to FDA information about any adverse event associated with the use of an approved drug, whether or not the adverse event is considered drug related. If a marketed drug is found to be potentially harmful or does not comply with applicable requirements, the manufacturer 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.

In August 2022, Congress passed the Inflation Reduction Act ("IRA"), which for the first time authorizes Centers for Medicare & Medicaid Services ("CMS") to negotiate Medicare reimbursement rates for certain high-cost prescription drug products, which may put limits on prices paid for drugs by government health programs. Additionally, the IRA requires drug manufacturers to pay rebates to Medicare if their drug prices increase faster than the rate of inflation. Effective in 2024, another provision will also eliminate 5% coinsurance for catastrophic coverage under Medicare Part D; while in 2025, the IRA will cap beneficiary annual out-of-pocket expenditure at $2,000 USD. These efforts to reduce aggregate beneficiary spending are expected to shift some costs to drug manufacturers.

Other restrictions under applicable federal and state healthcare laws and regulations may include the following:

- the federal Physician Self-Referral Law, which prohibits a physician from making referrals for certain designated health services payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship, and prohibits the entity from presenting or causing to be presented claims to Medicare for those referred services;
- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from soliciting, receiving, offering or providing remuneration, directly or indirectly, where one purpose is to induce either the referral of an individual for, or the purchase order or recommendation of, any item or services for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. The U.S. government has interpreted this law broadly to apply to the marketing and sales activities of medical device manufacturers;
- the federal civil and criminal false claims laws, including the False Claims Act ("FCA"), which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other federal healthcare programs that are false or fraudulent. Moreover, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA;
- the federal Civil Monetary Penalties Law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier;
- the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which, in addition to privacy protections applicable to healthcare providers and other entities, prohibits, among other things, executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- the federal Physician Payments Sunshine Act which requires certain applicable manufacturers of drugs, devices, biologics and medical supplies for which payment is available under certain federal healthcare programs, to monitor and report to CMS, certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors); certain other healthcare providers, including physician assistants and nurse practitioners, and teaching hospitals; as well as ownership and investment interests held by physicians and their immediate family members;
- U.S. federal consumer protection and unfair competition laws, which broadly regulate marketplace activities that potentially harm customers; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to item or services reimbursed by any third-party payor, including commercial insurers; state laws requiring device companies to comply with specific compliance standards, restrict payments made to healthcare providers and other potential referral sources, and report information related to payments and other transfers of value to healthcare providers or marketing expenditures and state laws related to insurance fraud in the case of claims involving private insurers.

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 may or may 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, 2022, we owned or had the rights to 30 issued patents (4 U.S. and 27 foreign) and 4 pending foreign applications. Patents and patent applications owned or licensed by us include claims to FPC in both dialysate and IV compositions, formulations and methods of making and parenteral nutritional compositions including Triferic.

	United States			Foreign		
Description	**Issued**	**Expiration**	**Pending**	**Issued**	**Expiration**	**Pending**
Triferic (IV and Dialysate)	3	2027 - 2036 (1), (3)	—	27 (2)	2028 - 2034 (1)	4
Triferic (TPN)	1	2030	—	—		—
Total	4		—	27		4

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. One granted European patent validated in 20 European states.
3. US patent for solid particulate composition for use in IV and dialysate will expired in 2036.

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

Human Capital

As of December 31, 2022, we had 253 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, senior and manager-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 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, together with all of the other information contained in this Annual Report on Form 10-K, 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 we are unable to successfully address these risks and challenges, our business, financial condition, results of operations, or prospects could be materially and adversely affected. 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

- We have limited capital resources and will likely need additional funding before we are able to achieve profitability.
- We may be unable to grow our concentrates business, either through acquisitions or organically, which could negatively impact our financial condition and prospects.

- If we are unable to increase our revenue and decrease our expenses, we may 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 contracts which provide for fixed prices. Our Products Purchase Agreement with DaVita ends at the end of 2023. If we are unable to extend the relationship on favorable terms or at all, our financial condition and results of operations will be materially and adversely affected.
- 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 and disruptions to the supply chain for pharmaceutical products in our clinical development programs, which could have a material adverse effect on our business.
- If our international partners are unable to or choose not to move forward to obtain regulatory approval in their jurisdictions for Triferic, we will not realize the value of these relationships.
- If we are unable to develop, obtain regulatory approval for, or successfully commercialize new therapies leveraging our FPC platform, or if we experience significant delays in doing so, the long-term success of our drug portfolio could be harmed.

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 $388.8 million since inception and we may incur further losses. As of December 31, 2022, we had approximately $21.5 million of cash, cash equivalents and investments available-for-sale, and working capital of $17.6 million. Net cash used in operating activities for the year ended December 31, 2021 was approximately $17.4 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 million. Net draw down proceeds at closing were approximately $21 million, net of estimated fees and expenses. As of December 31, 2022, $10 million remains drawn under the Loan Agreement.

Our ability to fund our planned activities will be dependent upon our ability to restructure our contract with our largest customer in our concentrates business, enter into new distribution and purchase agreements with former Baxter customers, increase our revenue and lower our expenses in our concentrates business and to raise additional funds in a defined timeline. 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 contract with our largest customer and entering into new contracts with former Baxter customers. If we are unable to achieve one or all of these objectives, we may be forced to implement cost-saving measures that could have a negative impact on our activities. If we are unable to restructure current or enter into new contracts in our concentrates business, increase our revenues and decrease our expenses or 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 actual concentrates revenue (measured on a quarterly basis). 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, in September 2021, we entered into an amendment to the Loan Agreement in which the Company, in exchange for Innovatus lowering the sales covenants (then based upon Triferic sales), agreed to (i) prepay an aggregate principal amount of $7.5 million 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 million if the aggregate principal amount of term loans is greater than $15 million pursuant to the liquidity covenant in the Loan Agreement. On November 10, 2022, the Company entered into the Second Amendment to Loan Agreement under which the Company (i) prepaid an aggregate principal amount of $5.0 million in outstanding term loans in one installment on November 14, 2022; (ii) agreed to make interest-only payments until September 2023 at which time the Company will resume scheduled debt payments in consideration for certain modifications to the financial covenants under the Loan Agreement. As of December 31, 2022, 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 the contract with our largest customer in our concentrates business;
- our ability to enter into new contracts and negotiate favorable terms with former Baxter customers;
- our ability to increase our prices to keep up with inflation;
- whether we experience significant input costs for, or disruptions to, the manufacturing or distribution of our products; and
- our international partners' commitment and ability to obtain regulatory approval for Triferic in their countries.

If we are required to raise additional capital to fund our operations, such 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 and pursue business opportunities, our business, results of operations, financial position and cash flows could be materially adversely affected.

Our revenue growth and profitability projections are based on various assumptions that may not come to fruition.

Our revenue growth and profitability projections are subject to many assumptions regarding our future operations, including that we are successful in expanding to new territories, that we successfully develop and launch new product offerings, that we are able to increase our prices to keep up with inflation, and that we do not experience significant disruptions to the manufacturing or distribution of our products, among other assumptions. If we are unsuccessful in one or more of those efforts, we may not be able to achieve our projected growth and profitability.

RISKS RELATED TO OUR BUSINESS

Our agreement with our largest customer in our concentrates business is set to expire on December 31, 2023 and our inability to negotiate a new agreement would have a material and adverse effect on our financial condition and results of operations.

Our Products Purchase Agreement with DaVita is set to expire on December 31, 2023. The Products Purchase Agreement is a fixed price agreement that contains a number of limitations on our ability to raise prices. In April 2022, we amended our Products Purchase Agreement to raise our prices in light of inflationary pressures. However, rising costs and declining volumes ordered by DaVita since April 2022 have had and could continue to have a negative impact on our business. The Products Purchase Agreement requires ninety (90) days' notice of non-renewal upon expiration. If we are unable to reach an agreement with DaVita on new terms that make economic sense for us, we do not expect to enter into a new agreement. This would result in the loss of approximately one-half of our current volume of concentrates products and would have a material and adverse effect on our financial condition and results of operations and would likely lead to the implementation of cost saving measures that would negatively impact our activities.

Market dynamics in our concentrates business that have resulted in lower volumes could lead to the implementation of cost saving measures that would have a material and adverse effect on our business.

Volumes have been decreasing in our concentrates business, due to the reduction in patient census caused by COVID-19 and cost saving measures by our customers. If these volumes decrease further, we may be forced to consolidate our operations and curtail our activities to lower our fixed costs. While our fixed costs would be reduced by such actions, we may not be able to realize the full amount of that reduction if our variable costs (such as transportation) increase and we are unable to pass along those increases to our customers. In addition, a consolidation or restructuring of our business could lead to significant one-time costs related to exiting operations. Such a consolidation could have a material and adverse effect our business, financial condition and results of operations.

Our reacquisition of distribution rights for our concentrates products from Baxter through the termination of our Exclusive Distribution Agreement has many attendant risks and may not result in the financial outcome we expect.

In 2022, we terminated our Exclusive Distribution Agreement with Baxter and reacquired the distribution rights related to our concentrates products for Baxter's portfolio of clinics. Our Distribution Agreement with Baxter enabled us to charge Baxter an amount above cost for our concentrates products, while limiting us to a capped percentage of sales for the transportation costs associated with delivering those products. Now that we have assumed full responsibility for selling and delivering our concentrates products to former Baxter customers and any other customers we may add, we bear all financial and other risk associated with the business. We may lose former Baxter customers if we need to increase the prices of our concentrates products due to rising costs or for other reasons. In addition, since we agreed to charge certain customers a fixed cost through March 31, 2023, we may lose money if those fixed costs do not cover our actual costs. We also may be unable to

renegotiate unprofitable contracts with certain customers. In addition, because we do not have access to all of the distribution channels Baxter utilized for our products, we may lose certain customers if we cannot find a suitable alternative channel by which to serve them. Each of these scenarios could result in the business we reacquired generating less revenue or less profit than we expect and could adversely impact our financial condition or results of operations.

Unfavorable weather, economic conditions or supply shortages 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 United States 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. In addition, weather-related events may jeopardize our ability to deliver our products as required by our contracts. For example, after Hurricane Ian severely damaged parts of the Florida Gulf Coast, many roads and bridges were destroyed. While we were able to make our deliveries after the storm, that may not always be the case. A weak or declining United States or global economy could also strain our suppliers, possibly resulting in supply disruption. In addition, due to macro-economic conditions in the global economy, there have been shortages in raw materials, parts and fuel that we need to run our business. Recently, our suppliers have experienced shortages in bicarbonate and acid, which are components of our dialysis concentrates, and parts needed for our equipment to make certain of our products. Diesel fuel has also been in short supply in the United States and our delivery trucks run on diesel. While we have been able to minimize the impact of these disruptions to date, there can be no assurance that will continue. 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.

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 contract.

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 contract with DaVita. The costs of chemicals and other raw materials are subject to price volatility based on supply and 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, due to short supply and excess demand. 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. In addition, as mentioned above, there has been a nationwide shortage of diesel fuel in the United States, which we use to run our delivery trucks. Such a shortage, has and in the future may result in an increase in the cost of diesel fuel or lack of availability of diesel fuel and we would need to find another way to deliver our products to clinics. If we are unable to do so, we could be in breach of our contracts. In addition, any increase in the use of third-party freight would significantly increase our costs, which we may not be able to pass on to our customers.

Our Product Purchase Agreement with DaVita provides for a fixed price to DaVita, with limited increases from year to year that must be agreed to by the parties, regardless of the increases in raw materials costs and transportation costs. As a result, we have in the past been unable to fully recover our costs for the products we sell to DaVita (including transportation costs). This has had and could in the future have 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 (subject to a cap), which are determined on a quarterly basis. Continued rising costs and declining volumes have had and could continue to have a negative impact on our business. In addition, if our costs exceed 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 Products Purchase Agreement, the increasing costs and decreasing volumes may continue to negatively impact our profit margins and materially and adversely affect our financial position.

