
# 2023 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, 2023**

**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. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☒

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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, 2023 (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 $91,048,814.

Number of shares outstanding of the registrant's Common Stock, par value $0.0001, as of March 21, 2024: 29,334,617 shares.

**Documents Incorporated by Reference**

Portions of the registrant's definitive Proxy Statement pertaining to the 2024 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, 2023, are herein incorporated by reference in Part III of this Annual Report on Form 10-K.

**Table Of Contents**


| | Page |
|---|---|
| **PART I** | |
| Item 1. Business. | 4 |
| Item 1A. Risk Factors. | 17 |
| Item 1B. Unresolved Staff Comments. | 30 |
| Item 1C. Cybersecurity. | 30 |
| Item 2. Properties. | 31 |
| Item 3. Legal Proceedings. | 31 |
| Item 4. Mine Safety Disclosures. | 31 |
| **PART II** | |
| Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities. | 32 |
| Item 6. Reserved. | 32 |
| Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations. | 32 |
| Item 7A. Quantitative and Qualitative Disclosures About Market Risk. | 39 |
| Item 8. Financial Statements and Supplementary Data. | 39 |
| Item 9. Changes In and Disagreements With Accountants on Accounting and Financial Disclosure. | 39 |
| Item 9A. Controls and Procedures. | 39 |
| Item 9B. Other Information. | 40 |
| Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections. | 40 |
| **PART III** | |
| Item 10. Directors, Executive Officers and Corporate Governance. | 41 |
| Item 11. Executive Compensation. | 41 |
| Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters. | 41 |
| Item 13. Certain Relationships and Related Transactions, and Director Independence. | 41 |
| Item 14. Principal Accounting Fees and Services. | 41 |
| **PART IV** | |
| Item 15. Exhibits, Financial Statement Schedules. | 42 |
| Item 16. Form 10-K Summary. | 43 |
| SIGNATURES | 45 |

**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. All statements other than statements of historical fact are forward-looking statements. 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," "project," "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 successfully integrate acquisitions; our ability to raise additional capital; our ability to successfully implement certain cost containment and cost-cutting measures; our ability to achieve profitability; our ability to successfully execute on our business strategy; 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 grow our 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 macroeconomic conditions, geopolitical events and pandemics on patients, our customers and distributors, and our business, including manufacturing operations and suppliers;
- 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;
- 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 capabilities;
- our expectations regarding the effect of changes in accounting guidance or standards on our operating results;
- the impact of any cybersecurity breaches or cyber crime that we, our vendors or our customers may experience;
- 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 2024 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.*

*CENTRISOL®, CitraPure®, Dri-Sate®, RenalPure®, RENASOL®, SteriLyte®, and Triferic® 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. The Company is the largest supplier of liquid bicarbonate concentrates and the second largest supplier of acid and dry 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 we believe 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. Additionally, in July 2023, the Company purchased customer relationships, equipment and inventory from Evoqua Water Technologies related to manufacturing and sale of hemodialysis concentrates products, all of which are manufactured under a cGMP contract manufacturing agreement with a third-party organization in Minnesota.

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.

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. We have included our website in this Annual Report on Form 10-K solely as an inactive textual reference, and content from or that can be accessed through our website is not part of, or incorporated by reference into, this Annual Report on Form 10-K.

#### SIGNIFICANT 2023 HIGHLIGHTS

Rockwell Medical's key developments from 2023 include:

- In February 2023, we signed a three-year, multi-million-dollar supply agreement with the largest non-profit dialysis provider in the United States.

- In February 2023, we signed a three-year, multi-million-dollar product purchase agreement with Concerto Renal Services.
- In February 2023, we were named a 'Great Place to Work'.
- In May 2023, we expanded our geographic footprint to sell our hemodialysis concentrates products into the United Arab Emirates.
- In June 2023, we were added to the Russell Microcap® Index.
- In June 2023, we entered into a three-year co-promotion services agreement with B. Braun Medical Inc.
- In July 2023, we acquired the hemodialysis concentrates business from Evoqua Water Technologies.
- In September 2023, we entered into an amended and restated products purchase agreement with DaVita, Inc. ("DaVita").
- In September 2023, we entered into a three-year product purchase agreement with Sanderling Renal Services and expanded our distribution capabilities westward into Utah.
- In October 2023, we entered into a three-year product purchase agreement with Centers for Dialysis Care.
- In October 2023, Joan Lau, Ph.D. was appointed to the Company's board of directors.
- In October 2023, Jesse Neri joined the Company as SVP, Finance.

**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 is focused on growing the Company's revenue-generating business, which currently includes its portfolio of hemodialysis concentrates products. Once the Company achieves sustainable profitability and cash flow from its revenue-generating business, it plans to 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 cGMP regulations. 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 receive 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 such 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. 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 an 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 an acetic acid-based product and is packaged in 55-gallon drums and in one-gallon jugs (sold in cases of four).

RenalPure Bicarbonate Concentrate

RenalPure bicarbonate is a dry powder mixed on-site at the clinic and is packaged in bulk and individual treatment sizes.

SteriLyte Bicarbonate Concentrate

SteriLyte bicarbonate is a liquid packaged in cases of four one-gallon jugs (sold in cases of four) and is used mainly in acute care settings.

CENTRISOL and RENALSOL Hemodialysis Concentrates

Our CENTRISOL hemodialysis concentrates consist of acid and bicarbonate formulations suitable for 45X dilution three-stream hemodialysis devices. Our RENASOL acid and bicarbonate concentrates are compatible with 36X dilution devices. CENTRISOL and RENASOL liquid acids are packaged in 55-gallon drums or in one-gallon jugs (sold in cases of four). CENTRISOL and RENASOL bicarbonate concentrates are packaged as liquid in one-gallon jugs (sold in cases of four) or as dry powder in bulk and individual treatment sizes.

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.

Ancillary Products

We offer certain ancillary products to selected customers including testing supplies, 5% acetic acid cleaning solution, 5% and 2% citric acid descaler, filtration salts, and other items used by hemodialysis providers.

***Market Opportunity:***

Rockwell's vision is to become the leading global supplier of all hemodialysis concentrates. Today, Rockwell is the leading supplier of liquid bicarbonate concentrates and the second largest supplier of acid and dry 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 is anticipated to grow to approximately $500 million by 2026, up from $380 million in 2022. This is driven primarily by an increasing number of patients suffering from end-stage kidney disease. Hemodialysis concentrates represent 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 more than 12,000 individual purchasing facilities (including outpatient dialysis clinics and hospitals) in the United States along with select international markets.

***Sales and Marketing:***

On November 9, 2022, Rockwell reacquired its distribution rights to its hemodialysis concentrates products from Baxter Healthcare Corporation ("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.

On June 29, 2023, the Company announced that it entered into a three-year co-promotion services agreement with B. Braun Medical Inc. ("B. Braun"), a leader in renal therapies including innovative, high-quality products for hemodialysis. As part of the agreement, Rockwell designates B. Braun as an independent, non-exclusive representative to promote the Company's hemodialysis concentrates products to dialysis providers in the United States with a focus on the west coast. All terms of the sale of any Rockwell product, including price, delivery schedule, and terms and conditions, are set by Rockwell at the Company's sole discretion. All orders are directed to, and processed by, Rockwell. B. Braun receives a fee for any sales generated by its promotional efforts.

On July 10, 2023, the Company executed and consummated the transactions contemplated by an Asset Purchase Agreement (the “Purchase Agreement”) with Evoqua Water Technologies LLC ("Evoqua") (the "Evoqua Acquisition"). Subject to the terms and conditions of the Purchase Agreement, at the closing of the transaction (the “Closing”), the Company purchased customer relationships, equipment and inventory from Evoqua, which were related to manufacturing and selling of hemodialysis concentrates products, all of which are manufactured under a contract manufacturing agreement with a third-party organization.

On September 18, 2023, Rockwell and our long-time partner, DaVita, a leading provider of kidney care, entered into an Amended and Restated Products Purchase Agreement (the "Amended Agreement"), which amends and restates the Product Purchase Agreement, dated July 1, 2019, as amended, under which the Company supplies DaVita with certain dialysis concentrates. Under the Amended Agreement, the Company and DaVita agreed to an increase in product pricing, effective September 1, 2023 and a one-time payment to Rockwell on or after December 1, 2023. The term of the Amended Agreement will expire on December 31, 2024. DaVita will have the right, in its sole discretion upon written notice to the Company given no later than September 30, 2024, to further extend the term through December 31, 2025. In the event of such an extension, product pricing will be increased for the extended term. In addition, DaVita is required to provide the Company with nine-month purchasing forecasts and a commitment to purchase at least the forecasted amounts. In the event that DaVita does not meet its forecasts, it is required to pay the Company for the amount forecasted, purchase additional product, or the Company may terminate the Amended Agreement. Upon expiration or termination of the Amended Agreement, and upon request by DaVita, the Company has agreed to provide transition services to DaVita during a transition period.

In 2023, Rockwell entered into several long-term product purchase agreements, which include supply and purchasing commitments from certain parties. These agreements include the largest non-profit dialysis provider in the United States; Concerto Renal Services, the largest provider of dialysis in skilled nursing facilities in the United States; Sanderling Renal Services, Inc., a full-service provider of in-center, home dialysis and renal telemedicine services focusing on patients in rural and underserved communities across the United States; Centers for Dialysis Care, the largest non-profit, independent outpatient

dialysis provider in Northeast Ohio; Houston Methodist, a leading health system and academic medical center; Dialyze Direct, a leading provider of home dialysis services in the skilled nursing facility setting; and Outset Medical (Nasdaq:OM), a medical technology company pioneering a first-of-its-kind technology to reduce the cost and complexity of dialysis with its Tablo® Hemodialysis System, which is FDA-cleared for use from the hospital to the home.

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 97.2% of our revenue for the year ended December 31, 2023, of which approximately 91.5% was 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 47% of our concentrate sales in 2023 and 46% of our concentrate sales in 2022. Our accounts receivable from this customer were $2.1 million and $1.9 million as of December 31, 2023 and 2022, respectively. In July 2019, we entered into the Products Purchase Agreement with DaVita, with an initial term expiring on December 31, 2023. 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). On September 18, 2023, we entered into the Amended Agreement with DaVita under which the Company supplies DaVita with certain dialysis concentrates. See "Material Agreements" below for more information on the Amended Agreement.

No other customers accounted for more than 10% of our sales in any of the last three years.