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 and adverse effect on our business, results of operations, financial position and cash flows.

Sales of our medical device products are highly concentrated in a few customers. One customer accounted for nearly half of our sales in each of the last three years and for a substantial number of the clinics we serve. The loss of any of these

significant customers could have a material adverse effect on our business, results of operations, financial position and cash flows.

We 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 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 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 our profitability.

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

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 end-stage renal disease ("ESRD") prospective payment system generally falling short of covering the increasing cost of dialysis care resulting in economic pressure of dialysis providers. We anticipate that dialysis providers will continue to seek ways to reduce their costs per treatment due to these reimbursement policies, 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. Any such reforms could potentially impact reimbursement by Medicare and Medicaid programs for 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 may not be successful in expanding our concentrates business or 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.

We may seek to make acquisitions or enter into business development arrangements in our concentrates business to expand our customer base or geographic footprint. In addition, 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 candidate portfolio, as well as other product or product candidates that we believe have substantial development potential. We may not be able to identify such opportunities. 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.

We rely on third party suppliers for raw materials and packaging components of our drug products that we supply and will supply to our international partners. 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 for our international partners and have a material adverse effect on our relationships with our international partners.

We may not be able to obtain the raw materials or packaging components we need to supply our international partners, 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, a 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. 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 for our international partners and our relationships may be materially adversely affected.

We depend on third parties to manufacture Triferic for our international partners. If these organizations are unable or unwilling to manufacture our drug products, or if these organizations fail to comply with applicable regulations or otherwise fail to meet our requirements, our business relationships with our international partners will be harmed.

We rely on CMOs to manufacture Triferic for our international partners. 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 international partners 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 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 international 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 international business relationships.

We may not be successful 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 our international partners are successful in obtaining the required regulatory approvals, they 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. 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. Our international partners may decide not to move forward with clinical trials or other steps necessary for foreign regulatory approval, which could result in their failure to meet milestones and the loss of potential revenue to us. 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 or if our current international partners delay or cease their efforts, 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 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 due to Triferic or any other drug product candidates being 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;
- unexpected changes in the safety profile;
- 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 prospects related to marketing products or product candidates outside the United States could suffer.

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 operations, product development, clinical and business development expertise of the principal members of our management, operations and clinical team. We have hired executive-level employees who are leading Company initiatives, including its operational initiatives. 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 manufacturing, sales and marketing, scientific, and clinical personnel is critical to our success. The loss of the services of our executive officers or other key employees could 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 due to the overall state of the labor pool and the difficulty finding the specialized skills

we require. 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 medical device, pharmaceutical and biotechnology companies for similar personnel.

Finding production associates for our manufacturing facilities and truck drivers for our transportation division has also presented challenges for us. There is similarly a great deal of competition for these workers. This competition has resulted in increasing compensation costs as we attempt to attract and retain workers.

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 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, 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 hazardous waste insurance coverage and our property and casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from 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.

RISKS RELATED TO OUR PRODUCT CANDIDATES

The long-term success of our drug product portfolio 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 or iron deficiency anemia. 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 prospects could be 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 important to our business prospects. 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. For example, we submitted an IND for FPC to be used in the home infusion setting and based upon the feedback we received from the FDA, we determined to put the program on hold due to the time and expense that would be required to satisfy the FDA's concerns.

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 ability to pursue our business plans and strategies related to our FPC platform.

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

The value of our FPC platform 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. The failure of our international partners 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 decision on whether to seek a partner to market our drug products in a particular country.

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 product candidates by third parties.

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 developing, manufacturing or selling our product candidates. Furthermore, payments under any licenses that we are able to obtain would reduce our profits derived from the covered products and services.

We have in-licensed rights to certain patents that cover our FPC 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 partners' ability to commercialize our products and our ability product candidates.

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, cover Triferic AVNU and have other claims that could cover Triferic and other product candidates. 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.

RISKS RELATED TO REGULATORY APPROVALS

Current and future legislation may increase the difficulty and cost for us, and any collaborators, to obtain marketing approval of and commercialize our drug candidates and affect the prices we, or they, may obtain.

Heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. We expect that additional state and federal healthcare reform measures will be adopted in the future, particularly in light of the new presidential administration, any of which could limit the amounts that federal and state governments will pay for healthcare therapies, which could result in reduced demand for our product candidates or additional pricing pressures. Most recently, on August 16, 2022, President Biden signed into law the Inflation Reduction Act of 2022 (“IRA”), which, among other provisions, included several measures intended to lower the cost of prescription drugs and related healthcare reforms. We cannot be sure whether additional legislation or rule making related to the IRA will be issued or enacted, or what impact, if any, such changes will have on the profitability of any of our drug candidates, if approved for commercial use, in the future.

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 limit our prospects and harm the long term viability of our drug portfolio.

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.

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. 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 we obtain 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, withdrawal of the product from the market, suspension of manufacturing or other actions.

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 attempt to incorporate 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 value of our drug product portfolio.

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. We may experience delays in clinical trials due to FDA requirements or otherwise, and may face administrative challenges or limitations when conducting clinical trials. 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, participants may experience undesirable side effects or the candidate may demonstrate a lack of efficacy, so that the clinical trial 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 drug product portfolio could be harmed.

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. 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. For example, the FDA conducted a routine GMP inspection of one of our manufacturing facilities and issued Form FDA-483 report with four observations, for which the inspector classified Voluntary Action Indicated. The Company submitted a voluntary corrective action plan, to which the FDA replied. While none of the findings were serious, management time and effort will be necessary for the correction and the FDA response. 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. For example, such actions could cause our customers to doubt the safety or efficacy of our products, which could adversely impact our business. Even a voluntary Class III recall, which is a recall of products for a defect that is unlikely to result in adverse health consequences, can have an adverse impact on the Company due to the costs of the recall or the reactions of customers. We recently conducted a Class III recall in our concentrates business due to the degradation of secondary seals on some of our bottles of concentrates, which consumed management time and effort. Further, in our discussions with the FDA, the FDA has indicated that it believes our recall, though completed, should be recharacterized as a Class II recall. 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 product candidates.

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 of our Products Purchase Agreement, providing DaVita 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 cost increases that we cannot recoup or that price increases exceed the thresholds specified in the Products Purchase Agreement, could give DaVita the right to terminate.

Our product candidates and drug products may have undesirable side effects and our product liability insurance may not be sufficient to protect us from material liability or harm to our business.

If concerns are raised regarding the safety of a 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 we are prevented from selling any of our concentrate or ancillary products due to a patent infringement or if our ability to sell any of our concentrate or ancillary products due to a patent infringement is materially and adversely affected, DaVita may be entitled to terminate our Products Purchase Agreement.

As is common in the medical device, 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 medical device and pharmaceutical industries 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. 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.

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 based upon decisions we make regarding our strategy or otherwise. 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 COMMON STOCK

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:

- the reporting of sales, operating results and cash resources;
- announcements by commercial partners or competitors of new commercial products, clinical progress or the lack thereof, significant contracts, commercial relationships or capital commitments;
- the entry into, or termination of, key agreements, including key commercial partner agreements;
- changes in the structure of healthcare payment systems;
- the loss of key employees;
- changes in estimates or recommendations by securities analysts, if any, who cover our common stock;
- our ability to obtain regulatory approvals for our product candidates, and delays or failures to obtain such approvals;
- failure of any of our product candidates, if approved, to achieve commercial success;
- issues in manufacturing our device products or product candidates;
- the results of any future clinical trials of our product candidates;
- 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; and
- the introduction of technological innovations or new therapies that compete with our products or product candidates.

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, 2022, there were 243,088 shares issuable upon the exercise of then-outstanding and exercisable stock options, 963,817 shares issuable upon the exercise of then-outstanding stock options that were not yet exercisable, and 16,200,990 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.

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 and were unable to regain compliance in the time allotted by Nasdaq. As a result, we moved our listing to The Nasdaq Capital Market and effected an 11-for-1 reverse stock split in May 2022 to regain compliance. While we have been in compliance with the minimum closing bid price requirement since that time, there can be no assurance that we will be able to maintain compliance with the minimum bid price requirement going forward.

If our common stock were 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.

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 medical device and 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 business could be adversely affected by economic downturns, inflation, increases in interest rates, natural disasters, public health crises such as the COVID-19 pandemic, political crises, geopolitical events, such as the crisis in Ukraine, or other macroeconomic conditions, which could have a material and adverse effect on our results of operations and financial condition.

The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including, among other things, diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, supply chain shortages, increases in inflation rates, higher interest rates, and uncertainty about economic stability. For example, the COVID-19 pandemic resulted in widespread unemployment, economic slowdown and extreme volatility in the capital markets. The Federal Reserve has raised interest rates multiple times in response to concerns about inflation and it may raise them again. Higher interest rates, coupled with reduced government spending and volatility in financial markets, may increase economic uncertainty and affect consumer spending. Similarly, the ongoing military conflict between Russia and Ukraine has created extreme volatility in the global capital markets and may have further global economic consequences, including disruptions of the global supply chain. Any such volatility and disruptions may adversely affect our business or the third parties on whom we rely. If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any necessary debt or equity financing more costly, more dilutive, or more difficult to obtain in a timely manner or on favorable terms, if at all. Increased inflation rates can adversely affect us by increasing our costs, including labor and employee benefit costs.

We have experienced and may in the future experience disruptions as a result of such macroeconomic conditions, including delays or difficulties in manufacturing sufficient quantities of materials. If we fail to maintain inventory or deliver product as a result of such delays or difficulties, we could breach the requirement in our Products Purchase Agreement with DaVita to maintain safety stock and maintain transportation and other services, which would allow DaVita to exercise various remedies under such agreement. Any one or a combination of these events could have a material and adverse effect on our results of operations and financial condition.

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 2026. In addition, Rockwell occupied 4,100 square feet of office space in Hackensack, New Jersey 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. We expect that we may need additional manufacturing capacity and distribution facilities to meet our business requirements.

Item 3. Legal Proceedings.

We may be involved in certain routine legal proceedings from time to time before various courts and governmental agencies. We cannot predict the final disposition of such proceedings. We regularly review legal matters and record provisions for claims considered probable of loss. The resolution of these pending proceedings is not expected to have a material effect on our operations or consolidated financial statements in the period in which they are resolved. Information pertaining to legal proceedings is provided under the heading "Litigation" in Note 15, Commitments and Contingencies, to the consolidated financial statements and is incorporated by reference herein.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information

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

Holders

As of February 28, 2023, there were 37 holders of record of our common stock.

Dividend 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

Rockwell Medical is a healthcare company that develops, manufactures, commercializes, and distributes a portfolio of hemodialysis products for dialysis providers worldwide.

Rockwell is a revenue-generating business and the second largest supplier of acid and bicarbonate concentrates for dialysis patients in the United States. Hemodialysis is the most common form of end-stage kidney disease treatment and is usually performed at freestanding outpatient dialysis centers, at hospital-based outpatient centers, at skilled nursing facilities, or in a patient's home. This represents a large market opportunity for which Rockwell's products are well-positioned to meet the needs of patients.

Rockwell manufactures hemodialysis concentrates under Current Good Manufacturing Practices ("cGMP") regulations at its three facilities in Michigan, Texas, and South Carolina totaling approximately 175,000 square feet, and manufactures its dry acid concentrate mixers at its facility in Iowa. Rockwell delivers the majority of its hemodialysis concentrates products and mixers to dialysis clinics throughout the United States and internationally utilizing its own delivery trucks and third-party carriers. Rockwell has developed a core expertise in manufacturing and delivering hemodialysis concentrates, and has built a longstanding reputation for reliability, quality, and excellent customer service.

In addition to its primary focus on hemodialysis concentrates, Rockwell also has a proprietary parenteral iron product, Triferic (ferric pyrophosphate citrate, ("FPC"), which is indicated to maintain hemoglobin in adult patients with hemodialysis-dependent chronic kidney disease. While Rockwell has discontinued commercialization of Triferic in the United States, the Company has established several international partnerships with companies seeking to develop and commercialize Triferic outside the United States and is working closely with these international partners to develop and commercialize Triferic in their respective regions. Additionally, Rockwell continues to evaluate the viability of its FPC platform and FPC's potential to treat iron deficiency, iron deficiency anemia, and acute heart failure.

Reverse Stock Split

On May 9, 2022, the Company's stockholders authorized the Company's Board of Directors to effect a reverse stock split of all outstanding shares of common stock, warrants and options. The Board of Directors subsequently approved the implementation of a reverse stock split at a ratio of one-for-eleven shares, which became effective on May 13, 2022. The Company's outstanding stock options were also adjusted to reflect the one-for-eleven reverse stock split of the Company's

common stock. Outstanding stock options were proportionately reduced and the respective exercise prices, if applicable, were proportionately increased. The reverse stock split resulted in an adjustment to the Series X convertible preferred stock conversion prices to reflect a proportional decrease in the number of shares of common stock to be issued upon conversion. All share and per share data in these condensed consolidated financial statements and related notes hereto have been retroactively adjusted to the account for the effect of the reverse stock split for the periods ended December 31, 2022 and 2021, respectively.

Results of Operations

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

	For the Year Ended December 31,				
	2022	% of Revenue	2021	% of Revenue	% Change
Net Sales	**$ 72,810**		**$ 61,931**		**17.6 %**
Cost of Sales	68,733	94.4 %	64,351	103.9 %	6.8
Gross (Loss) Profit	4,077	5.6	(2,420)	(3.9)	(268.5)
Research and Product Development	3,119	4.3	6,835	11.0	(54.4)
Selling and Marketing	2,094	2.9	5,733	9.3	(63.5)
General and Administrative	15,644	21.5	15,348	24.8	1.9
Operating Loss	**$ (16,780)**	**(23.0)%**	**$ (30,336)**	**(49.0)%**	**(44.7)%**

Net Sales

During the year ended December 31, 2022, our net sales were $72.8 million compared to net sales of $61.9 million during the year ended December 31, 2021. Net sales of hemodialysis concentrates to dialysis providers and distributors in the United States and abroad were $71.7 million for the year ended December 31, 2022 compared to $60.8 million for the year ended December 31, 2021. Net sales of Triferic (dialysate) were $1.2 million and $1.1 million for the years ended December 31, 2022 and 2021, respectively. The increase of $10.9 million is primarily related to the amendment of our supply agreement with DaVita and increased pricing to other customers. During 2022, the Company made a strategic decision to discontinue its NDAs for Triferic and Triferic AVNU in the United States.

Cost of Sales and Gross Profit

Cost of sales during the year ended December 31, 2022 was $68.7 million, resulting in gross profit of $4.1 million, compared to cost of sales of $64.4 million and a gross loss of $2.4 million during the year ended December 31, 2021. Gross profit increased by $6.4 million during the year ended December 31, 2022 compared to the year ended December 31, 2021 due to price increases for all business during the year including the amended products purchase agreement with DaVita, offset by volume reductions and increased distribution costs.

Research and Product Development Expense

Research and product development expenses were $3.1 million for the year ended December 31, 2022 compared with $6.8 million during the year ended December 31, 2021. The decrease of $3.7 million is related to headcount reductions and the decision to put all research related to our FPC for Home Infusion program on hold due to the significant capital expenditure and resources to support additional re-formulation work and conduct a Phase 2 study.

Selling and Marketing Expense

Selling and marketing expenses were $2.1 million during the year ended December 31, 2022 compared with $5.7 million during the year ended December 31, 2021. The decrease of $3.6 million is due to a decrease in marketing spend for our Triferic products and a headcount reduction.

General and Administrative Expense

General and administrative expenses were $15.6 million during the year ended December 31, 2022 compared with $15.3 million during the year ended December 31, 2021. The $0.3 million increase was driven primarily by increases in executive severance expenses of $1.4 million, legal costs of $0.2 million and travel expense of $0.1 million, offset by decreases in employee incentives of $0.6 million, various cost cutting measures of $0.5 million, and FDA fees of $0.2 million.

Other Income (Expense)

Other income consisted of interest income of $33,000 and $22,000 for the years ended December 31, 2022 and December 31, 2021, respectively. Other expense consisted of interest expense related to our debt facility (see Note 16 to the financial statements for more information on our debt facility) totaling $1.9 million and $2.4 million for the years ended December 31, 2022 and December 31, 2021, respectively.

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, 2022, we had an accumulated deficit of approximately $388.8 million and shareholders' equity of $14.1 million. As of December 31, 2022, we had approximately $21.5 million of cash, cash equivalents and investments available-for-sale, and working capital of $17.6 million. Net cash used in operating activities for the year ended December 31, 2022 was approximately $17.4 million. 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, if needed, and remain in compliance with financial and reporting covenants under the Company's secured loan.

During the year ended December 31, 2022, the Company continued to experience significant inflationary pressures in its dialysis concentrates business, which has resulted in operating losses associated with this business line. As a result of these inflationary pressures, and in light of the fact that the Company's concentrates business operated 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.

On April 6, 2022, the Company and DaVita entered into an amendment (the "Amendment") to the Products Purchase Agreement, dated July 1, 2019, under which the Company supplies DaVita with certain dialysis concentrates. Under the Amendment, the Company and DaVita agreed to certain price increases, effective May 1, 2022, as well as the pass-through of certain inflationary costs, determined on a quarterly basis. 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 of $10 million, or the Company will be in default under the Products Purchase Agreement. An event of default could result in termination of that agreement.

On April 6, 2022, the Company and DaVita entered into the SPA, pursuant to which the Company issued $15 million of preferred stock to DaVita in two separate tranches. The Company initially issued 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 $7.5 million. On June 15, 2022, the Company issued to DaVita an additional 7,500 shares of Series X Preferred Stock in a second closing (the "Second Tranche") for an additional $7.5 million. The Second Tranche was conditioned upon the Company raising an additional $15.0 million in capital within a certain timeline, which took place on June 2, 2022.

On April 8, 2022, 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 up to $12,200,000 of shares of Company's common stock through the Agent. During the quarter ended December 31, 2022, no sales were made pursuant to the Sales Agreement. Subject to restrictions under General Instruction I.B.6 to Form S-3, approximately $12.2 million remains available for sale under the ATM facility.

On May 30, 2022, the Company entered into a Securities Purchase Agreement (the "RD Purchase Agreement") with the purchaser named therein (the "Purchaser"), pursuant to which the Company agreed to issue and sell, in a registered direct offering (the "Offering"), 844,613 shares of its common stock at price of $1.39 per share, and prefunded warrants to purchase up to an aggregate of 7,788,480 shares of common stock (the "Pre-Funded Warrants" and the shares of common stock underlying the Pre-Funded Warrants, the "Warrant Shares"). The purchase price of each Pre-Funded Warrant was equal to the

price at which a share of common stock was sold to the public in the Offering, minus $0.0001, and the exercise price of each Pre-Funded Warrant is $0.0001 per share.

Also on May 30, 2022, concurrently with the Offering, the Company entered into a Securities Purchase Agreement with the Purchaser (the "PIPE Purchase Agreement") relating to the offering and sale (the "Private Placement") of warrants to purchase up to a total of 9,900,990 shares of common stock and pre-funded warrants to purchase up to a total of 1,267,897 shares of common stock (the "PIPE Warrants"). Each warrant was sold at a price of $0.125 per underlying warrant share and is exercisable at an exercise price of $1.39 per share. The purchase price of each Pre-Funded Warrant was equal to the price at which a share of common stock was sold to the public in the Offering, minus $0.0001, and the exercise price of each prefunded warrant is $0.0001 per share. The Offering and the Private Placement closed on June 2, 2022. The net proceeds to the Company from the Offering and the Private Placement were approximately $14.9 million, after deducting fees and expenses.

On November 10, 2022, the Company entered into a Second Amendment to the Loan and Security Agreement (the "Second Amendment") dated as of November 14, 2022 with Innovatus, which amended the Loan Agreement. Pursuant to the Second Amendment, the Company (i) prepaid an aggregate principal amount of $5.0 million in Term Loans (as defined in the Loan Agreement) in one installment on November 14, 2022; (ii) shall pay interest only payments until September 2023 at which time will resume scheduled debt payments (see Note 16 to the consolidated financial statements included elsewhere in this Form 10-K for more information on our debt facility).

Management evaluated it's going concern by reviewing the Company's operational plans which include executing on the projected financial information including price increases, acquisition of new customers, projected growth of margins and cost containment activities. Additionally, the Company's operational plans also include raising capital, if needed, by using our ATM facility or other methods or forms of financings, subject to existing limitations. Based on the currently available working capital, expectation of the ability of management to execute on the Company's operational plans noted above, management believes the Company currently has sufficient funds to meet its operating requirements for at least the next twelve months from the date of the filing of this report. Accordingly, management believes that the factors noted above which raised substantial doubt about the Company's ability to continue as a going concern have been alleviated.

The Company may require additional capital to sustain its operations and make the investments it needs to execute its strategic plan. If the Company attempts to obtain additional debt or equity financing, the Company cannot assume such financing will be available on favorable terms, if at all.

In addition, the Company is subject to certain covenants and cure provisions under its Loan Agreement with Innovatus. As of December 31, 2022, the Company is in compliance with all financial covenants (See Note 16 to the consolidated financial statements included elsewhere in this Form 10-K for more information on our debt facility).

Global Economic Considerations

The COVID-19 pandemic and resulting domestic and global disruptions, particularly in the supply chain and labor market, among other areas, have adversely affected Rockwell's business and operations, including, but not limited to, the Company's sales and marketing efforts and its research and development activities, the Company's plant and transportation operations, and the operations of third parties upon whom Rockwell relies. The Company's international business development activities may also continue to be negatively impacted by COVID-19.

In addition, the global macroeconomic environment is uncertain, and could be negatively affected by, among other things, increased U.S. trade tariffs and trade disputes with other countries, instability in the global capital and credit markets, supply chain weaknesses, and instability in the geopolitical environment, including as a result of the Russian invasion of Ukraine and other political tensions, and lingering effects of the COVID-19 pandemic. Such challenges have caused, and may continue to cause, recession fears, rising interest rates, foreign exchange volatility and inflationary pressures. At this time, we are unable to quantify the potential effects of this economic instability on our future operations.

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.

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 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 our ability to fund our activities in the long term will be highly dependent upon (i) our ability to execute on the growth strategy of our hemodialysis concentrates business, (ii) our ability to achieve profitability, and (iii) our ability to identify, develop, in-license, or acquire new products in developing our renal care product portfolio. All of these strategies are subject to significant risks and uncertainties such that there can be no assurance we will be successful in achieving them. If we are unsuccessful in executing our business plan and 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 $17.4 million for the year ended December 31, 2022. 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 $3.9 million, consisting primarily of $2.0 million of amortization of the right to use assets, $0.6 million of depreciation and amortization, $0.6 million of inventory reserves, $0.4 million of debt financing cost amortization and accretion of discount, $0.3 million of stock-based compensation, and a $2.6 million net change in assets and liabilities.

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.

Cash Provided by (Used in) Investing Activities

Net cash used in investing activities was $2.4 million during the year ended December 31, 2022. The net cash provided was primarily due to the purchase of investments available-for-sale of $21.3 million, offset by $19.2 million sale of our available-for-sale investments and $0.3 million for the purchase of equipment.

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.

Cash (Used in) Provided by Financing Activities

Net cash provided by financing activities was $16.6 million during the year ended December 31, 2022. The net cash provided by financing activities was primarily due to proceeds from issuance of equity securities of $29.8 million offset by payments on the Company's debt and short term note payable of $13.2 million.