DaVita 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 9% of our overall sales in 2023 and 2022, 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 concentrates 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 products.

We operate under FDA regulations 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's Labeling and Packaging Control Requirements, including a Unique Device Identifier ("UDI") code, to ensure traceability of distributed products. Our quality program activities also include qualification and ongoing 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 drums, bottles, caps, film/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**

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 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 New Drug Applications ("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 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. Rockwell continues to support its partners outside the United States that have exclusive license agreements to develop and commercialize Triferic.

**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 was required to pay Baxter a fee for the reacquisition of its distribution rights. This fee was paid 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.

**Products Purchase Agreement with DaVita**

On September 18, 2023, Rockwell and our long-time partner, DaVita, a leading provider of kidney care, entered into the Amended Agreement. Under the Amended Agreement, the Company and DaVita agreed to an increase in product pricing, effective September 1, 2023 and a one-time payment of $0.4 million to Rockwell on or after December 1, 2023. The term of the Amended Agreement will expire on December 31, 2024. DaVita will have the right, in its sole discretion upon written notice to the Company given no later than September 30, 2024, to further extend the term through December 31, 2025. In the event of such an extension, product pricing will be increased for the extended term. In addition, DaVita is required to provide the Company with nine-month purchasing forecasts and a commitment to purchase at least the forecasted amounts. In the event that DaVita does not meet its forecasts, it is required to pay the Company for the amount forecasted, purchase additional product, or the Company may terminate the Amended Agreement. Upon expiration or termination of the Amended Agreement, and upon request by DaVita, the Company has agreed to provide transition services to DaVita during a transition period.

**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 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.

**Medical Device Approval and Regulation**

Pursuant to its authority under the FD&C Act, the FDA has jurisdiction over medical devices. The FDA regulates, among other things, the research, design, development, preclinical and clinical testing, manufacturing, safety, effectiveness, packaging, labeling, storage, recordkeeping, pre-market clearance or approval, adverse event reporting, marketing, promotion, sales, distribution and import and export of medical devices. Unless an exemption applies, each new or significantly modified medical device requires either a premarket notification to the FDA requesting permission for commercial distribution under Section 510(k) of the FD&C Act, also referred to as a 510(k) clearance, or FDA approval of a premarket approval application ("PMA").

*Device Classification*

Under the FD&C Act, medical devices are classified into one of three classes—Class I, Class II or Class III—depending on the degree of risk associated with each medical device and the extent of control needed to provide reasonable assurances with respect to safety and effectiveness.

Class I includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be reasonably assured by adherence to General Controls, which require compliance with the applicable portions of the FDA's Quality System Regulation ("QSR"), facility registration and product listing, reporting of adverse events and malfunctions, and appropriate, truthful and non-misleading labeling and promotional materials. Some Class I devices also require premarket clearance by the FDA through the 510(k) premarket notification process described below. Most Class I products are exempt from the premarket notification requirements.

Class II devices are those that are subject to the General Controls, as well as Special Controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. These Special Controls can include performance standards, patient registries, FDA guidance documents, and post-market surveillance. Most Class II devices are subject to premarket review and clearance by the FDA. Premarket review and clearance by the FDA for Class II devices is accomplished through the 510(k) premarket notification process.

Class III devices include devices deemed by the FDA to pose the greatest risk such as life-supporting or life-sustaining devices, or implantable devices, in addition to those deemed novel and not substantially equivalent following the 510(k) process. The safety and effectiveness of Class III devices cannot be reasonably assured solely by the General Controls and Special Controls described above. Therefore, these devices are subject to the PMA application process, which is generally more costly and time-consuming than the 510(k) process. Through the PMA application process, the applicant must submit data and information demonstrating reasonable assurance of the safety and effectiveness of the device for its intended use to the FDA's satisfaction.

*510(k) Pathway*

To obtain 510(k) clearance, a premarket notification must be submitted under Section 510(k) of the FD&C Act demonstrating that the proposed device is "substantially equivalent" to a predicate device. A predicate device is a legally-

marketed device that is not subject to premarket approval, i.e., a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was found substantially equivalent through the 510(k) process. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data is sometimes required to support substantial equivalence. The FDA's 510(k) clearance pathway usually takes from three to 12 months from the date the notification is submitted, but it can take considerably longer, depending on the extent of FDA's requests for additional information and the amount of time a sponsor takes to fulfill them. After a 510(k) is submitted, the FDA determines whether to accept it for substantive review. If it lacks necessary information for substantive review, the FDA will refuse to accept the 510(k) submission. If it is accepted for filing, the FDA begins a substantive review. By statute, the FDA is required to complete its review of a 510(k) premarket notification within 90 days of receiving the 510(k) submission. As a practical matter, clearance often takes longer, and clearance is never assured.

Although many 510(k) premarket notifications are cleared without clinical data, the FDA may require further information, including clinical data, to make a determination regarding substantial equivalence, which may significantly prolong the review process. If the FDA agrees that the device is substantially equivalent to a predicate device, it will grant clearance to commercially market the device. If the FDA determines that the device is not "substantially equivalent" to a predicate device, or if the device is automatically classified into Class III, the device sponsor must then fulfill the much more rigorous premarketing requirements of the PMA process, or seek reclassification of the device through the *de novo* process.

After a device receives 510(k) clearance, any modification, including modification to or deviation from design, manufacturing processes, materials, packaging and sterilization that could significantly affect its safety or effectiveness, or that would constitute a new or major change in its intended use, may require a new 510(k) clearance or, depending on the modification, could require a PMA application. The FDA requires each manufacturer to make this determination initially, but the FDA can review any such decision and can disagree with a manufacturer's determination. If the FDA requires a new 510(k) clearance or approval of a PMA application for any modifications to a previously-cleared product, the applicant may be required to cease marketing or recall the modified device until clearance or approval is received. In addition, in these circumstances, the FDA can impose significant regulatory fines or penalties for failure to submit the requisite 510(k) or PMA application(s).

Medical device types that the FDA has not previously classified as Class I, II, or III are automatically classified into Class III regardless of the level of risk they pose. The Food and Drug Administration Modernization Act of 1997 established a new route to market for low to moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, called the "Request for Evaluation of Automatic Class III Designation," or the *de novo* classification procedure.

The *de novo* classification procedure allows a manufacturer whose novel device is automatically classified into Class III to request down-classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA application. Prior to the enactment of the Food and Drug Administration Safety and Innovation Act of 2012 (the "FDASIA"), a medical device could only be eligible for *de novo* classification if the manufacturer first submitted a 510(k) premarket notification and received a determination from the FDA that the device was not substantially equivalent. The FDASIA streamlined the *de novo* classification pathway by permitting manufacturers to request *de novo* classification directly without first submitting a 510(k) premarket notification to the FDA and receiving a not substantially equivalent determination. Under the FDASIA, the FDA is required to classify the device within 120 days following receipt of the *de novo* application, though in practice the process may take significantly longer. If the manufacturer seeks reclassification into Class II, the manufacturer must include a draft proposal for Special Controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. In addition, the FDA may reject the reclassification petition if it identifies a legally marketed predicate device that would be appropriate for a 510(k) or determines that the device is not low to moderate risk or that General Controls would be inadequate to control the risks and Special Controls cannot be developed.

*PMA Pathway*

A PMA must be submitted if a device cannot be cleared through the 510(k) clearance or *de novo* process. A PMA must be supported by extensive data, including, but not limited to, technical information, preclinical data, clinical trial data, manufacturing data, and labeling, to demonstrate to the FDA's satisfaction the safety and efficacy of the device for its intended use.

Following receipt of a PMA, the FDA conducts an administrative review to determine whether the application is sufficiently complete to permit a substantive review. If it is not, the agency will refuse to file the PMA. If it is, the FDA will accept the application for filing and begin the review. The FDA, by statute and by regulation, has 180 days to review a filed PMA, although the review of an application more often occurs over a significantly longer period of time. During this review period, the FDA may request additional information or clarification of information already provided, and the FDA may issue a major deficiency letter to the applicant, requesting the applicant's response to deficiencies communicated by the FDA. The FDA considers a PMA or PMA supplement to have been voluntarily withdrawn if an applicant fails to respond to an FDA request for information (*e.g.*, major deficiency letter) within a total of 360 days. Before approving or denying a PMA, an FDA advisory panel may review the PMA at a public meeting and provide the FDA with the committee's recommendation on whether the FDA should approve the submission, approve it with specific conditions, or not approve it. The FDA is not bound by the recommendations of an advisory panel, but it considers such recommendations carefully when making decisions. Prior to approval of a PMA, the FDA may conduct a bioresearch monitoring inspection of the clinical trial data and clinical trial sites, and a QSR inspection of the manufacturing facility and processes. The FDA can delay, limit, or deny approval of a PMA for many reasons, including:

- the device may not be shown safe or effective to the FDA's satisfaction;
- the data from preclinical studies and/or clinical trials may be found unreliable or insufficient to support approval;
- the manufacturing process or facilities may not meet applicable requirements; and
- changes in FDA approval policies or adoption of new regulations may require additional data.

If the FDA evaluation of a PMA is favorable, the FDA will issue either an approval letter or an approvable letter. The latter usually contains a number of conditions that must be met in order to secure final approval of the PMA. When and if those conditions have been fulfilled to the satisfaction of the FDA, the agency will issue a PMA approval letter authorizing commercial marketing of the device, subject to the conditions of approval and the limitations established in the approval letter. If the FDA's evaluation of a PMA or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. The FDA also may determine that additional tests or clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and data are submitted in an amendment to the PMA, or the PMA is withdrawn and resubmitted when the data are available. The PMA process can be expensive, uncertain, and lengthy and a number of devices for which the FDA approval has been sought by other companies have never been approved by the FDA for marketing.

New PMAs or PMA supplements may be required for modifications to the manufacturing process, equipment or facility, quality control procedures, sterilization, packaging, expiration date, labeling, device specifications, components, materials or design of a device that has been approved through the PMA process. PMA supplements often require submission of the same type of information as an initial PMA, except that the supplement is limited to information needed to support any changes from the device covered by the approved PMA and may or may not require as extensive technical or clinical data or the convening of an advisory panel, depending on the nature of the proposed change.