Net cash used in financing activities was $2.2 million during the year ended December 31, 2021. The net cash used in financing activities was primarily due to payments on the Company's debt and 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. 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, 2022 and 2021, 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 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. On November 9, 2022, Rockwell reacquired its distribution rights to its hemodialysis concentrates products from Baxter and terminated the Distribution Agreement. The Company recognized revenue of approximately $2.5 million and $1.9 million related to the Baxter agreement for each of the years ended December 31, 2022 and 2021, 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, 2022 and 2021. Deferred revenue related to the Wanbang Agreement totaled $2.3 million and $2.5 million for the years ended December 31, 2022 and 2021, 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) 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, 2022 and 2021. Deferred revenue related to the Sun Pharma Agreement totaled $0.1 million as of December 31, 2022 and 2021, respectively.

On September 7, 2020, the Company entered into a license and supply agreements with Jeil Pharmaceutical (the "Jeil Agreements"), for the rights to commercialize Triferic (dialysate) in South Korea. Under the terms of the Jeil Agreements, Jeil Pharmaceutical will be the exclusive development and commercialization partner for Triferic (dialysate) in South Korea, and the Company will supply the product to Jeil Pharmaceutical. 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 Pharmaceutical, will guide the development and execution for Triferic (dialysate) in South Korea. Jeil Pharmaceutical 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 $18,158 and $10,000 during the year ended December 31, 2022 and

2021, respectively. Deferred revenue related to the Jeil Agreement totaled $0.4 million and $0.2 million as of December 31, 2022 and 2021, respectively.

On June 2021, the Company entered into license and supply agreements with Drogsan Pharmaceuticals (the "Drogsan Agreements"), for the rights to commercialize Triferic (dialysate) and Triferic AVNU in Turkey. Under the terms of the Drogsan Agreements, Drogsan Pharmaceuticals 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 Pharmaceuticals, will guide the execution for Triferic (dialysate) and Triferic AVNU in Turkey. Drogsan Pharmaceuticals will be responsible for all regulatory approval and commercialization activities, and the Company will supply the product to Drogsan Pharmaceuticals 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 $15,000 and $7,500 during the year ended December 31, 2022 and 2021, respectively. Deferred revenue related to the Drogsan Agreements totaled approximately $0.1 million as of December 31, 2022 and 2021 respectively.

Stock-Based Compensation

The Company expenses stock-based compensation to employees over the requisite service period based on the estimated grant-date fair value of the awards. For stock-based compensation awards to non-employees, the Company re-measures the fair value of the non-employee awards at each reporting period prior to vesting and finally at the vesting date of the award. Changes in the estimated fair value of these non-employee awards are recognized as compensation expense in the period of change. The Company estimates the fair value of stock option grants using the Black-Scholes option pricing model, and the assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. For the years ended December 31, 2022 and 2021, 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, 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, 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, 2022. Based upon that evaluation, our Chief Executive Officer concluded that our disclosure controls and procedures were effective as of December 31, 2022. Additionally, the Company's management, including the Chief Executive 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, our management evaluated the effectiveness of our internal control over financial reporting as of December 31, 2022. 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, 2022.

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, 2022, 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 2023 Annual Meeting of Stockholders (the "2023 Proxy Statement"), which we expect to be filed with the SEC within 120 days of the end of our fiscal year ended December 31, 2022, including under headings "Election of Directors," "Directors Continuing in Office," "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 2023 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 2023 Proxy Statement, including under heading "Security Ownership of Certain Beneficial Owners and Management."

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, 2022:

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)	788,615	$ 12.29	107,335
Equity compensation plans not approved by security holders (2)	544,181	$ 3.50	—
Total	1,332,796	$ 8.32	107,335

(1) Consists of 662,724 stock options with a weighted average exercise price of $12.29, 125,000 restricted stock units issued at $1.47 and 891 restricted stock awards issued at $62.70.

(2) Consists of 544,181 stock options with a weighted average exercise price of $3.50.

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 2023 Proxy Statement, including under headings "Independence" and "Certain Relationships 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 2023 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 (Exhibit 3.3 to the Company's Form 8-K filed August 30, 2019).
3.2	Certificate of Amendment to Certificate of Incorporation of Rockwell Medical, Inc. related to the Reverse Stock Split, dated May 12, 2022 (Exhibit 3.1 to the Company's Form 8-K filed on May 13, 2022).
3.3	Certificate of Designation of Preferences, Rights and Limitations of Series X Convertible Preferred Stock (Exhibit 3.1 to the Company's Form 8-K filed on April 8, 2022).
3.4	Amended and Restated Bylaws (Exhibit 3.1 to the Company's Form 10-Q filed November 14, 2022).
4.1	Form of Common Stock Warrant, dated October 17, 2018 (Exhibit 4.1 to the Company's Form 8-K filed October 19, 2018).
4.2	Description of Securities (Exhibit 4.2 to the Company's Form 10-K filed on April 8, 2022)
4.3	Form of Warrant (Exhibit 4.1 to the Company's Form 8-K filed on September 25, 2020).
4.4	Form of Pre-Funded Warrant (Exhibit 4.2 to the Company's Form 8-K filed on September 25, 2020).
4.5	Form of Warrant to Purchase Common Stock for Innovatus (Exhibit 4.1 to the Company's Form 8-K filed March 20, 2020).
4.6	Form of Pre-Funded Warrant (Exhibit 4.1 to the Company's Form 8-K filed on June 2, 2022).
4.7	Form of PIPE Warrant (Exhibit 4.2 to the Company's Form 8-K filed on June 2, 2022).
4.8	Form of PIPE Pre-Funded Warrant (Exhibit 4.3 to the Company's Form 8-K filed on June 2, 2022).
10.1	Registration Rights Agreement, dated October 17, 2018 (Exhibit 10.83 to the Company's Form 8-K filed October 19, 2018).
10.2	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 (Exhibit 10.1 to the Company's Form 10-Q filed on May 11, 2020).
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 (Exhibit 10.1 to the Company's Form 8-K filed on September 30, 2021)
10.4	Second Amendment to Loan and Security Agreement dated November 10, 2022 by and among the Company, Innovatus Life Sciences Lending Fund I, LP and the lenders party thereto (Exhibit 10.3 to the Company's Form 10-Q filed on November 14, 2022).
10.5	Sales Agreement, dated April 8, 2022, between Rockwell Medical, Inc. and Cantor Fitzgerald & Co. (Exhibit 1.1 to the Company's Form 8-K filed on April 8, 2022).
10.6	Securities Purchase Agreement, dated April 6, 2022, by and between the Company and DaVita, Inc. (Exhibit 10.1 to the Company's Form 10-Q filed on May 16, 2022).
10.7	RD Securities Purchase Agreement, dated May 30, 2022, by and between the Company and the Purchaser signatory therein (Exhibit 10.1 to the Company's Form 8-K filed on June 2, 2022).
10.8	PIPE Securities Purchase Agreement, dated May 30, 2022, by and between the Company and the Purchaser signatory therein (Exhibit 10.2 to the Company's Form 8-K filed on June 2, 2022).
10.9	Registration Rights Agreement, dated June 2, 2022, by and between the Company and the Holder signatory thereto (Exhibit 10.3 to the Company's Form 8-K filed on June 2, 2022).
10.10+	Products Purchase Agreement, dated July 1, 2019, by and between the Company and DaVita Inc. (f/k/a DaVita Healthcare Partners Inc.) (Exhibit 10.1 to the Company's Form 10-Q filed November 12, 2019).
10.11+	Amendment One to Products Purchase Agreement, dated April 6, 2022, by and between the Company and DaVita, Inc. (Exhibit 10.2 to the Company's Form 10-Q filed on May 16, 2022).
10.12	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) (Exhibit 10.57 to the Company's Form 10-K filed March 3, 2015).

10.13	Investment Agreement, dated October 2, 2014, by and between the Company and Baxter Healthcare Corporation (Exhibit 10.58 to the Company's Form 10-K filed March 3, 2015).
10.14	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) (Exhibit Company's Form 10-Q filed August 9, 2017).
10.15+#	Distribution Termination and Acquisition Agreement dated November 8, 2022 between the Company and Baxter Healthcare Corporation.
10.16+	Licensing Agreement, dated January 7, 2002, by and among the Company, Charak LLC and Dr. Ajay Gupta (Exhibit 10.18 to the Company's Form 10-KSB filed April 1, 2002).
10.17	Amending Agreement, dated January 16, 2006, by and among the Company, Charak LLC and Dr. Ajay Gupta (Exhibit 10.13 to the Company's Form 10-KSB filed March 21, 2006).
10.18	Master Services and IP Agreement, dated October 7, 2018, by and among the Company, Charak, LLC and Dr. Ajay Gupta (Exhibit 10.34 Company's Form 10-K filed on March 18, 2019).
10.19	Amendment to License Agreement, dated October 7, 2018, by and among the Company, Charak, LLC and Dr. Ajay Gupta (Exhibit 10.35 to the Company's Form 10-K filed on March 18, 2019).
10.20	Commercialization and Technology License Agreement IV Triferic, dated October 7, 2018, by and among the Company, Charak, LLC and Dr. Ajay Gupta (Exhibit 10.36 to the Company's Form 10-K filed on March 18, 2019).
10.21	Technology License Agreement TPN Triferic, dated October 7, 2018, by and among the Company, Charak, LLC and Dr. Ajay Gupta (Exhibit 10.37 to the Company's Form 10-K filed on March 18, 2019).
10.22*	Rockwell Medical, Inc. Amended and Restated 2007 Long Term Incentive Plan, as amended effective May 21, 2015 (Appendix to the Company's Proxy Statement for the 2015 Annual Meeting of Shareholders filed on April 13, 2015).
10.23*	Form of Nonqualified Stock Option Agreement (2007 Long Term Incentive Plan) (Director Version) (Exhibit 10.22 to the Company's Form 8-K filed December 20, 2007).
10.24*	Form of Nonqualified Stock Option Agreement (2007 Long Term Incentive Plan) (Employee Version) (Exhibit 10.23 to the Company's Form 8-K filed December 20, 2007).
10.25*	Form of Restricted Stock Award Agreement (2007 Long Term Incentive Plan) (Director Version) (Exhibit 10.62 to the Company's Form 10-K filed February 29, 2016).
10.26*	Form of Restricted Stock Award Agreement (2007 Long Term Incentive Plan) (Executive Version) (Exhibit 10.54 to the Company's Form 10-Q filed May 12, 2014).
10.27*	Form of Performance Share Award Agreement March 2017 (Executive Version) (Exhibit 10.64 to the Company's Form 10-Q filed May 9, 2017).
10.28*	Form of Performance Share Award Agreement March 2017 (Director Version) (Exhibit 10.65 to the Company's Form 10-Q filed May 9, 2017).
10.29*	Rockwell Medical, Inc. Amended and Restated 2018 Long Term Incentive Plan (Exhibit 10.8 to the Company's Form 10-Q filed on August 15, 2022).
10.30*	Form of Stock Option Agreement (2018 Long Term Incentive Plan) (Exhibit 10.2 to the Company's Form 10-Q filed on November 14, 2022).
10.31*	Form of Contingent Option Agreement for Directors (2018 Long Term Incentive Plan) (Exhibit 10.76 to the Company's Form 8-K filed March 21, 2018).
10.32*#	Form of Restricted Stock Unit Award Agreement Employee Version (2018 Long Term Incentive Plan).
10.33*#	Form of Restricted Stock Unit Award Agreement Director Version (2018 Long Term Incentive Plan).
10.34*	Rockwell Medical, Inc. Short Term Incentive Plan (Exhibit 10.1 to the Company's Form 10-Q filed on November 14, 2022).
10.35*	Form of Indemnification Agreement (Exhibit 10.1 to the Company's Form 8-K filed August 30, 2019).
10.36*	Stock Appreciation Right Agreement, dated September 5, 2017, by and between the Company and John G. Cooper (Exhibit 10.71 to the Company's Form 10-Q filed November 8, 2017).
10.37*	Employment Agreement, dated June 21, 2022, between Rockwell Medical, Inc. and Mark Strobeck (Exhibit 10.7 to the Company's Form 10-Q filed on August 15, 2022).
10.38*	Russell Ellison Employment Agreement, dated April 17, 2020 (Exhibit 10.1 to the Company's Form 8-K filed on April 20, 2020).
10.39*	Russell Skibsted Employment Agreement, dated September 15, 2020 (Exhibit 10.1 to the Company's Form 8-K filed on September 16, 2020).
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).
32.1#	Certification 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.

\# Filed herewith

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/ Mark Strobeck

Mark Strobeck

President and Chief Executive Officer

Date: March 30, 2023

POWER OF ATTORNEY

KNOW BY ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Mark Strobeck and Megan Timmins, 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/ Mark Strobeck Mark Strobeck	President, Chief Executive Officer and Director (Principal Executive Officer and Principal Financial Officer)	March 30, 2023
/s/ Paul McGarry Paul McGarry	Senior Vice President, Finance and Chief Accounting Officer	March 30, 2023
/s/ John G. Cooper John G. Cooper	Director	March 30, 2023
/s/ Robert S. Radie Robert S. Radie	Director	March 30, 2023
/s/ Allen Nissenson Allen Nissenson	Director	March 30, 2023
/s/ Andrea Heslin Smiley Andrea Heslin Smiley	Director	March 30, 2023
/s/ Mark H. Ravich Mark H. Ravich	Director	March 30, 2023

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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, 2022 and 2021, 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, 2022, 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, 2022 and 2021, and the consolidated results of its operations and its cash flows for each of the two years in the period ended December 31, 2022, 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

The critical audit matters communicated below 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.

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 2022, 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, entering into new distribution and purchase agreements with former Baxter customers, restructuring the Company's contract with its largest customer in the concentrates business, 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 analyzed the terms in the agreement to the projected financial information, such as the projected revenue and gross margins.
- We evaluated and tested management's assumptions, including, but not limited to, projected price increases to subsequent customer activity to validate the significant assumptions in the projected financial information, such as the projected revenue, gross margins, growth rates and operating expenses.
- We examined the executed Distribution Termination and Acquisition Agreement and analyzed the terms in the agreement to the significant assumptions in the projected financial information, such as the projected revenue and gross margins from customers reacquired under this agreement.
- We examined the executed Second Amendment to the Loan and Security Agreement and tested management's inputs and calculations of compliance with the projected required financial covenants, such as, concentrate revenue and minimum cash requirements.
- We tested certain assumptions for 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
March 30, 2023

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(Dollars in Thousands)

	December 31, 2022	December 31, 2021
ASSETS		
Cash and Cash Equivalents	$ 10,102	$ 13,280
Investments Available-for-Sale	11,390	9,158
Accounts Receivable, net of a reserve of $33 for 2022 and $16 for 2021	6,259	5,913
Inventory	5,814	4,076
Prepaid and Other Current Assets	1,745	2,861
Total Current Assets	**35,310**	**35,288**
Property and Equipment, net	2,194	2,486
Inventory, Non-Current	1,276	1,523
Right of Use Assets, net	6,411	7,737
Goodwill	921	921
Other Non-Current Assets	523	619
Total Assets	**$ 46,635**	**$ 48,574**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts Payable	$ 4,053	$ 3,739
Accrued Liabilities	7,702	5,090
Lease Liability - Current	2,005	2,004
Deferred License Revenue	1,731	2,171
Term Loan - Net of Issuance Costs	1,631	7,381
Insurance Financing Note Payable	503	437
Customer Deposits	66	144
Total Current Liabilities	**17,691**	**20,966**
Lease Liability - Long-Term	4,669	5,887
Term Loan, Net of Issuance Costs	7,555	13,186
Deferred License Revenue - Long-Term	2,600	5,986
Long Term Liability - Other	14	14
Total Liabilities	**32,529**	**46,039**
Commitments and Contingencies (See Note 14)		
Stockholders' Equity:		
Preferred Stock, $0.0001 par value, 2,000,000 shares authorized, 15,000 and nil shares issued and outstanding at December 31, 2022 and 2021, respectively	—	—
Common Stock, $0.0001 par value, 170,000,000 shares authorized, 12,163,673 and 8,544,225 shares issued and outstanding at December 31, 2022 and 2021, respectively	1	1
Additional Paid-in Capital	402,701	372,562
Accumulated Deficit	(388,759)	(370,080)
Accumulated Other Comprehensive Income	163	52
Total Stockholders' Equity	**14,106**	**2,535**
Total Liabilities and Stockholders' Equity	**$ 46,635**	**$ 48,574**

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, 2022 and 2021
(Dollars in thousands, except per share amounts)

	2022	2021
Net Sales	**$ 72,810**	**$ 61,931**
Cost of Sales	68,733	64,351
Gross (Loss) Profit	4,077	(2,420)
Research and Product Development	3,119	6,835
Selling and Marketing	2,094	5,733
General and Administrative	15,644	15,348
Operating Loss	**(16,780)**	**(30,336)**
Other Expense		
Realized Gain on Investments	4	—
Interest Expense	(1,936)	(2,360)
Interest Income	33	22
Total Other Expense	**(1,899)**	**(2,338)**
Net Loss	**$ (18,679)**	**$ (32,674)**
Basic and Diluted Net Loss per Share	**$ (1.89)**	**$ (3.83)**
Basic and Diluted Weighted Average Shares Outstanding	**9,866,844**	**8,526,186**

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, 2022 and 2021

(Dollars in Thousands)

	2022	2021
Net Loss	**$ (18,679)**	**$ (32,674)**
Unrealized Gain (Loss) on Available-for-Sale Investments	114	(6)
Foreign Currency Translation Adjustments	(3)	1
Comprehensive Loss	**$ (18,568)**	**$ (32,679)**

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, 2022 and 2021

(Dollars in Thousand)

	PREFERRED STOCK		COMMON STOCK		ADDITIONAL PAID-IN CAPITAL	ACCUMULATED DEFICIT	ACCUMULATED OTHER COMPREHENSIVE INCOME / (LOSS)	TOTAL STOCKHOLDERS' EQUITY
	SHARES	AMOUNT	SHARES	AMOUNT				
Balance as of January 1, 2021	**—**	**$ —**	**8,506,651**	**$ 1**	**$ 371,518**	**$ (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	—	—	23,483	—	(6)	—	—	(6)
Warrant Modification Expense	—	—	14,091	—	107	—	—	107
Stock-based Compensation	—	—	—	—	943	—	—	943
Balance as of December 31, 2021	**—**	**$ —**	**8,544,225**	**$ 1**	**$ 372,562**	**$ (370,080)**	**$ 52**	**$ 2,535**
Net Loss	—	—	—	—	—	(18,679)	—	(18,679)
Unrealized Loss on Available-for-Sale Investments	—	—	—	—	—	—	114	114
Foreign Currency Translation Adjustments	—	—	—	—	—	—	(3)	(3)
Vesting of Restricted Stock Units Issued, net of taxes withheld	—	—	10,958	—	—	—	—	—
Issuance of Common Stock, net of Issuance Costs / Public offering	—	—	844,613	—	14,893	—	—	14,893
Issuance of Common Stock, net of Issuance Costs / At-the-market offerings	—	—	7,500	—	15	—	—	15
Issuance of preferred stock, net of offering costs	15,000	—	—	—	14,916	—	—	14,916
Issuance of common stock upon exercise of prefunded warrants	—	—	2,756,377	—	—	—	—	—
Stock-based Compensation	—	—	—	—	315	—	—	315
Balance as of December 31, 2022	**15,000**	**$ —**	**12,163,673**	**$ 1**	**$ 402,701**	**$ (388,759)**	**$ 163**	**$ 14,106**

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, 2022 and 2021
(Dollars in Thousands)

	2022	2021
Cash Flows From Operating Activities:		
Net Loss	**$ (18,679)**	**$ (32,674)**
Adjustments To Reconcile Net Loss To Net Cash Used In Operating Activities:		
Depreciation and Amortization	576	668
Stock-based Compensation	315	943
Increase in Inventory Reserves	610	146
Amortization of Right of Use Asset	2,013	1,847
Amortization of Debt Financing Costs and Accretion of Debt Discount	369	369
Loss on Disposal of Assets	(3)	8
Realized Loss on Sale of Investments Available-for-Sale	(4)	—
Foreign Currency Translation Adjustment	(3)	2
Changes in Assets and Liabilities:		
Increase in Accounts Receivable, net	(346)	(1,742)
Increase in Inventory	(2,101)	(656)
Decrease in Other Assets	2,720	1,823
(Decrease) Increase in Accounts Payable	314	(416)
Decrease in Lease Liability	(1,903)	(1,771)
(Decrease) Increase in Other Liabilities	2,534	(48)
Decrease in Deferred License Revenue	(3,826)	(2,033)
Changes in Assets and Liabilities	(2,608)	(4,843)
Cash Used In Operating Activities	**(17,414)**	**(33,534)**
Cash Flows From Investing Activities:		
Purchase of Investments Available-for-Sale	(21,297)	(26,058)
Sale of Investments Available-for-Sale	19,182	26,891
Purchase of Equipment	(281)	(522)
Cash (Used In) Provided By Investing Activities	**(2,396)**	**311**
Cash Flows From Financing Activities:		
Payments on Short Term Note Payable	(1,443)	(1,530)
Payments on Debt	(11,750)	(750)
Proceeds from the Issuance of Common Stock / Public Offering	15,016	—
Offering Costs from the Issuance of Common Stock / Public Offering	(106)	—
Proceeds from the Issuance of Common Stock / At-the Market Offerings	15,000	—
Offering Costs from the Issuance of Common Stock / At-the Market Offerings	(85)	—
Proceeds from issuance of Common Stock for payment related to services provided	—	107
Repurchase of Common Stock to Pay Employee Withholding Taxes	—	(6)
Cash Provided By (Used in) Financing Activities	**16,632**	**(2,179)**
Decrease In Cash and Cash Equivalents	(3,178)	(35,402)
Cash and Cash Equivalents At Beginning Of Period	13,280	48,682
Cash and Cash Equivalents At End Of Period	**$ 10,102**	**$ 13,280**
Supplemental Disclosure of Cash Flow Information:		
Cash Paid for Interest	$ 1,470	$ 1,827
Supplemental Disclosure of Noncash Investing Activities:		
Change in Unrealized Loss on Marketable Securities Available-for-Sale	$ 114	$ (6)
Insurance Financing Note Payable	$ 503	$ 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 is a healthcare company that develops, manufactures, commercializes, and distributes a portfolio of hemodialysis products for dialysis providers worldwide.

Rockwell is a revenue-generating business and the second largest supplier of acid and bicarbonate concentrates for dialysis patients in the United States. Hemodialysis is the most common form of end-stage kidney disease treatment and is usually performed at freestanding outpatient dialysis centers, at hospital-based outpatient centers, at skilled nursing facilities, or in a patient's home. This represents a large market opportunity for which Rockwell's products are well-positioned to meet the needs of patients.

Rockwell manufactures hemodialysis concentrates under Current Good Manufacturing Practices ("cGMP") regulations at its three facilities in Michigan, Texas, and South Carolina totaling approximately 175,000 square feet, and manufactures its dry acid concentrate mixers at its facility in Iowa. Rockwell delivers the majority of its hemodialysis concentrates products and mixers to dialysis clinics throughout the United States and internationally utilizing its own delivery trucks and third-party carriers. Rockwell has developed a core expertise in manufacturing and delivering hemodialysis concentrates, and has built a longstanding reputation for reliability, quality, and excellent customer service.