In approving a PMA, as a condition of approval, the FDA may also require some form of postmarket studies or postmarket surveillance, whereby the applicant follows certain patient groups for a number of years and makes periodic reports to the FDA on the clinical status of those patients when necessary to protect the public health or to provide additional or longer term safety and effectiveness data for the device. The FDA may require postmarket surveillance for certain devices approved under a PMA or cleared under a 510(k) notification, such as implants or life-supporting or life-sustaining devices used outside a device user facility, devices where the failure of which would be reasonably likely to have serious adverse health consequences, or devices expected to have significant use in pediatric populations. The FDA may also approve a PMA with other post-approval conditions intended to ensure the safety and effectiveness of the device, such as, among other things, restrictions on labeling, promotion, sale, distribution, and use.

*Clinical Trials*

Clinical trials are almost always required to support a PMA and are sometimes required for a 510(k) premarket notification. In the United States, these trials often require submission of an application for an investigational device exemption ("IDE") if the investigation involves a significant risk device. Some types of studies deemed to present "non-significant risk" are deemed to have an approved IDE—without affirmative submission of an IDE application to the FDA—once certain requirements are addressed and institutional review board ("IRB") approval is obtained. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE must be approved in advance by the FDA for a specified number of patients, unless the product candidate is deemed a non-significant risk device and is eligible for more abbreviated IDE requirements. Clinical trials for a significant risk device may begin once the IDE application is approved by the FDA and

appropriate IRBs at the clinical trial sites. Submission of an IDE will not necessarily result in the ability to commence clinical trials, and although the FDA's approval of an IDE allows clinical testing to go forward for a specified number of subjects, it does not bind the FDA to accept the results of the trial as sufficient to prove the product's safety and efficacy, even if the trial meets its intended success criteria.

All clinical trials must be conducted in accordance with the FDA's IDE regulations that govern investigational device labeling, prohibit promotion, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. Clinical trials must further comply with the FDA's Good Clinical Practices ("GCP") requirements for IRB approval and for informed consent and other human subject protections. Required records and reports are subject to inspection by the FDA. The results of clinical testing may be unfavorable, or, even if the intended safety and efficacy success criteria are achieved, may not be considered sufficient for the FDA to grant marketing approval or clearance of a product candidate.

*Postmarket Requirements—U.S.*

After the FDA permits a device to enter commercial distribution, numerous regulatory requirements continue to apply. These include:

- establishment registration and device listing with the FDA;
- the FDA's QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, production, control, supplier/contractor selection, complaint handling, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- labeling regulations, unique device identification requirements and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label uses;
- advertising and promotion requirements;
- Restrictions on sale, distribution or use of a device;
- PMA annual reporting requirements;
- PMA approval or clearance of a 510(k) for certain product modifications;
- medical device reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur;
- medical device correction and removal reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FD&C Act that may present a risk to health;
- recall requirements, including a mandatory recall if there is a reasonable probability that the device would cause serious adverse health consequences or death;
- an order of repair, replacement or refund;
- device tracking requirements; and
- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

Additionally, manufacturers are subject to unannounced inspections by the FDA to determine compliance with the QSR, which cover the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation and servicing of finished devices intended for human use. The QSR also requires, among other things, maintenance of a device master file, device history file, and complaint files. Manufacturers are subject to periodic scheduled or unscheduled inspections by the FDA. A failure to maintain compliance with the QSR requirements could result in the shut-down of, or restrictions on, manufacturing operations and the recall or seizure of products. The discovery of previously unknown problems with products, including unanticipated adverse events or adverse events of increasing severity or frequency, whether resulting from the use of the device within the scope of its clearance or approval or off-label by a physician in the practice of medicine, could result in restrictions on the device, including the removal of the product from the market or voluntary or mandatory device recalls. In addition, the FDA can issue warning letters or untitled letters, impose injunctions, suspend regulatory clearance or approvals, ban certain medical devices, detain or seize adulterated or misbranded medical devices, order repair, replacement or refund of these devices, and require notification of health professionals and others with regard to medical devices that present unreasonable risks of substantial harm to the public health. The FDA may also initiate action for civil penalties and/or criminal prosecution of such violations.

There are also certain requirements of state, local, and foreign governments that we must comply with in the manufacturing and marketing of our products. We will need to maintain customer complaint files, record all lot numbers of disposable products, and conduct periodic audits to assure compliance with applicable regulations. We place special emphasis

on customer training and advise all customers that device operation should be undertaken only by qualified personnel. In addition to laws and regulations in the United States, we are subject to a variety of laws and regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our product candidates.

*Postmarket Requirements—EU*

The regulatory review process varies from country to country and may in some cases require the submission of clinical data. Our international sales are subject to regulatory requirements in the countries in which our product candidates are sold. In addition, the EU has adopted the EU Medical Device Regulation (EU 2017/745) (the "EU MDR") which imposes stricter requirements for the marketing and sale of medical devices than in the United States, including in the area of clinical evaluation requirements, quality systems and post-market surveillance. The transition period provided for in the EU MDR for existing CE certifications issued under the previous Medical Devices Directive will end on May 26, 2024. For certain medical devices, the transition period was extended, ending between December, 31, 2026 and December 31, 2028, depending on the class of the device and the fulfillment of certain additional conditions. (Regulation (EU) 2023/607). Complying with these regulations may require us to incur significant expenditures. Failure to meet these regulatory requirements could adversely impact our business in the EU and other regions that tie their product registrations to the EU requirements.

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.

**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 authorizes the U.S. Department of Health and Human Services to negotiate prices of certain drugs with participating manufacturers in federal healthcare programs. The IRA provides Centers for Medicare & Medicaid Services ("CMS") with significant new authorities intended to curb drug costs and to encourage market competition. For the first time, CMS will be able to directly negotiate prescription drug prices and to cap out-of-pocket costs. Each year, CMS will select and negotiate a preset number of high-spend drugs and biologics that are covered under Medicare Part B and Part D that do not have generic or biosimilar competition. These price negotiations began in 2023. The IRA also provides a new "inflation rebate" covering Medicare patients that took effect in 2023 and is intended to counter certain price increases in prescriptions drugs. The inflation rebate provision will require drug manufacturers to pay a rebate to the federal government if the price for a drug or biologic under Medicare Part B and Part D increases faster than the rate of inflation. Notwithstanding these provisions, the IRA's impact on commercialization and competition remains largely uncertain.

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, 2023, we owned or had the rights to 6 issued patents (4 U.S. and 2 foreign) and 1 pending foreign application. 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. We have allowed several Charak-licensed and Company-owned patents and applications that are not material to our business to lapse.

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

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

**Human Capital**

As of December 31, 2023, we had 237 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 to enable 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 continue to follow the CDC protocol for safe return-to-work for affected employees and remain steadfast in our efforts to keep employees healthy and protected.

**Item 1A. Risk Factors.**

*Investing in our common stock involves a high degree of risk and there can be no assurance that our 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. 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. It is not possible to predict or identify all such risks; our operations could also be affected by factors, events or uncertainties that are not presently known to us or that we currently do not consider to present significant risks to our operations. Therefore, you should not consider the following risks to be a complete statement of all the potential risks or uncertainties that we face.*

**RISK FACTOR SUMMARY**

- We have limited capital resources and will likely need additional funding to operate and expand our business. If we are unable to raise additional capital on attractive terms, or at all, we may be unable to grow our operations.
- Our A&R 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.
- Our existing capital resources may not be adequate to finance our operating cash requirements beyond 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 agreement with our largest customer in our concentrates business is set to expire on December 31, 2024 and our inability to negotiate a new agreement would have a material and adverse effect on our financial condition and results of operations.

- 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.
- We may fail to realize the anticipated benefits of the Evoqua Acquisition, including an improved financial position, and those benefits may take longer to realize than expected.
- Our business is 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 business operations may subject us to numerous commercial disputes, claims, lawsuits and/or investigations.
- Our business could be adversely affected by economic downturns, inflation, increases in interest rates, natural disasters, public health crises, cybercrime, political crises, geopolitical events, such as the crisis in Ukraine and the Middle East, or other macroeconomic conditions, which could have a material and adverse effect on our results of operations and financial condition.

## RISKS RELATED TO OUR FINANCIAL POSITION

***We have limited capital resources and will likely need additional funding to operate and expand our business. 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 $397.2 million since inception and we may incur further losses. As of December 31, 2023, we had approximately $10.9 million of cash, cash equivalents and investments available-for-sale, and working capital of $12.1 million. Net cash used in operating activities for the year ended December 31, 2023 was approximately $9.4 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, 2023, $8 million remains drawn under the Loan Agreement. While we expect to have sufficient capital through 12 months from the date of this filing, there is uncertainty beyond that period.

Our ability to fund our planned activities will be dependent upon our ability to restructure our contracts with some of our customers, raise additional capital, control our costs and maintain or increase our gross margin on sales. These factors are subject to significant risks and uncertainties and there can be no assurance that we will be successful in raising additional capital, controlling costs and restructuring our customer relationships. If we are unable to achieve one or all of these objectives, we may be forced to implement further cost-saving measures that could have a negative impact on our activities. If we are unable to increase our revenues and decrease our expenses or raise any required capital, we may be forced to curtail our activities and, ultimately, cease operations. In addition, our day-to-day operations depend in part on the amount of credit our suppliers will extend to us. If we are unable to maintain a favorable financial position, that credit may be curtailed, which could significantly impact our 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 A&R 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 A&R 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 hemodialysis products revenue (measured on a biannual basis). The A&R 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 A&R 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 A&R 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, on November 10, 2022, we entered into the Second Amendment to Loan Agreement under which we (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 we resumed scheduled debt payments) in consideration for certain modifications to the financial covenants under the Loan Agreement. The A&R Loan Agreement provides for us to make interest-only payments for thirty months, or up to thirty-six months if certain conditions are met. The loan will mature on January 1, 2029, unless earlier repaid. The A&R Loan Agreement includes a financial covenant that requires actual consolidated revenue from the sale and supply of hemodialysis products for the trailing six-month period (ended on the date when tested), to be not less than 85.0% of the projections for the same period and, beginning with the quarter ending September 30, 2024, actual consolidated revenue from the sale and supply of hemodialysis products for the trailing six-month period (ended on the date when tested), to be not less than 80.0% of the projections for the same period. The A&R Loan Agreement also includes a liquidity covenant that requires that us to maintain minimum liquidity of the greater of (x) our three-month cash burn or (y) the sum of $1.5 million and the aggregate amount of capital lease payments required to be made during the succeeding 12 months (or during a continuing event of default, the aggregate amount of capital lease payments required to be made during the entire term of such capital leases). Although we are currently in compliance with all reporting and financial covenants, there can be no assurance that we will be able to continue to maintain compliance in the future.