In addition to its primary focus on hemodialysis concentrates, Rockwell also has a proprietary parenteral iron product, Triferic® (ferric pyrophosphate citrate ("FPC")), which is indicated to maintain hemoglobin in adult patients with hemodialysis-dependent chronic kidney disease. While Rockwell has discontinued commercialization of Triferic in the United States, the Company has established several international partnerships with companies seeking to develop and commercialize Triferic outside the United States and is working closely with these international partners to develop and commercialize Triferic in their respective regions. Additionally, Rockwell continues to evaluate the viability of its FPC platform and FPC's potential to treat iron deficiency, iron deficiency anemia, and acute heart failure.

Rockwell was incorporated in the state of Michigan in 1996 and re-domiciled to the state of Delaware in 2019. Rockwell's headquarters is located at 30142 Wixom Road, Wixom, Michigan 48393.

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, 2022, Rockwell had an accumulated deficit of approximately $388.8 million and stockholders' equity of $14.1 million. As of December 31, 2022, Rockwell had approximately $21.5 million of cash, cash equivalents and investments available-for-sale, and working capital of $17.6 million. Net cash used in operating activities for the year ended December 31, 2022 was approximately $17.4 million. 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, if needed, and remain in compliance with financial and reporting covenants under the Company's secured loan.

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, under which the Company supplies DaVita with certain dialysis concentrates. Under the Amendment, the Company and DaVita agreed to certain price increases, 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 of $10 million, or the Company will be in default under the Products Purchase Agreement. An event of default could result in termination of that agreement.

On April 6, 2022, the Company and DaVita entered into a Securities Purchase Agreement (the "SPA"), pursuant to which the Company issued $15 million of preferred stock to DaVita in two separate tranches. The Company initially issued 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. On June 15, 2022, the Company issued 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. The Second

Tranche was conditioned upon the Company raising an additional $15,000,000 in capital within a certain timeline, which took place on June 2, 2022.

On April 8, 2022, 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 up to $12,200,000 of shares of Company's common stock through the Agent. During the year ended December 31, 2022, the Company sold 7,500 shares of its common stock pursuant to the Sales Agreement for gross proceeds of $15,135, at a weighted average selling price of approximately $2.02 The Company paid $378 in commissions and offering fees. Approximately $12.2 million remains available for sale under the ATM facility.

On May 30, 2022, the Company entered into a Securities Purchase Agreement (the "RD Purchase Agreement") with the purchaser named therein (the "Purchaser"), pursuant to which the Company agreed to issue and sell, in a registered direct offering (the "Offering"), 844,613 shares of its common stock at price of $1.39 per share, and prefunded warrants to purchase up to an aggregate of 7,788,480 shares of common stock (the "Pre-Funded Warrants" and the shares of common stock underlying the Pre-Funded Warrants, the "Warrant Shares"). The purchase price of each Pre-Funded Warrant was equal to the price at which a share of common stock was sold to the public in the Offering, minus $0.0001, and the exercise price of each Pre-Funded Warrant is $0.0001 per share.

Also on May 30, 2022, concurrently with the Offering, the Company entered into a Securities Purchase Agreement with the Purchaser (the "PIPE Purchase Agreement") relating to the offering and sale (the "Private Placement") of warrants to purchase up to a total of 9,900,990 shares of common stock and pre-funded warrants to purchase up to a total of 1,267,897 shares of common stock (the "PIPE Warrants"). Each warrant was sold at a price of $0.125 per underlying warrant share and is exercisable at an exercise price of 1.39 per share. The purchase price of each Pre-Funded Warrant was equal to the price at which a share of common stock was sold to the public in the Offering, minus $0.0001, and the exercise price of each prefunded warrant is $0.0001 per share. The Offering and the Private Placement closed on June 2, 2022. The net proceeds to the Company from the Offering and the Private Placement were approximately $14.9 million, after deducting fees and expenses.

On November 10, 2022, the Company entered into a Second Amendment to the Loan and Security Agreement (the "Second Amendment") dated as of November 14, 2022 with Innovatus, which amended the Loan Agreement. Pursuant to the Second Amendment, the Company (i) prepaid an aggregate principal amount of $5.0 million in Term Loans (as defined in the Loan Agreement) in one installment on November 14, 2022; (ii) shall pay interest only payments until September 2023 at which time will resume scheduled debt payments (See Note 16 for more information on our debt facility).

Management evaluated it's going concern by reviewing the Company's operational plans which include executing on the projected financial information including price increases, acquisition of new customers, projected growth of margins and cost containment activities. Additionally, the Company's operational plans also include raising capital, if needed, by using our ATM facility or other methods or forms of financings, subject to existing limitations. Based on the currently available working capital, expectation of the ability of management to execute on the Company's operational plans noted above, management believes the Company currently has sufficient funds to meet its operating requirements for at least the next twelve months from the date of the filing of this report. Accordingly, management believes that the factors noted above which raised substantial doubt about the Company's ability to continue as a going concern have been alleviated.

The Company may require additional capital to sustain its operations and make the investments it needs to execute its strategic plan. If the Company attempts to obtain additional debt or equity financing, the Company cannot assume such financing will be available on favorable terms, if at all.

Currently, because the Company's public float is less than $75 million, it is subject to the baby shelf limitations under Form S-3, which limits the amount the Company may offer pursuant to its registration statement on Form S-3.

In addition, the Company is subject to certain covenants and cure provisions under its Loan Agreement with Innovatus. As of December 31, 2022, the Company is in compliance with all financial covenants (See Note 16 for further detail).

Global Economic Conditions

The COVID-19 pandemic and resulting domestic and global disruptions, particularly in the supply chain and labor market, among other areas, have adversely affected the Company's business and operations, including, but not limited to, its sales and marketing efforts and its research and development activities, its plant and transportation operations and the operations of third parties upon whom the Company relies. The Company's international business development activities may also continue to be negatively impacted by COVID-19.

In addition, the global macroeconomic environment is uncertain, and could be negatively affected by, among other things, increased U.S. trade tariffs and trade disputes with other countries, instability in the global capital and credit markets, supply chain weaknesses, and instability in the geopolitical environment, including as a result of the Russian invasion of Ukraine and other political tensions, and lingering effects of the COVID-19 pandemic. Such challenges have caused, and may continue to cause, recession fears, rising interest rates, foreign exchange volatility and inflationary pressures. At this time, the Company is unable to quantify the potential effects of this economic instability on our future operations.

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.

On November 9, 2022, Rockwell reacquired its distribution rights to its hemodialysis concentrates products from Baxter and agreed to terminate the exclusive distribution agreement dated October 2, 2014. Exclusivity and other provisions associated with the distribution agreement terminated November 9, 2022 and the remaining operational elements of the agreement terminated December 31, 2022. Rockwell agreed to provide certain services to a group of Baxter customers until March 31, 2023.Remaining upfront fees will continue to be recognized through March 31, 2023 as Rockwell continues to have product sales obligations to a group of specific Baxter customers.

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, 2022		
Products By Geographic Area	Total	U.S.	Rest of World
Drug Revenues			
Product Sales - Point-in-time	$ 903	$ 561	$ 342
License Fee – Over time	256	—	256
Total Drug Products	1,159	561	598
Concentrate Products			
Product Sales – Point-in-time	69,162	62,715	6,447
License Fee – Over time	2,489	2,489	—
Total Concentrate Products	71,651	65,204	6,447
Net Revenue	$ 72,810	$ 65,765	$ 7,045

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 – Over time	1,942	1,942	—
Total Concentrate Products	60,855	54,556	6,299
Net Revenue	$ 61,931	$ 55,391	$ 6,540

For the years ended December 31, 2022 and 2021, license fee revenue was $2.7 million and 2.2 million respectively. For the years ended December 31, 2022 and 2021, product sales revenue was $70.1 million and $59.7 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, 2022	December 31, 2021
Receivables, which are included in "Trade and other receivables"	$ 6,259	$ 5,913
Contract liabilities	$ 4,331	$ 8,157

There were no impairment losses recognized related to any receivables arising from the Company's contracts with customers for the years ended December 31, 2022 and 2021.

For the years ended December 31, 2022 and 2021, 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, 2022 and 2021. 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, 2022 or 2021.

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, 2022, 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 $2.9 million and $8.2 million as of December 31, 2022 and 2021, 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.

Reverse Stock Split

On May 9, 2022, the stockholders of the Company authorized the Board of Directors to effect a reverse stock split of all outstanding shares of common stock. The Board of Directors subsequently approved the implementation of a reverse stock split as a ratio of one-for-eleven shares, which became effective on May 13, 2022. The Company's outstanding stock options were also adjusted to reflect the one-for-eleven reverse stock split of the Company's common stock. Outstanding stock options were proportionately reduced and the respective exercise prices, if applicable, were proportionately increased. The reverse stock split resulted in an adjustment to the Series X convertible preferred stock conversion prices to reflect a proportional decrease in the number of shares of common stock to be issued upon conversion. All share and per share data in these condensed consolidated financial statements and related notes hereto have been retroactively adjusted to account for the effect of the reverse stock split for the periods ended December 31, 2022 and 2021, respectively.

Use of Estimates

The preparation of the consolidated financial statements in conformity with accounting principles generally accepted in the United States of America 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 and debt securities at the time of purchase and reevaluates such determination at each balance sheet date. Marketable equity 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, 2022 and 2021, there were no impairments of long-lived assets.

Goodwill and Intangible Assets

Goodwill is the excess of purchase price over the fair value of identified net assets of businesses acquired. Intangible assets with indefinite useful lives are measured at their respective fair values as of the acquisition date.

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

Intangible assets with definite lives are amortized over their estimated useful lives. Intangible assets subject to amortization are reviewed for potential impairment whenever events or circumstances indicate that carrying amounts may not be recoverable.

Definite-lived intangible assets consist of our license fees related to the technology, intellectual property and marketing rights for Triferic covered under certain issued patents have been capitalized and are being amortized over the life of the related patents which is generally 17 years.

Deferred Revenue

In October 2014, the Company entered into a Distribution Agreement with Baxter, which had 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.

On November 9, 2022, Rockwell reacquired its distribution rights to its hemodialysis concentrates products from Baxter and terminated the Distribution Agreement. Under the Distribution Agreement, Baxter distributed and commercialized Rockwell's hemodialysis concentrates products and provided customer service and order delivery to nearly all United States customers. Following the reacquisition of these rights, Rockwell will now be able to sell its hemodialysis concentrates products to dialysis clinics throughout the United States and around the world.

Rockwell will pay Baxter a fee for the reacquisition of its distribution rights. This fee is payable in two equal installments on January 1, 2023 and April 1, 2023. To ensure that customer needs continue to be met after January 1, 2023, Baxter and Rockwell are working closely together to transition customers' purchases of Rockwell's hemodialysis concentrates from Baxter to Rockwell. The Company recognized revenue of approximately $2.5 million and $1.9 million for the years ended December 31, 2022 and 2021, respectively. Deferred revenue related to the Distribution Agreement totaled $1.5 million and $5.2 million as of December 31, 2022 and 2021, respectively.

During the year ended December 31, 2016, the Company entered into a distribution agreement with Wanbang Biopharmaceuticals (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 during each of the years ended December 31, 2022 and 2021. Deferred revenue related to the Wanbang Agreement totaled $2.3 million and $2.5 million as of December 31, 2022 and 2021, respectively.

In January 2020, the Company entered into license and supply agreements with Sun Pharma (the "Sun Agreements"), for the rights to commercialize Triferic (dialysate) in India. Under the terms of the Sun 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 each of the years ended December 31, 2022 and 2021. Deferred revenue related to the Sun Pharma Agreement totaled $0.1 million as of December 31, 2022 and 2021, respectively.

In September 2020, the Company entered into a license and supply agreements with Jeil Pharmaceutical (the "Jeil Agreements"), for the rights to commercialize Triferic (dialysate) in South Korea. Under the terms of the Jeil Agreements, Jeil Pharmaceutical will be the exclusive development and commercialization partner for Triferic (dialysate) in South Korea, and the Company will supply the product to Jeil Pharmaceutical. In consideration for the license, the Company received an upfront fee of $0.4 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 Pharmaceutical, will guide the development and execution for Triferic (dialysate) in South Korea. Jeil Pharmaceutical 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 $18,158 and $10,000 during the years ended December 31, 2022 and 2021, respectively. Deferred revenue related to the Jeil Agreement totaled $0.4 million and $0.2 million as of December 31, 2022 and 2021, respectively.

In June 2021, the Company entered into license and supply agreements with Drogsan Pharmaceuticals (the "Drogsan Agreements"), for the rights to commercialize Triferic (dialysate) and Triferic AVNU in Turkey. Under the terms of the Drogsan Agreements, Drogsan Pharmaceuticals 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 Pharmaceuticals, will guide the execution for Triferic (dialysate) and Triferic AVNU in Turkey. Drogsan Pharmaceuticals will be responsible for all regulatory approval and commercialization activities, and the Company will supply the product to Drogsan Pharmaceuticals 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 $15,000 and $7,500 during the years ended December 31, 2022 and 2021, respectively. Deferred revenue related to the Drogsan Agreements totaled approximately $0.1 million as of December 31, 2022 and 2021, respectively.

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 $3.1 million and $6.8 million for the years ended December 31, 2022 and 2021, 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, 2022 and 2021, 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, 2022 and 2021 were as follows:

	As of December 31,	
	2022	2021
Options to purchase common stock	1,206,905	528,591
Unvested restricted stock awards	891	7,118
Unvested restricted stock units	125,000	29,289
Convertible Preferred Stock	1,363,636	—
Common stock issuable under pre-funded warrants	6,300,000	—
Warrants to purchase common stock	10,196,268	2,402,442
Total	19,192,700	2,967,440

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 debt 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, 2022 and 2021 (tables in thousands):

	December 31, 2022				
	Amortized Cost	Unrealized Gain	Unrealized Loss	Accrued Interest Income	Fair Value
Available-for-Sale Securities					
Bonds	$ 11,315	$ 75	$ —	$ —	$ 11,390

	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

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, 2022 and 2021, 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 46% of Rockwell's sales in 2022 and 47% of its sales in 2021 (see Note 12). Rockwell's accounts receivable from DaVita were $1.9 million and $1.0 million as of December 31, 2022 and 2021, 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 had been assigned to Baxter.

On November 9, 2022, Rockwell reacquired its distribution rights to its hemodialysis concentrates products from Baxter and has agreed to terminate the exclusive distribution agreement dated October 2, 2014. Exclusivity and other provisions associated with the distribution agreement terminated November 9, 2022 and the remaining operational elements of the agreement terminate December 31, 2022. Rockwell agreed to provide certain services to a group of Baxter customers until March 31, 2023.Under the exclusive distribution agreement, Baxter distributed and commercialized Rockwell's hemodialysis concentrates products and provided customer service and order delivery to nearly all United States customers. Following the reacquisition of these rights, Rockwell will now be able to sell its hemodialysis concentrates products to dialysis clinics throughout the United States and around the world. For 2022 and 2021, Rockwell's direct sales to Baxter aggregated approximately 29% and 26% of sales, respectively, and the Company had a receivable from Baxter of $2.3 million and $3.5 million as of December 31, 2022 and 2021, respectively.

DaVita and the accounts previously 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 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 9% and 10% of its total sales in 2022 and 2021, respectively. One international customer, Nipro Medical Corporation, accounted for 7% and 8% of its total sales for 2022 and 2021, respectively.

Note 6. Distribution Agreement

In October 2014, Rockwell entered into the Distribution Agreement with Baxter, 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 retained sales, marketing and distribution rights for its hemodialysis concentrate products for its international customers and in those countries in which it had an established commercial presence.

Pursuant to the Distribution Agreement, Rockwell received an upfront fee of $20 million in October 2014. The upfront fee was deferred and was 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. Rockwell recognized revenue associated with the upfront fee totaling $2.5 million and $1.9 million for the years ended December 31, 2022, and 2021, respectively.

On November 9, 2022, Rockwell reacquired its distribution rights to its hemodialysis concentrates products from Baxter and terminated the Distribution Agreement. Exclusivity and other provisions associated with the distribution agreement terminated November 9, 2022 and the remaining operational elements of the agreement terminate December 31, 2022. Rockwell agreed to provide certain services to a group of Baxter customers until March 31, 2023.Under the Distribution Agreement, Baxter distributed and commercialized Rockwell’s hemodialysis concentrates products and provided customer service and order delivery to nearly all United States customers. Following the reacquisition of these rights, Rockwell is able to sell its hemodialysis concentrates products to dialysis clinics throughout the United States and around the world.

Rockwell will pay Baxter a fee for the reacquisition of its distribution rights. This fee is payable in two equal installments on January 1, 2023 and April 1, 2023. To ensure that customer needs continue to be met after January 1, 2023, Baxter and Rockwell are working closely together to transition customers’ purchases of Rockwell’s hemodialysis concentrates from Baxter to Rockwell through March 31, 2023.

Note 7. Inventory

Components of inventory, net of reserves as of December 31, 2022 and 2021 are as follows (table in thousands):

	December 31, 2022	December 31, 2021
Raw Materials	$ 4,627	$ 3,434
Work in Process	351	201
Finished Goods	2,112	1,964
Total	$ 7,090	$ 5,599

As of December 31, 2022 and 2021, the Company classified $1.3 million and $1.5 million, respectively, of inventory as non-current all of which was related to Triferic raw materials. This Triferic inventory will be utilized for the Company's international partnerships. The Company has discontinued its NDAs for Triferic and Triferic AVNU in the United States. As a result, Rockwell reserved an additional $606,000 representing all remaining API and finished goods related to Triferic. As of December 31, 2022 and 2021, Rockwell had total Concentrate inventory aggregating $5.8 million and $4.0 million, respectively, against which Rockwell had reserved $25,000 and $21,000, respectively.

Note 8. Property and Equipment

As of December 31, 2022 and 2021, the Company’s property and equipment consisted of the following (table in thousands):

	2022	2021
Leasehold Improvements	$ 1,256	$ 1,204
Machinery and Equipment	5,922	5,864
Information Technology & Office Equipment	1,845	1,845
Laboratory Equipment	807	676
	9,830	9,589
Accumulated Depreciation	(7,636)	(7,103)
Net Property and Equipment	$ 2,194	$ 2,486

Depreciation expense during the years ended December 31, 2022 and 2021 is as follows (table in thousands):

	2022	2021
Depreciation expense	$ 576	$ 668

Note 9. Goodwill and Intangible Assets

Total goodwill was $0.9 million at each of December 31, 2022 and 2021. Rockwell completed its annual impairment tests as of December 31, 2022 and 2021, and determined that no adjustment for impairment of goodwill was required during the years ended December 31, 2022 and 2021.

Note 10. Accrued Liabilities

Accrued liabilities as of December 31, 2022 and 2021 consisted of the following (table in thousands):

	2022	2021
Accrued Research & Development Expense	$ 43	$ 366
Accrued Compensation and Benefits	2,568	1,791
Accrued Unvouchered Receipts	585	796
Accrued Workers Compensation	306	382
Other Accrued Liabilities	4,200	1,755
Total Accrued Liabilities	$ 7,702	$ 5,090

Note 11. Insurance Financing Note Payable

On July 3, 2022, the Company entered into a short-term note payable for $2.0 million, bearing interest at 5.40% per annum to finance various insurance policies. Principal and interest payments related to this note began on July 3, 2022 and are paid on a straight-line amortization over 9 month and the final payment is due on March 3, 2023. As of December 31, 2022, the Company's insurance note payable balance was $0.5 million.

Note 12. Stockholders' Equity

Reverse Stock Split

On May 9, 2022, the stockholders of the Company authorized the Board of Directors to effect a reverse stock split of all outstanding shares of common stock. The Board of Directors subsequently approved the implementation of a reverse stock split as a ratio of one-for-eleven shares, which became effective on May 13, 2022. The Company's outstanding stock options were also adjusted to reflect the one-for-eleven reverse stock split of the Company's common stock. Outstanding stock options were proportionately reduced and the respective exercise prices, if applicable, were proportionately increased.

Preferred Stock

On April 6, 2022, the Company and DaVita entered into the SPA, which provided for the issuance by the Company of up to $15 million of preferred stock to DaVita. On April 6, 2022, the Company issued 7,500 shares of Series X Preferred Stock for gross proceeds of $7.5 million. On June 2, 2022, the Company met the conditions for the Second Tranche through a Registered Direct and Private Placement Offering by raising $15 million in additional capital. As a result, on June 16, 2022 the

Company issued an additional 7,500 shares of the Series X Preferred Stock to DaVita for gross proceeds of $7.5 million (by virtue of this transaction, DaVita rises to the level of related party).

The Series X Preferred Stock was issued for a price of $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 $22.00 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 $11.00 per share (subject to adjustment for future stock splits, reverse stock splits and similar recapitalization events). As a result, each share of Series X Preferred Stock will initially convert into approximately 91 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. 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.

Additionally, the Series X Preferred Stock has a deemed liquidation event and redemption clause which could be triggered if the sale of all or substantially all of the Company's assets relating to the Company's dialysis concentrates business line. Since the Series X Preferred Stock may be redeemed if certain assets are sold at the option of the holder, but is not mandatorily redeemable, the preferred stock has been classified as permanent equity and initially recognized at fair value of $15 million (the proceeds on the date of issuance) less issuance costs of $0.1 million, resulting in an initial value of $14.9 million. The Company will assess at each reporting period whether conditions have changed to now meet the mandatorily redemptive definition which could trigger liability classification.

As of December 31, 2022 and 2021, there were 2,000,000 shares of preferred stock, $0.0001 par value per share, authorized and 15,000 and nil shares of preferred stock issued or outstanding, respectively.

Common Stock

As of December 31, 2022 and 2021, there were 170,000,000 shares of common stock, $0.0001 par value per share, authorized and 12,163,673 and 8,544,225 shares issued and outstanding, respectively.

As of December 31, 2022 and 2021, the Company has reserved for issuance the following shares of common stock related to the potential exercise of employee stock options, unvested restricted stock, convertible preferred stock, pre-funded warrants and all other warrants:

	As of December 31,	
	2022	2021
Options to purchase common stock	1,206,905	528,591
Unvested restricted stock awards	891	7,118
Unvested restricted stock units	125,000	29,289
Convertible Preferred Stock	1,363,636	—
Common stock issuable under pre-funded warrants	6,300,000	—
Warrants to purchase common stock	10,196,268	2,402,442
Total	19,192,700	2,967,440

During the years ended December 31, 2022 and 2021, 2,756,377 and nil pre-funded warrants were exercised, respectively.

During the years ended December 31, 2022 and 2021, no vested employee stock options were exercised.

Controlled Equity Offering

On April 8, 2022, the Company entered into the Sales Agreement with Cantor Fitzgerald & Co. as Agent, pursuant to which the Company may offer and sell from time to time up to $12,200,000 of shares of Company's common stock through the Agent (subject to restrictions under General Instruction I.B.6 to Form S-3).

In May 2022, the Company sold $7,500 shares of its common stock pursuant to the Sales Agreement for gross proceeds of $15,135, at a weighted average selling price of approximately $2.02 per share. The Company paid $378 in commissions and offering fees related to the sale of shares of common stock.

Registered Direct Offering

On May 30, 2022, the Company entered into the RD Purchase Agreement with the Purchaser named therein, pursuant to which the Company agreed to issue and sell, in a registered direct offering (the "Offering"), 844,613 shares of its common stock at price of 1.39 per share, and pre-funded warrants to purchase up to an aggregate of 7,788,480 shares of common stock (the "Pre-Funded Warrants" and the shares of common stock underlying the Pre-Funded Warrants, the "Warrant Shares"). The purchase price of each Pre-Funded Warrant is equal to the price at which a share of common stock was sold to the public in the Offering, minus $0.0001, and the exercise price of each Pre-Funded Warrant is $0.0001 per share.