The A&R 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 A&R Loan Agreement. Upon the occurrence and continuation of an event of default, all amounts due under the A&R 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 A&R 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 A&R 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 extension of the contract with our largest customer in our concentrates business;
- our ability to enter into new contracts and negotiate favorable terms with our 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;
- whether we expand into new territories; and
- whether we develop and launch new product offerings.

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 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, 2024 and our inability to negotiate a new agreement would have a material and adverse effect on our financial condition and results of operations.***

Our Amended and Restated Products Purchase Agreement (the "Products Purchase Agreement") with DaVita is set to expire on December 31, 2024. The Products Purchase Agreement is a fixed price agreement. In September 2023, we amended the original Products Purchase Agreement with DaVita to raise our prices in light of inflationary pressures and to remove certain provisions. The Products Purchase Agreement may be extended by DaVita for one year in its sole discretion. When the Products Purchase Agreement is again up for renewal, we may be unable to reach an agreement with DaVita on new terms that make economic sense for us. In that case, we would 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 have resulted in fluctuating volumes that could lead to the implementation of cost-saving measures that would have a material and adverse effect on our business.***

Volumes have fluctuated in our concentrates business, due to the reduction in patient census caused by COVID-19 and cost saving measures by our customers, including switching to single use bicarbonate canisters. If these volumes decrease substantially, 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 on our business, financial condition and results of operations.

***We may fail to realize the anticipated benefits of the Evoqua Acquisition, including an improved financial position, and those benefits may take longer to realize than expected.***

On July 10, 2023, we completed our acquisition of the hemodialysis concentrates assets (the "Evoqua Acquisition") from Evoqua. Our synergistic goals with regard to the acquisition include an improved financial position, expanded geographic footprint, customer base and product offerings, and increased manufacturing capacity. While we have completed the integration of Evoqua's former assets, there can be no assurance that we will be able to operate Evoqua's former product line profitably. In addition, many of the former Evoqua customers that we inherited as a result of the Evoqua Acquisition are not subject to contractual purchasing commitments and may discontinue their business with us as a result of the transition of ownership.

Following the Evoqua Acquisition, the number of our customers is significantly larger than prior to the Evoqua Acquisition. The Company's future success depends, in part, upon our ability to manage this expanded business, which will pose substantial challenges for our management, including challenges related to the management and monitoring of new operations and associated increased costs and complexity. The dedication of management resources to this portion of our business could detract attention from our current day-to-day operations.

Because we have limited financial resources, by investing in the Evoqua Acquisition, we may forgo or delay pursuit of other future opportunities that may have proven to have greater commercial potential. Also, we now possess certain liabilities and obligations, including contractual liabilities and obligations, that were assumed by us upon closing of the Evoqua Acquisition. Further, it is possible that undisclosed, contingent, or other liabilities, problems or obligations may arise in the future of which we were previously unaware. These disclosed and undisclosed liabilities could have an adverse effect on our business, financial condition and results of operations.

These factors, including the failure of the expanded business to perform as expected, could decrease or delay the expected accretive effect of the Evoqua Acquisition, negatively affect our stock price, result in impairment of our intangible assets, and harm our financial condition, results of operations or business prospects. As a result, it cannot be assured that the Evoqua Acquisition will result in the full realization of the benefits anticipated from the Evoqua Acquisition or in the anticipated time frames or at all.

***We depend on a third party to manufacture products for the business that was the subject of the Evoqua Acquisition. If this organization is unable or unwilling to manufacture our newly acquired concentrates products, or if the organization fails to comply with applicable regulations or otherwise fails to meet our requirements, our business will be harmed.***

We rely on a contract manufacturing organization ("CMO") to manufacture the concentrates products that were the subject of the Evoqua Acquisition. If that CMO is unable to manufacture those products in sufficient quantities and on a consistent basis, or if it becomes unwilling to produce the products for us, we may not be able to fulfill our contractual requirements or sell those products while we look for an alternative. We currently have a single-source supplier, and our supply contract expires at the end of 2024. If we were to experience a supply disruption, it could take an extended period of time to take over the manufacturing ourselves. The manufacturing facilities and processes used by our CMO must be approved by the FDA before the products manufactured by such CMO can be sold. After approval, our CMO must meet certain ongoing regulatory requirements for product testing and stability of commercially marketed products. We do not control the manufacturing processes of our CMO and depend on it 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 business. If that was to happen, we may be forced to find another capable CMO or take over production ourselves. Any such circumstance could significantly hamper our ability to supply our customers in a timely manner, which may have a material adverse effect on our financial condition and results of operations.

***We have been and may continue to be materially and adversely affected by increases in raw material, labor and transportation costs and may be unable to recover certain costs due to provisions in our largest customer contract and other fixed price contracts and we may lose other customers due to price sensitivity.***

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 the Products Purchase Agreement with DaVita and other fixed price contracts. 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. In addition, labor costs have been steadily rising and our manufacturing process is labor intensive, which increases our costs to produce our products.

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. In addition, in many areas, we have a single source of raw materials, which makes us particularly sensitive to cost increases. 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, there has, in the past, 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). Continued rising costs and declining volumes have had and could continue to have a negative impact on our business.

We expect that if we continue to be subject to the limitations in the Products Purchase Agreement and other fixed price contracts, the increasing costs and decreasing volumes may continue to negatively impact our profit margins and materially and adversely affect our financial position.

Some of our customers buy products from us on a purchase order basis or pursuant to contracts that allow for price increases at least once per year. In situations where we are able to increase prices to keep up with our costs, we may lose customers if such customers are unwilling to pay higher prices. That would result in lost revenue for the Company and may negatively impact our financial position and results of operations.

***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 materially and adversely affect our business, results of operations, financial position and cash flows.***

Sales of our medical device products are highly concentrated among 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. Due to the composition of Evoqua's customer portfolio, we experienced further concentration with regard to that customer and an additional customer through the Evoqua Acquisition. The loss of any of these significant customers could materially and adversely affect our business, results of operations, financial position and cash flows.

***Unfavorable weather, economic conditions or supply shortages could materially and adversely affect our business, financial condition or results of operations.***

Our results of operations could be materially and 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, in 2023, winter storms led to delays in our operations, particularly in the transportation division as equipment froze and roads became impassible. 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 (including inflation), there have been shortages in raw materials, parts and fuel that we need to run our business. For example, from time to time, 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 at times 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 face competition in the concentrates market and have a large competitor with substantial resources.***

The primary competitor in the market for our concentrates 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 concentrates products. We may be at a disadvantage in competing against these strategies to sell concentrates 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 production and other processes are largely manual, which introduces risk of error and may result in rising production costs.***

The production of our hemodialysis concentrates products is largely manual and involves considerable unskilled labor. The manual nature of production can introduce the risk of error. In addition, manual processes involving high amounts of labor can result in significant production costs. Many of our products are "made to order," which can further increase production costs as we have to frequently change production runs. Unless we are able to automate our production processes, our costs may continue to increase and we may be unable to recover those rising costs or may lose customers altogether, which could negatively impact on our financial position.

***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 most 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 materially decrease, 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.

***Our medical device products are life sustaining and any failure to supply them to our customers and resulting scrutiny related to such circumstances could negatively impact our reputation and stock price.***

Our hemodialysis concentrates products are critical to sustain the lives of patients who need them. Routine business actions we take under our contractual arrangements with purchasers or individual clinics, such as price increases or discontinuation of supply to customers who fail to pay us on time or at all, could mean that our customers may need to find alternative sources of supply and may not be able to serve their patients. This may result in increased governmental or other scrutiny on our business. Such actions could also result in reputational harm to us and have a negative impact on our stock price.

***We may not be successful in expanding our business 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.***

In addition to the Evoqua Acquisition, we may seek to make further 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, we may seek to acquire or in-license products or product candidates that we believe are a complementary fit with our business, 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 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 product may not be able to be brought to market as profitably as expected or at all. If the results of any new product initiative are materially worse than expected, it could have a material adverse effect on our business, results of operations, financial position and cash flows.

***Our international partnerships for Triferic involve risks that may materially impact those international relationships or our business generally.***

We have international partnerships for Triferic that require us to supply the drug product to be marketed and sold in foreign countries. 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, increased costs of raw materials, a failure of a supplier to comply with cGMP standards, which could result in quality or product failures, adulteration, contamination and/or recall and other factors beyond our control.

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.

In addition, the third parties that we depend on to manufacture Triferic for our international partners may be unable or unwilling to manufacture our drug products, which could also harm our relationships with those partners. 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 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 partners' Triferic commercialization efforts.

Finally, we may be subject to additional risks due to Triferic 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;
- compliance with 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 pandemics, 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 Triferic outside the United States by our international partners could suffer.

***We have in-licensed rights to certain patents that cover Triferic. 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 result in our noncompliance with those partnership agreements.***

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. 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. Such an event would also result in our failure to comply with our distribution agreements with our international partners. Any of these occurrences could significantly harm our results of operations.

***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. 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. From time to time, we are subject to phishing attempts. In the fourth quarter of 2023, we discovered a business email compromise caused by phishing. We do not believe that it had a material adverse effect on our business. We implemented remedial measures promptly following this incident; however, we cannot guarantee that those remedial measures will prevent additional related, as well as unrelated, incidents.

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.

***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.

***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 the operation of our business and any development or expansion 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 LEGAL AND REGULATORY**

***Our business is 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 business is 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 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, in 2023, the FDA conducted a routine GMP inspection of one of our manufacturing facilities and issued Form FDA-483 report with one observation. The Company performed corrective actions and resolved the issue. While the finding was not serious, management time and effort was expended for the correction. 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.

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.

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 concentrates 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 we may not be able to recover under our fixed price contracts.

***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 products may have or have had undesirable side effects, and our product liability insurance may not be sufficient to protect us from material liability or harm to our business.***

We sell hemodialysis concentrates that are used in dialysis procedures in the United States and foreign countries. In addition, prior to its discontinuation, we marketed and sold Triferic in the United States for four years and prior to that, engaged in clinical trials to support the submission of the NDA for approval. Our international partners continue to market and sell Triferic in foreign countries. If patients experience side effects from the use of our hemodialysis concentrates or from Triferic and the statutes of limitation and repose have not expired, such side effects may result in litigation against us by private litigants.

Although 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 otherwise, 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 products infringes on the third party's patent, it may sue us even if we have received our own patent protection for the technology. If we infringe the rights of a third party, we could be prevented from manufacturing and selling products, forced to pay damages, compelled to license technology from the party claiming infringement and lose the opportunity to license our technology to others and collect royalty payments, any of which could have a material adverse effect

on our business. If 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 products. Many of these consultants were previously employed at, may have previously been, or are currently providing consulting services to, other biotechnology or pharmaceutical companies, including our competitors or potential competitors. As such, the Company advises consultants not to disclose, or use trade secrets, or proprietary information of their former employers or their former or current customers. Although no claims against us are currently pending, we may be subject to claims that these consultants or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers or their former or current customers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management and day-to-day business operations.

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 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.***

We were subjected to a proxy contest at our 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;
- issues in manufacturing our products;

- 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.

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. 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, 2023, there were 361,531 shares issuable upon the exercise of then-outstanding and exercisable stock options, 967,090 shares issuable upon the exercise of then-outstanding stock options that were not yet exercisable, and 3,793,000 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 and warrants and the sale of the underlying common stock. The holders of these options and warrants 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 and warrants.

***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. In 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 us. 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 us 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, political crises, geopolitical events, such as the crisis in Ukraine and the Middle East, 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. 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 and the conflict in the Middle East have 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 and the occurrence of natural disasters and public health crises, 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 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 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;

- establish advance notice requirements for nominations for election to our Board or for proposing matters that can be acted upon by stockholders at our annual stockholder meetings;
- permit our Board 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 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 1C. Cybersecurity.**

We believe we maintain an information technology and security program appropriate for a company our size, taking into account our operations and risks. The Company recognizes the critical importance of maintaining the trust and confidence of our investors, employees, customers and vendors. The Company's cybersecurity policies and processes are integrated into the Company's enterprise risk management program and are informed by recognized frameworks established by the National Institute of Standards and Technology, and other applicable industry standards.

In the ordinary course of our business, we collect, use, store, and transmit digitally confidential, sensitive, proprietary, and personal information. The secure maintenance of this information and our information technology systems is important to our operations and business strategy. To this end, we have implemented processes designed to assess, identify, and manage risks from potential unauthorized occurrences on or through our information technology systems that may result in adverse effects on the confidentiality, integrity, and availability of these systems and the data residing therein. These processes are managed and monitored by an outside information technology vendor in cooperation with our information technology consultant, under the supervision of our Chief Corporate Affairs Officer, and include mechanisms, controls, technologies, systems, and other processes designed to prevent or mitigate data loss, theft, misuse, or other security incidents or vulnerabilities affecting the data and maintain a stable and secure information technology environment. For example, we conduct ongoing monitoring of critical systems for any compromised or potentially compromised accounts. We conduct regular trainings on cyber and information security, along with phishing simulations, among other topics. We conduct security audits

and ongoing risk assessments, including due diligence on our key technology vendors, and other contractors and suppliers. In addition, we consult with our outside information technology vendor and our information technology consultant on a regular basis to assist with assessing, identifying, and managing cybersecurity risks, including to anticipate future threats and trends, and their impact on the Company's risk environment.

Our Chief Corporate Affairs Officer, who reports directly to the Chief Executive Officer, and our IT Consultant, who has three decades of experience managing and leading cybersecurity oversight, together with our other executive officers, are responsible for assessing and managing cybersecurity risks. The Company's executive officers each hold undergraduate and graduate degrees in their respective fields and have extensive experiencing managing risks at the Company and at similar companies, including risks arising from cybersecurity threats. In the last fiscal year, we have not identified any risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected us, including our operations, business strategy, results of operations, or financial condition. If we were to experience a material cybersecurity incident in the future, such incidents are reasonably likely to materially affect us, including our operations, business strategy, results of operations, or financial condition. For more information regarding cybersecurity risks that we face and potential impacts on our business related thereto, see the risk factor titled, "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."

The Company's Board of Directors, as a whole and at the committee level, has oversight for the most significant risks facing us and for our processes to identify, prioritize, assess, manage, and mitigate those risks. The Audit Committee, which is composed solely of independent directors, has been designated by our Board to oversee cybersecurity risks. The Audit Committee and the Board receive updates on cybersecurity and information technology matters and related risk exposures from our Chief Corporate Affairs Officer, as well as our other executive officers. The Board also receives updates from the Company's management on cybersecurity risks on at least an annual basis.

## 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 believe that our existing leased properties are adequate and suitable for the conduct of our business and that our capital resources are sufficient to purchase, lease or construct any additional facilities required to meet our expected long-term growth needs. We expect that we may need additional manufacturing capacity and distribution facilities to meet our business requirements and anticipate they will be available on commercially available terms.

## 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 29, 2024, 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 liquid and powder 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 typically performed at freestanding outpatient dialysis centers, hospital-based outpatient centers, skilled nursing facilities, or in a patient's home. This represents a large market opportunity for which we believe Rockwell's products are well-positioned to meet the needs of patients.

Rockwell provides the hemodialysis community with products controlled by a Quality Management System regulated by the U.S. Food and Drug Administration ("FDA"). Rockwell is ISO 13485 Certified and adheres to current Good Manufacturing Practices ("cGMP") and Association for Advancement of Medical Instrumentation ("AAMI") standards. Rockwell manufactures hemodialysis concentrates at its facilities in Michigan, South Carolina, and Texas totaling approximately 175,000 square feet, and manufactures its dry acid concentrate mixers at its facility in Iowa. In addition, the Company manufactures the former Evoqua product line in Minnesota under a contract manufacturing agreement with a contract manufacturing organization. (See Note 4 of the accompanying consolidated financial statements for further detail). On February 12, 2024, the Company entered into an amendment to its contract manufacturing agreement to extend the term to December 31, 2024. The Company plans to transfer the manufacturing of the former Evoqua product line to one of its own manufacturing facilities by the end of 2024, which the Company believes will reduce production costs for these products. 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.

On July 10, 2023, the Company executed and consummated the transactions contemplated by the Evoqua Acquisition. Subject to the terms and conditions of the Purchase Agreement, at the Closing, the Company purchased customer relationships, equipment and inventory from Evoqua, which were related to manufacturing and selling of hemodialysis concentrates products, all of which are manufactured under a contract manufacturing agreement with a third-party organization. Total consideration was $17.4 million, comprising a cash payment at Closing of $12.4 million (inclusive of transaction costs) and two $2.5 million

deferred payments, the first to be paid on the first anniversary and the second to be paid on the second anniversary of the Closing. See Note 4 for further detail.

On August 7, 2023, Rockwell was informed by Wanbang, the Company's commercialization partner in China for Triferic, that the main efficacy results of Wanbang's clinical trial for Triferic (dialysate) compared with placebo were not obtained and Wanbang will not will not bring the product forward to registration. As a result, the remaining $2.1 million of deferred license revenue was recorded into revenue, and the related portion of long-term inventory of $1.1 million was reserved for.

On September 18, 2023, Rockwell and our long-time partner, DaVita, Inc. ("DaVita"), a leading provider of kidney care, entered into an Amended and Restated Products Purchase Agreement (the "Amended Agreement"), which amends and restates the Product Purchase Agreement, dated July 1, 2019, as amended, under which the Company supplies DaVita with certain dialysis concentrates. Under the Amended Agreement, the Company and DaVita agreed to an increase in product pricing, effective September 1, 2023 and a one-time payment to Rockwell on or after December 1, 2023. The term of the Amended Agreement will expire on December 31, 2024. DaVita will have the right, in its sole discretion upon written notice to the Company given no later than September 30, 2024, to further extend the term through December 31, 2025. In the event of such an extension, product pricing will be increased for the extended term. In addition, DaVita is required to provide the Company with nine-month purchasing forecasts and a commitment to purchase at least the forecasted amounts. In the event that DaVita does not meet its forecasts, it is required to pay the Company for the amount forecasted, purchase additional product, or the Company may terminate the Amended Agreement. Upon expiration or termination of the Amended Agreement, and upon request by DaVita, the Company has agreed to provide transition services to DaVita during a transition period.

Additionally, during the year ended December 31, 2023, Rockwell entered into several long-term product purchase agreements, which include supply and purchasing commitments from certain parties. These agreements include the largest non-profit dialysis provider in the United States; Concerto Renal Services, the largest provider of dialysis in skilled nursing facilities in the United States; Sanderling Renal Services, Inc., a full-service provider of in-center, home dialysis and renal telemedicine services focusing on patients in rural and underserved communities across the United States; Centers for Dialysis Care, the largest non-profit, independent outpatient dialysis provider in Northeast Ohio; Houston Methodist, a leading health system and academic medical center; Dialyze Direct, a leading provider of home dialysis services in the skilled nursing facility setting; and Outset Medical (Nasdaq:OM), a medical technology company pioneering a first-of-its-kind technology to reduce the cost and complexity of dialysis with its Tablo® Hemodialysis System, which is FDA-cleared for use from the hospital to the home.

On January 2, 2024, the Company's Loan Agreement was amended to include, among other things, an interest-only period for 30 months, or up to 36 months if certain conditions are met, and extend the maturity date to January 1, 2029. (See Note 19 for further detail).

**Results of Operations**

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

| | For the Year Ended December 31, | | | | |
|---|---|---|---|---|---|
| | 2023 | % of Revenue | 2022 | % of Revenue | % Change |
| **Net Sales** | **$ 83,612** | | **$ 72,810** | | **14.8 %** |
| Cost of Sales | 74,908 | 89.6 % | 68,733 | 94.4 % | 9.0 % |
| Gross Profit | 8,704 | 10.4 % | 4,077 | 5.6 % | 113.5% |
| | | | | | |
| Research and Product Development | 1,107 | 1.3 % | 3,119 | 4.3 % | (64.5) % |
| Selling and Marketing | 2,125 | 2.5 % | 2,094 | 2.9 % | 1.5 % |
| General and Administrative | 12,142 | 14.5 % | 15,644 | 21.5 % | (22.4) % |
| **Operating Loss** | **$ (6,670)** | **(8.0)%** | **$ (16,780)** | **(23.0)%** | **(60.3)%** |

**Net Sales**

During the year ended December 31, 2023, our net sales were $83.6 million compared to net sales of $72.8 million during the year ended December 31, 2022. Net sales of hemodialysis concentrates to dialysis providers and distributors in the

United States and abroad were $81.3 million for the year ended December 31, 2023 compared to $71.7 million for the year ended December 31, 2022. Net sales of Triferic (dialysate) were $2.3 million and $1.2 million for the years ended December 31, 2023 and 2022, respectively. The increase in net sales of Triferic (dialysate) was due to Wanbang's decision to not bring the product forward to registration. The increase of $10.8 million in net sales is primarily due to the restructuring of our products purchase agreement with DaVita, the reacquired rights to commercialize and distribute our products, the asset acquisition of Evoqua, onboarding of new customers 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, 2023 was $74.9 million, resulting in gross profit of $8.7 million, compared to cost of sales of $68.7 million and a gross profit of $4.1 million during the year ended December 31, 2022. Gross profit increased by $4.6 million during the year ended December 31, 2023 compared to the year ended December 31, 2022 primarily due to the restructuring of our supply contract with DaVita in 2022, lower distribution costs, onboarding of new customers, increased pricing to other customers and net impact of recording the remaining deferred license revenue associated with Wanbang and the associated inventory reserve as described above.