A holder (together with its affiliates) may not exercise any portion of the Pre-Funded Warrants to the extent the holder would own more than 9.99% of the Company's outstanding common stock immediately after exercise, as such percentage ownership is determined in accordance with the terms of the Pre-Funded Warrant. The RD Purchase Agreement contains customary representations and warranties and agreements of the Company and the Purchaser and customary indemnification rights and obligations of the parties.

A total of 6,300,000 Pre-Funded Warrants remained outstanding as of December 31, 2022.

Private Placement

Also on May 30, 2022, concurrently with the Offering, the Company entered into the PIPE Purchase Agreement relating to the offering and sale (the "Private Placement") of warrants to purchase up to a total of 9,900,990 shares of common stock and pre-funded warrants to purchase up to a total of 1,267,897 shares of common stock (the "PIPE Warrants"). Each warrant was sold at a price of $0.125 per underlying warrant share and is exercisable at an exercise price of $1.39 per share. The warrants to purchase up to a total of 9,900,990 shares of common stock which expire in November 2027 contain certain valuation provisions on unexercised outstanding warrants if the Company were to experience a fundamental transaction as described in section 3(d) of the warrant agreement. The purchase price of each Pre-Funded Warrant was equal to the price at which a share of common stock was sold to the public in the Offering, minus $0.0001, and the exercise price of each prefunded warrant is $0.0001 per share.

As of December 31, 2022, 9,900,990 PIPE Warrants and no Pre-Funded PIPE Warrants remained outstanding.

In connection with the Private Placement, the Company entered into a Registration Rights Agreement with the Purchaser, dated as of June 2, 2022 (the "RRA"). Pursuant to the RRA, the Company was required to prepare and file a registration statement with the SEC no later than July 1, 2022, and to use its reasonable best efforts to have the registration statement declared effective as promptly as possible, subject to certain specified penalties if timely effectiveness is not achieved. The Company filed a registration statement on June 22, 2022 which became effective on July 5, 2022.

The Offering and the Private Placement closed on June 2, 2022. The net proceeds to the Company from the Offering and the Private Placement were approximately $14.9 million, after deducting fees and expenses. Subject to certain ownership limitations, the PIPE Warrants are exercisable upon issuance.

The Company has accounted for the common stock related to the Offering and Private Placement as equity on the accompanying consolidated balance sheets as of December 31, 2022. The amount allocated to common stock was $2.0 million. This allocation is equal to the total proceeds of $15.0 million less the amount allocated to Warrants of $12.9 million and is also net of the direct and incremental costs associated with the Offering and Private Placement of $0.1 million. The Black-Scholes pricing model was used to calculate the value of Warrants relating to the Offering and Private Placement.

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 1,045,455 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 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 263,636 and on May 9,2022, at the 2021 Annual Meeting, the Company's stockholders approved the amended and restatement of the Rockwell Medical, Inc. 2018 Long Term Incentive Plan to increase the number of shares of common stock issuable thereunder by 454,546 shares bringing common stock reserve for issuance up to 1,018,182 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, 2022 and 2021 as follows (table in thousands):

	Year Ended December 31,	
	2022	2021
Service based awards:		
Restricted stock units	$ 129	$ 344
Stock option awards	576	1,354
	$ 705	$ 1,697
Performance based awards:		
Restricted stock awards	$ (390)	$ (390)
Stock option awards	—	(364)
	(390)	(754)
Total	$ 315	$ 943

Restricted Stock Awards

A summary of the Company's restricted stock awards during the years ended December 31, 2022 and 2021 is as follows:

	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested at January 1, 2021	13,345	$ 62.70
Forfeited	(6,227)	$ 62.70
Unvested at December 31, 2021	7,118	62.70
Forfeited	(6,227)	—
Unvested at December 31, 2022	891	$ 62.70

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, 2022, all unvested restricted stock awards were related to performance based awards. The 6,227 forfeited performance-based restricted stock awards were due to the termination of the Company's former Chief Development Officer on March 25, 2022. These forfeited awards reduced stock-based compensation expense by $0.4 million. Stock-based compensation expense of nil was recognized for each of the years ended December 31, 2022 and 2021. As of December 31, 2022, 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, 2022 and 2021 is as follows:

	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested at January 1, 2021	24,136	$ 28.60
Granted	28,186	9.90
Forfeited	(1,073)	52.91
Vested	(21,960)	24.97
Unvested at December 31, 2021	29,289	12.87
Granted	125,000	1.47
Forfeited	(5,774)	19.00
Vested	(23,515)	11.33
Unvested at December 31, 2022	125,000	$ 1.47

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 $0.1 million was recognized for each of the years ended December 31, 2022 and 2021. As of December 31, 2022, the unrecognized stock-based compensation expense was $0.1 million over the next 12 months.

Performance Based Restricted Stock Units

As of December 31, 2022, there were no issued or outstanding performance-based restricted stock units. As a result, 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, 2022 and 2021 were based on the following assumptions:

	December 31,	
	2022	2021
Exercise price	$1.28 - $1.66	$5.94 - $5.94
Expected stock price volatility	76.2% - 78.5%	75.0% - 77.7%
Risk-free interest rate	1.97% - 3.44%	0.47% - 1.30%
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, 2022 and 2021 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, 2021	519,814	$ 50.05	6.6	$ —
Granted	177,014	9.68	6.0	—
Expired	(128,064)	(77.00)		
Forfeited	(40,173)	(24.42)	—	
Outstanding at December 31, 2021	528,591	$ 32.01	7.5	$ —
Granted	898,659	1.49	—	—
Expired	(96,199)	(78.06)	—	
Forfeited	(124,146)	(5.70)	—	
Outstanding at December 31, 2022	1,206,905	$ 28.31	8.9	$ —
Exercisable at December 31, 2022	243,088	$ 4.81	6.8	$ —

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, 2022 and 2021, the service based stock options granted consisted of 898,659 and 177,014 options granted to employees, respectively. As of December 31, 2022, 243,088 vested options were exercisable at a weighted average price of $28.31 per share.

During the year ended December 31, 2022 and 2021, stock-based compensation expense of $0.6 million and $1.4 million was recognized, respectively. As of December 31, 2022, total stock-based compensation expense related to 963,817 unvested options not yet recognized totaled approximately $0.9 million over the next 3.7 years.

Performance Based Stock Options

As of December 31, 2022, there were no performance based stock options outstanding.

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, 2022 and 2021, the Company has accrued $87,900 and $86,400, 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, 2022.

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 2026. 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, 2022	For the year ended December 31, 2021
Operating leases		
Operating lease cost	$ 1,710	$ 1,793
Variable lease cost	388	373
Operating lease expense	2,098	2,166
Finance leases		
Amortization of right-of-use assets	565	313
Interest on lease obligations	179	99
Finance lease expense	744	412
Short-term lease rent expense	17	17
Total rent expense	$ 2,859	$ 2,595
Other information		
Operating cash flows from operating leases	$ 1,772	$ 1,772
Operating cash flows from finance leases	$ 179	$ 99
Financing cash flows from finance leases	$ 482	$ 255
Right of use assets exchanged for operating lease liabilities	$ 768	$ 4,217
Right of use assets exchanged for finance lease liabilities	$ —	$ 2,431
Weighted-average remaining lease term - operating leases	3.0	3.5
Weighted-average remaining lease term – finance leases	4.4	5.4
Weighted-average discount rate - operating leases	6.4 %	6.3 %
Weighted-average discount rate – finance leases	6.4 %	6.4 %

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

	Operating	Finance
Year ending December 31, 2023	$ 1,672	$ 668
Year ending December 31, 2024	1,405	672
Year ending December 31, 2025	937	676
Year Ended December 31, 2026	310	666
Year Ended December 31, 2027	121	311
Remaining future payments	—	—
Total	4,445	2,993
Less present value discount	$ (380)	$ (384)
Operating and Finance lease liabilities.	$ 4,065	$ 2,609

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 $621,000 in aggregate coverage for the policy year ending July 1, 2023. The total amount at December 31, 2022 by which retention limits exceed the claims paid and accrued is approximately $534,000 for the policy year ending July 1, 2023. Estimated loss and additional future claims of approximately $306,000 have been reserved and accrued for the year ended December 31, 2022.

As of December 31, 2022, approximately $0.4 million was held in cash collateral and escrow by the insurance carrier for workers' compensation insurance. At December 31, 2022, 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 $31.0 million, which include $29.4 million for concentrate manufacturing and $1.6 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, 2022, interest expense amounted to $1.5 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, 2022. 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, 2022 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 $7.5 million 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 $5.0 million if the aggregate principal amount of term loans is greater than $15.0 million pursuant to the liquidity covenant in the Loan Agreement.

On November 10, 2022, the Company entered into a Second Amendment to the Loan and Security Agreement (the "Second Amendment") dated as of November 14, 2022 with Innovatus. Pursuant to the Second Amendment, the Company (i) prepaid an aggregate principal amount of $5.0 million in Term Loans in one installment on November 14, 2022; and (ii) shall pay interest only payments until September 2023 at which time will resume scheduled debt payments. As of December 31, 2022, the Company was in compliance with its financial and reporting covenants.

As of December 31, 2022, the outstanding balance of the Term Loan was $9.2 million, net of unamortized issuance costs and discount of $0.8 million.

The following table reflects the schedule of principal payments on the Term Loan as of December 31, 2022 (in thousands):

Year	Principal Payments
2023	2,000
2024	6,000
2025	2,000
	$ 10,000

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):

	2022	2021
Tax Expense (Benefit) Computed at 22.68% and 22.62% of Pretax Income (Loss)	$ (4,361)	$ (6,744)
Changes in Tax Laws	—	—
Foreign Income Tax Expense	—	—
Effect of Change in Valuation Allowance	4,361	6,744
Total Income Tax Expense	$ —	$ —

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

	December 31,	
	2022	2021
Deferred tax assets:		
Net Operating Loss Carryforward	$ 70,686	$ 66,895
Stock Based Compensation	7,792	7,726
Deferred Revenue	983	1,846
General Business Credit	6,872	6,872
Accrued Expenses	605	174
Inventories	234	88
Book over Tax Depreciation	—	6
Research & Experimental Expenses	371	—
Other Deferred Tax Assets	1,274	865
Total Deferred Tax Assets	88,817	84,472
Deferred Tax Liabilities:		
Book over Tax Depreciation	8	—
Goodwill & Intangible Assets	224	183
Prepaid Expenses	316	381
Total Deferred Tax Liabilities	548	564
Subtotal	88,269	83,908
Valuation Allowance	(88,269)	(83,908)
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 $311.6 million of which approximately $165.3 million expire between 2023 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, 2022, and 2021. Considered together with the Company's limited history of operating income and its net losses in 2022 and 2021, management has placed a full valuation allowance against the net deferred tax assets as of December 31, 2022 and 2021. The portion of the valuation allowance resulting from excess tax benefits on share based compensation that would be credited directly to contributed capital if recognized in subsequent periods is $3.9 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, 2022 and 2021. The Company has not been under tax examination in any jurisdiction for the years ended December 31, 2022 and 2021. Tax examination years of 2018 to 2021 remain open.

Note 18. Subsequent Events

On January 25, 2023, 389,000 of Pre-Funded Warrants were exercised. The exercise price of each Pre-Funded Warrant is $0.0001 per share. (See Note 12 for more detail on the Pre-Funded Warrants).

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ROCKWELL MEDICAL, INC.

Corporate Information

Annual Meeting

The Annual Meeting of the Stockholders will be held:

Tuesday May 23, 2023
At 10:00 am ET
Virtual Stockholder Meeting
www.virtualshareholdermeeting.com/RMTI 2023

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, 2022 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

Equiniti
6201 15th Avenue
Brooklyn, NY 11219
Shareholder Services (800) 937-5449

Stockholder Information

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

2022 ANNUAL REPORT

www.rockwellmed.com