**Research and Product Development Expense**

Research and product development expenses were $1.1 million for the year ended December 31, 2023 compared with $3.1 million during the year ended December 31, 2022. The decrease of $2.0 million is due to a reduction in wages and project costs resulting from the decision to pause all research related to our FPC for Home Infusion program. Approximately 37% of research and development expenses for the year ended December 31, 2023 were comprised of severance costs.

**Selling and Marketing Expense**

Selling and marketing expenses were $2.1 million during the year ended December 31, 2023 compared with $2.1 million during the year ended December 31, 2022. We continue to evaluate marketing spend and focus on target opportunities for greater return on investments.

**General and Administrative Expense**

General and administrative expenses were $12.1 million during the year ended December 31, 2023 compared with $15.6 million during the year ended December 31, 2022. The $3.5 million decrease was driven primarily by a reduction in wages and incentive compensation of $0.9 million, legal costs of $0.9 million, insurance costs of $0.9 million, and FDA fees relating to approved products of $0.9 million.

**Other Expense**

Total other expense for the years ended December 31, 2023 and December 31, 2022 was $1.8 million and $1.9 million, respectively, which was primarily related to interest expense incurred on our debt facility of $2.3 million and $1.9 million for the years ended December 31, 2023 and December 31, 2022, respectively. See Note 17 to the consolidated financial statements for more information on our debt facility.

**Liquidity and Capital Resources**

Since inception, we have incurred significant net losses and have funded our operations primarily through revenue from commercial products, proceeds from the issuance of debt and equity securities and payments from partnerships. At December 31, 2023, we had an accumulated deficit of approximately $397.2 million and stockholders’ equity of $21.3 million. As of December 31, 2023, we had approximately $10.9 million of cash, cash equivalents and investments available-for-sale, and working capital of $12.1 million. Net cash used in operating activities for the year ended December 31, 2023 was approximately $9.4 million.

On July 10, 2023, Armistice Capital Master Fund Ltd. (“Armistice”) exercised its warrant to purchase 9,900,990 shares of common stock with an exercise price of $1.39 per share (the "Prior Warrant") and the Company received gross proceeds of approximately $13.8 million (See Note 12 to the consolidated financial statements included elsewhere in this Form 10-K).

On July 10, 2023, the Company completed the Evoqua Acquisition. Total consideration was $17.4 million, comprising a cash payment at Closing of $12.4 million (inclusive of transaction costs) and two $2.5 million deferred payments, the first to be paid on the first anniversary and the second to be paid on the second anniversary of the Closing. See Note 4 to the consolidated financial statements for further detail.

During the year ended December 31, 2023, the Company continued to experience 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 2022, 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.

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. 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.

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.

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. Based on the currently available working capital and 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. Additionally, the Company's plans include raising capital, if needed, by using the $11 million remaining on its ATM facility or other methods or forms of financings, subject to existing limitations.

In 2023, the Company was no longer subject to the "baby shelf" limitations under Form S-3, which limit the amount the Company may offer pursuant to its registration statement on Form S-3.

The Company is subject to certain covenants and cure provisions under its Loan Agreement with Innovatus. As of December 31, 2023, the Company is in compliance with all covenants (See Note 17 to the consolidated financial statements included elsewhere in this Form 10-K for more information on our debt facility).

**Global Economic Considerations**

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, the Israel-Hamas conflict and other political tensions, and the occurrence of natural disasters and public health crises. 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.

***Cash Used in Operating Activities***

Net cash used in operating activities was $9.4 million for the year ended December 31, 2023. The net loss for this period was less than net cash used in operating activities by $1.0 million, which was primarily attributable to increases of non-cash expenses of $6.3 million, consisting primarily of $2.0 million of changes to the right to use assets, $1.4 million of depreciation and amortization, $1.1 million of inventory reserves, $0.9 million of stock-based compensation, $1.1 million of debt financing cost amortization and accretion of discount and premium, and a $7.2 million net change in assets and liabilities.

Net cash used in operating activities was $16.9 million for the year ended December 31, 2022. The net loss for this period was higher than net cash used in operating activities by $1.8 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 $2.1 million net change in assets and liabilities.

***Cash Used in Investing Activities***

Net cash used in investing activities was $3.0 million during the year ended December 31, 2023. The net cash used was primarily due to the $12.4 million of cash paid in connection with the Evoqua acquisition, $5.7 million in purchases of our available-for-sale investments and $0.3 million for the purchase of equipment, offset by proceeds from the sale of our available-for-sale investments of $15.3 million.

Net cash used in investing activities was $2.4 million during the year ended December 31, 2022. The net cash used 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.

***Cash Provided by Financing Activities***

Net cash provided by financing activities was $11.3 million during the year ended December 31, 2023. The net cash provided by financing activities was primarily due to the net proceeds from issuance of equity securities of $14.9 million, primarily comprised of gross proceeds from the issuance of common stock of $13.8 million in connection with Armistice's exercise of the Prior Warrant, offset by payments on the Company's debt, short term note payable, and financing leases which aggregated $3.5 million during the year ended December 31, 2023.

Net cash provided by financing activities was $16.2 million during the year ended December 31, 2022. The net cash provided by financing activities was primarily due to net 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.

**Contractual Obligations and Other Commitments**

We generally expect to satisfy our material cash requirements, including contractual obligations and commitments, with cash on hand and cash provided by operating activities. See Notes 14, 15, 16, and 17 to the consolidated financial statements included elsewhere in this Form 10-K for additional disclosures.

**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.

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.

*Fair Value Measurements*

*Nonrecurring Valuations.* The assets acquired through the Evoqua Acquisition were recorded at relative fair value, which required the determination of the fair values of assets acquired as of the acquisition date. In making these fair value determinations, we were required to make estimates and assumptions that affected the recorded amounts, including, but not limited to, (i) for the customer relationships intangible asset, expected future cash flows, discount rates and remaining useful life and (ii) for the equipment, replacement cost. To assist us in making these fair value determinations, we engaged third-party valuation specialists. Our estimates of fair value are based upon assumptions we believe to be reasonable, but which are inherently uncertain.

*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.

Deferred License Revenue - Upfront fees received under distribution and license agreements have been deferred as a contract liability. For all existing distribution and license agreements, the distribution and license agreement is not a distinct performance obligation from the underlying product sales. In instances where regulatory approval of the product has not been established and we do 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 the estimated product sales under the agreement occur.

*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 based on future forecasts, historical loss information, and current economic conditions. All accounts or portions thereof deemed to be uncollectible are written off to the allowance for credit losses and credit loss expense.

*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 and definite-lived intangible assets, 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, 2023 and 2022, 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 customer relationships intangible asset recorded in connection with the Evoqua Acquisition, which is being amortized over 20 years.

*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, 2023 and 2022, 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, 2023. Based upon that evaluation, our Chief Executive Officer concluded that our disclosure controls and procedures were effective as of December 31, 2023. 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, 2023. 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, 2023.

**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, 2023, that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## Item 9B. Other Information.

**(a) Appointment of Principal Accounting Officer**

Effective March 20, 2024, the Company's Senior Vice President of Finance, Jesse Neri, 46, has, in addition to his current responsibilities, assumed the role of principal accounting officer. Mr. Neri will not receive any additional compensation related to this appointment.

Prior to joining the Company in October 2023, Mr. Neri was Executive Director of Finance for Hemavant Sciences from August 2022 to October 2023. Before joining Hemavant, he was Executive Director of Financial Planning and Analysis for Aruvant Sciences from August 2021 to August 2022. From July 2020 to August 2021, he provided financial consulting services to a variety of life sciences companies. Previously, he served in a variety of finance roles at Zyla Life Sciences from June 2015 to July 2020, including most recently as Senior Vice President of Finance from January 2020 to July 2020. Mr. Neri has a B.S. in Business Administration from Villanova University and an MBA from Drexel University.

Mr. Neri has no familial relationships with any executive officer or director of the Company. There have been no transactions in which the Company has participated and in which Mr. Neri had a direct or indirect material interest that would be required to be disclosed under Item 404(a) of Regulation S-K.

**(b) Trading Arrangements**

None of our directors or executive officers adopted or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement during the quarter ended December 31, 2023, as such terms are defined under Item 408(a) of Regulation S-K.

## 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 2024 Annual Meeting of Stockholders (the "2024 Proxy Statement"), which we expect to be filed with the SEC within 120 days of the end of our fiscal year ended December 31, 2023, 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, principal accounting 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 by applicable rules, 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 within 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 2024 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 2024 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, 2023:

| 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) | 964,192 | $ 7.61 | 1,403,325 |
| Equity compensation plans not approved by security holders (2) | 624,204 | $ 2.53 | — |
| Total | 1,588,396 | $ 5.22 | 1,403,325 |

(1) Consists of 704,417 stock options with a weighted average exercise price of $7.61, 258,885 restricted stock units issued at $1.97 and 890 restricted stock awards issued at $62.70.
(2) Consists of 624,204 stock options with a weighted average exercise price of $2.53.

### 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 2024 Proxy Statement, including under headings "Independence" and "Certain Relationships and Related Party Transactions."

### Item 14. Principal Accountant Fees and Services.

The information required by this Item 14 is incorporated herein by reference to information in our 2024 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 | Description of Securities (Exhibit 4.2 to the Company's Form 10-K filed on April 8, 2022) |
| 4.2 | Form of Warrant (Exhibit 4.1 to the Company's Form 8-K filed on September 25, 2020). |
| 4.3 | Form of Pre-Funded Warrant (Exhibit 4.2 to the Company's Form 8-K filed on September 25, 2020). |
| 4.4 | Form of Warrant to Purchase Common Stock for Innovatus (Exhibit 4.1 to the Company's Form 8-K filed March 20, 2020). |
| 4.5 | Form of Pre-Funded Warrant (Exhibit 4.1 to the Company's Form 8-K filed on June 2, 2022). |
| 4.6 | Form of PIPE Warrant (Exhibit 4.2 to the Company's Form 8-K filed on June 2, 2022). |
| 4.7 | Form of PIPE Pre-Funded Warrant (Exhibit 4.3 to the Company's Form 8-K filed on June 2, 2022). |
| 4.8 | Common Stock Purchase Warrant, dated July 10, 2023, issued to Armistice Capital Master Fund Ltd. (Exhibit 4.1 to the Company's Form 10-Q filed on August 14, 2023). |
| 4.9 | Form of January 2024 Warrant to Purchase Common Stock issued to Innovatus Life Sciences Lending Fund I, LP (Exhibit 4.1 to the Company's Form 8-K filed on January 8, 2024). |
| 10.1 | Third Amendment to and Restatement of Loan and Security Agreement, dated January 1, 2024, by and among the Company, Rockwell Transportation, Inc., Innovatus Life Sciences Lending Fund I, LP and the lenders party thereto (Exhibit 10.1 to the Company's Form 8-K filed on January 8, 2024). |
| 10.2 | 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). |
| 10.3 | 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). |
| 10.4 | 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). |
| 10.5 | 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). |
| 10.6 | Letter Agreement, dated July 10, 2023, by and between Rockwell Medical, Inc. and Armistice Capital Master Fund Ltd. (Exhibit 10.2 to the Company's Form 10-Q filed on August 14, 2023). |
| 10.7 | 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). |
| 10.8+ | 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). |
| 10.9 | 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). |
| 10.10 | 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). |
| 10.11 | 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). |
| 10.12 | 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). |

| | |
|---|---|
| 10.13 | 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). |
| 10.14 | Asset Purchase Agreement dated July 10, 2023 by and between Rockwell Medical, Inc. and Evoqua Water Technologies LLC (Exhibit 10.2 to the Company's Form 10-Q filed on August 14, 2023). |
| 10.15+ | Amended and Restated Products Purchase Agreement dated September 18, 2023 by and between Rockwell Medical, Inc. and DaVita Inc. (Exhibit 10.1 to the Company's Form 10-Q filed on November 14, 2023). |
| 10.16* | 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). |
| 10.17* | 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). |
| 10.18* | 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). |
| 10.19* | 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). |
| 10.20* | Form of Performance Share Award Agreement March 2017 (Director Version) (Exhibit 10.65 to the Company's Form 10-Q filed May 9, 2017). |
| 10.21* | Rockwell Medical, Inc. Amended and Restated 2018 Long Term Incentive Plan (Exhibit 10.3 to the Company's Form 10-Q filed on August 14, 2023). |
| 10.22* | 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). |
| 10.23* | 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). |
| 10.24* | Form of Restricted Stock Unit Award Agreement Employee Version (2018 Long Term Incentive Plan). |
| 10.25* | Form of Restricted Stock Unit Award Agreement Director Version (2018 Long Term Incentive Plan). |
| 10.26* | Rockwell Medical, Inc. Short Term Incentive Plan (Exhibit 10.1 to the Company's Form 10-Q filed on November 14, 2022). |
| 10.27* | Form of Indemnification Agreement (Exhibit 10.1 to the Company's Form 8-K filed August 30, 2019). |
| 10.28* | 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). |
| 10.29* | 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). |
| 10.30*# | Employment Agreement dated July 21, 2021 between Rockwell Medical, Inc. and Megan Timmins. |
| 10.31# | Rockwell Medical, Inc. Amended and Restated Clawback Policy. |
| 10.32# | Rockwell Medical, Inc. Statement of Company Policy Prohibiting Insider Trading. |
| 21.1 | List of Subsidiaries (Company's Form 10-K filed on March 31, 2021). |
| 23.1# | Consent of EisnerAmper LLP. |
| 23.2# | 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 21, 2024

## 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<br>Mark Strobeck | President, Chief Executive Officer and Director (Principal Executive Officer and Principal Financial Officer) | March 21, 2024 |
| /s/ Jesse Neri<br>Jesse Neri | Senior Vice President, Finance and Principal Accounting Officer | March 21, 2024 |
| /s/ John G. Cooper<br>John G. Cooper | Director | March 21, 2024 |
| /s/ Joan Lau<br>Joan Lau | Director | March 21, 2024 |
| /s/ Allen Nissenson<br>Allen Nissenson | Director | March 21, 2024 |
| /s/ Robert S. Radie<br>Robert S. Radie | Director | March 21, 2024 |
| /s/ Mark H. Ravich<br>Mark H. Ravich | Director | March 21, 2024 |
| /s/ Andrea Heslin Smiley<br>Andrea Heslin Smiley | Director | March 21, 2024 |

## INDEX TO CONSOLIDATED FINANCIAL STATEMENTS


| | PAGE |
|---|---|
| Report of Independent Registered Public Accounting Firm - EisnerAmper LLP (PCAOB Identification Number 274) | F-2 |
| Report of Independent Registered Public Accounting Firm - Marcum LLP | F-4 |
| Consolidated Balance Sheets at December 31, 2023 and 2022 | F-5 |
| Consolidated Statements of Operations for the years ended December 31, 2023 and 2022 | F-7 |
| Consolidated Statements of Comprehensive Loss for the years ended December 31, 2023 and 2022 | F-8 |
| Consolidated Statements of Changes in Stockholders' Equity for the years ended December 31, 2023 and 2022 | F-9 |
| Consolidated Statements of Cash Flows for the years ended December 31, 2023 and 2022 | F-10 |
| Notes to the Consolidated Financial Statements | F-11 – F-33 |

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM - EISNERAMPER LLP**

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

***Opinion on the Financial Statements***

We have audited the accompanying consolidated balance sheet of Rockwell Medical, Inc. and Subsidiaries (the "Company") as of December 31, 2023, and the related consolidated statements of operations, comprehensive loss, changes in stockholders' equity, and cash flows for the year then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2023, and the consolidated results of their operations and their cash flows for the year then ended, 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 audit. 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. 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 audit, 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 audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

***Critical Audit Matter***

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter 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 matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

*Valuation of the intangible asset acquired in the Evoqua asset acquisition*

As described in Notes 3 and 4 to the consolidated financial statements, on July 10, 2023, the Company executed and consummated the transactions contemplated by an Asset Purchase Agreement (the "Purchase Agreement") with Evoqua Water Technologies, LLC ("Evoqua")(the "Evoqua Acquisition"). At the closing of the transaction, the Company acquired assets, including an intangible asset, from Evoqua for consideration of $17.4 million and the transaction was accounted for as an asset acquisition. The acquired intangible asset was a customer list valued on a relative fair value basis at $11.0 million on the acquisition date. Establishing the relative fair value of the customer list intangible asset required management to first perform a fair value assessment, which was completed using a multi-period excess earnings method ("MPEEM"). The method used to estimate the fair value of the acquired

intangible asset involved significant assumptions. The significant assumptions applied by the Company in estimating the fair value of the acquired customer list intangible asset included cash flow projections, discount rates, and the estimated useful life of the customer relationships.

We identified the valuation of the acquired customer list intangible asset as a critical audit matter due to the significant judgement by management involved with developing the estimates to determine the fair value of the customer list intangible asset, specifically those relating to the projected cash flows, discount rates, and the estimated useful life of the customer relationships. As such, there was a high degree of auditor judgement and subjectivity, and significant audit effort was required in performing procedures to evaluate management's conclusions.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures include, among others, (i) obtaining an understanding of and evaluating the design of controls related to the valuation of the acquired customer list intangible asset; and (ii) reading the Purchase Agreement and testing management's process for estimating the fair value of the acquired customer list intangible asset, which included evaluating the appropriateness of the valuation models, testing the completeness, accuracy, and relevance of underlying data used in the models, and testing the reasonableness of significant assumptions, including cash flow projections, discount rates, and the estimated useful life of the customer relationships. Evaluating the cash flow projections involved considering the current performance of the acquired assets, the consistency with external market and industry data, and whether these assumptions were consistent with other evidence obtained in other areas of the audit. Professionals with specialized skill and knowledge were used to assist in evaluating the reasonableness of the significant assumptions, including discount rates and the estimated useful life of customer relationships.

/s/ EisnerAmper LLP

We have served as the Company's auditor since 2023.

EISNERAMPER LLP
West Palm Beach, Florida
March 21, 2024

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM - MARCUM LLP

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

### Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Rockwell Medical Inc. and Subsidiaries (the "Company") as of December 31, 2022, the related consolidated statement of operations, comprehensive loss, changes in stockholders' equity and cash flows for the year then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2022, and the consolidated results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

### Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. We are a public accounting firm registered with the 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. 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 audit, 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 audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

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

We served as the Company's auditor from 2018 to 2023.

Chicago, Illinois
March 30, 2023

## ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

## CONSOLIDATED BALANCE SHEETS

**(In thousands, except share and par value amounts)**

| | December 31, 2023 | December 31, 2022 |
|---|---|---|
| **ASSETS** | | |
| Cash and Cash Equivalents | $ 8,983 | $ 10,102 |
| Investments Available-for-Sale | 1,952 | 11,390 |
| Accounts Receivable, net of a reserve of $81 for 2023 and $33 for 2022 | 10,901 | 6,259 |
| Inventory, net | 5,871 | 5,814 |
| Prepaid and Other Current Assets | 1,063 | 1,745 |
| **Total Current Assets** | **28,770** | **35,310** |
| Property and Equipment, net | 6,402 | 2,194 |
| Inventory, Non-Current | 178 | 1,276 |
| Right of Use Assets - Operating, net | 2,713 | 3,943 |
| Right of Use Assets - Financing, net | 1,903 | 2,468 |
| Intangible Assets, net | 10,759 | — |
| Goodwill | 921 | 921 |
| Other Non-Current Assets | 527 | 523 |
| **Total Assets** | **$ 52,173** | **$ 46,635** |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Insurance Financing Note Payable | $ 244 | $ 503 |
| Accounts Payable | 4,516 | 4,053 |
| Accrued Liabilities | 7,149 | 7,702 |
| Deferred Consideration, Current | 2,500 | — |
| Lease Liabilities - Operating, Current | 1,381 | 1,483 |
| Lease Liabilities - Financing, Current | 558 | 522 |
| Deferred License Revenue, Current | 46 | 1,731 |
| Term Loan, Current - Net of Issuance Costs and Premium Accretion | — | 1,631 |
| Customer Deposits | 243 | 66 |
| **Total Current Liabilities** | **16,637** | **17,691** |
| | | |
| Lease Liabilities - Operating - Long-Term | 1,433 | 2,581 |
| Lease Liabilities - Financing - Long-Term | 1,530 | 2,088 |
| Term Loan - Long-Term, Net of Issuance Costs and Premium Accretion | 8,293 | 7,555 |
| Deferred License Revenue - Long-Term | 475 | 2,600 |
| Deferred Consideration - Long-Term | 2,500 | — |
| Long Term Liability - Other | 14 | 14 |
| **Total Liabilities** | **30,882** | **32,529** |
| | | |
| **Commitments and Contingencies (See Note 15)** | | |
| | | |
| **Stockholders' Equity:** | | |
| Preferred Stock, $0.0001 par value, 2,000,000 shares authorized, 15,000 shares issued and outstanding at December 31, 2023 and 2022 | — | — |
| Common Stock, $0.0001 par value, 170,000,000 shares authorized, 29,130,607 and 12,163,673 shares issued and outstanding at December 31, 2023 and 2022 | 3 | 1 |
| Additional Paid-in Capital | 418,487 | 402,701 |
| Accumulated Deficit | (397,198) | (388,759) |
| Accumulated Other Comprehensive (Loss) Income | (1) | 163 |

| | | |
|---|---|---|
| **Total Stockholders' Equity** | **21,291** | **14,106** |
| **Total Liabilities and Stockholders' Equity** | **$ 52,173** | **$ 46,635** |

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

**ROCKWELL MEDICAL, INC. AND SUBSIDIARIES**
**CONSOLIDATED STATEMENTS OF OPERATIONS**
**(In thousands, except share and per share amounts)**

| | Years Ended December 31, | |
|---|---|---|
| | **2023** | **2022** |
| Net Sales | $ 83,612 | $ 72,810 |
| Cost of Sales | 74,908 | 68,733 |
| Gross Profit | 8,704 | 4,077 |
| Research and Product Development | 1,107 | 3,119 |
| Selling and Marketing | 2,125 | 2,094 |
| General and Administrative | 12,142 | 15,644 |
| **Operating Loss** | **(6,670)** | **(16,780)** |
| | | |
| **Other Expense:** | | |
| Realized Gain on Investments | 321 | 4 |
| Interest Expense | (2,301) | (1,936) |
| Interest Income | 211 | 33 |
| **Total Other Expense, net** | **(1,769)** | **(1,899)** |
| | | |
| **Net Loss** | **$ (8,439)** | **$ (18,679)** |
| | | |
| **Net Loss Per Share Attributable to Common Stockholders - Basic and Diluted** | **$ (0.37)** | **$ (1.31)** |
| **Weighted Average Number of Shares of Common Stock Outstanding - Basic and Diluted** | **23,322,915** | **14,304,512** |

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

**ROCKWELL MEDICAL, INC. AND SUBSIDIARIES**

**CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**

**(In thousands)**

| | Years Ended December 31, | |
|---|---|---|
| | 2023 | 2022 |
| **Net Loss** | **$ (8,439)** | **$ (18,679)** |
| Unrealized (Loss) Gain on Available-for-Sale Investments | (159) | 114 |
| Foreign Currency Translation Adjustments | (5) | (3) |
| **Comprehensive Loss** | **$ (8,603)** | **$ (18,568)** |

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

## ROCKWELL MEDICAL, INC. AND SUBSIDIARIES
## CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
**(In thousands, except share amounts)**

| | 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, 2022** | **—** | **$ —** | **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 Pre-Funded 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** |
| Net Loss | — | — | — | — | — | (8,439) | — | (8,439) |
| Unrealized Loss on Available-for-Sale Investments | — | — | — | — | — | — | (159) | (159) |
| Foreign Currency Translation Adjustments | — | — | — | — | — | — | (5) | (5) |
| Vesting of Restricted Stock Units Issued, net of taxes withheld | — | — | 125,000 | — | — | — | — | — |
| Issuance of Common Stock in connection with exercise of Prior Warrant and Pre-Funded Warrants, net of offering costs | — | — | 16,200,990 | 2 | 13,718 | — | — | 13,720 |
| Issuance of Common Stock, net of Issuance Costs / At-the-market offerings | — | — | 640,944 | — | 1,136 | — | — | 1,136 |
| Stock-based Compensation | — | — | — | — | 932 | — | — | 932 |
| **Balance as of December 31, 2023** | **15,000** | **$ —** | **29,130,607** | **$ 3** | **$ 418,487** | **$ (397,198)** | **$ (1)** | **$ 21,291** |

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

**ROCKWELL MEDICAL, INC. AND SUBSIDIARIES**
**CONSOLIDATED STATEMENTS OF CASH FLOWS**
**(In thousands)**

| | Years Ended December 31, | |
|---|---|---|
| | **2023** | **2022** |
| Cash Flows From Operating Activities: | | |
| **Net Loss** | **$ (8,439)** | **$ (18,679)** |
| Adjustments To Reconcile Net Loss To Net Cash Used In Operating Activities: | | |
| Depreciation and Amortization | 1,444 | 576 |
| Stock-based Compensation | 932 | 315 |
| Increase in Inventory Reserves | 1,098 | 610 |
| Non-cash Lease Expense from Right of Use Assets | 2,010 | 2,013 |
| Amortization of Debt Financing Costs and Accretion of Debt Discount and Premium | 1,107 | 369 |
| Loss (Gain) on Disposal of Assets | 1 | (3) |
| Realized Gain on Sale of Investments | (321) | (4) |
| Changes in Assets and Liabilities: | | |
| Accounts Receivable, net | (4,642) | (346) |
| Inventory | 1,176 | (2,101) |
| Prepaid and Other Assets | 1,410 | 2,720 |
| Accounts Payable | 463 | 314 |
| Lease Liabilities | (1,465) | (1,421) |
| Accrued and Other Liabilities | (376) | 2,534 |
| Deferred License Revenue | (3,810) | (3,826) |
| Changes in Operating Assets and Liabilities | (7,244) | (2,126) |
| **Cash Used In Operating Activities** | **(9,412)** | **(16,929)** |
| Cash Flows From Investing Activities: | | |
| Purchase of Investments Available-for-Sale | (5,701) | (21,297) |
| Sale of Investments Available-for-Sale | 15,301 | 19,182 |
| Purchase of Equipment | (284) | (281) |
| Cash Paid in Connection with Evoqua Asset Acquisition | (12,361) | — |
| **Cash Used In Investing Activities** | **(3,045)** | **(2,396)** |
| Cash Flows From Financing Activities: | | |
| Payments on Debt | (2,000) | (11,750) |
| Payments on Insurance Financing Note Payable | (992) | (1,443) |
| Payments on Financing Lease Liabilities | (522) | (482) |
| Proceeds from Issuance of Common Stock | 14,861 | 15,016 |
| Offering Costs from Issuance of Common Stock | (5) | (106) |
| Proceeds from Issuance of Preferred Stock | — | 15,000 |
| Offering Costs from Issuance of Preferred Stock | — | (85) |
| **Cash Provided By Financing Activities** | **11,342** | **16,150** |
| Effect of Exchange Rate Changes on Cash and Cash Equivalents | (4) | (3) |
| Decrease In Cash and Cash Equivalents | (1,119) | (3,178) |
| Cash and Cash Equivalents At Beginning Of Year | 10,102 | 13,280 |
| **Cash and Cash Equivalents At End Of Year** | **$ 8,983** | **$ 10,102** |
| **Supplemental Disclosure of Cash Flow Information:** | | |
| Cash Paid for Interest | $ 1,209 | $ 1,470 |
| **Supplemental Disclosure of Noncash Investing and Financing Activities:** | | |
| Change in Unrealized (Loss) Gain on Marketable Securities Available-for-Sale | $ (159) | $ 114 |
| Increase in Prepaid Assets from Insurance Financing Note Payable | $ 733 | $ 503 |
| Fair Value of Warrants issued related to Debt Financing | $ — | $ 501 |
| Deferred Consideration from Evoqua Asset Acquisition | $ 5,000 | $ — |

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

## Note 1. Description of Business

Rockwell Medical, Inc. (the "Company", "Rockwell", "we", or "us") 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 liquid and powder 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 typically performed at freestanding outpatient dialysis centers, hospital-based outpatient centers, skilled nursing facilities, or in a patient’s home.

Rockwell provides the hemodialysis community with products controlled by a Quality Management System regulated by the U.S. Food and Drug Administration ("FDA"). Rockwell manufactures hemodialysis concentrates at its facilities in Michigan, South Carolina and Texas 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.

On July 10, 2023, the Company executed and consummated the transactions contemplated by an Asset Purchase Agreement (the "Purchase Agreement") with Evoqua Water Technologies LLC ("Evoqua") (the "Evoqua Acquisition"). Subject to the terms and conditions of the Purchase Agreement, at the closing of the transaction (the "Closing"), the Company purchased customer relationships, equipment and inventory from Evoqua, which were related to its manufacturing and selling of hemodialysis concentrates products, all of which are manufactured under a contract manufacturing agreement with a third-party organization. See Note 4 for further detail.

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 had established international partnerships with companies and sought to develop and commercialize Triferic outside the United States and was working closely with these international partners to develop and commercialize Triferic in their respective regions. During the year ended December 31, 2023, the ongoing Triferic development effort was terminated resulting in an acceleration of the corresponding deferred license revenue (see Note 10) and a reserve on the non-current inventory (see Note 7). 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, 2023, Rockwell had an accumulated deficit of approximately $397.2 million and stockholders' equity of $21.3 million. As of December 31, 2023, Rockwell had approximately $10.9 million of cash, cash equivalents and investments available-for-sale, and working capital of $12.1 million. Net cash used in operating activities for the year ended December 31, 2023 was $9.4 million.

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. Based on the currently available working capital and 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. Additionally, the Company's plans include raising capital, if needed, by using the $11 million remaining on its ATM facility or other methods or forms of financings, subject to existing limitations.

**Global Economic Conditions - Risks and Uncertainties**

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, Israel-Hamas conflict and other political tensions, and the occurrence of natural disasters and public health crises. 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 have been prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”). The 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 2019 for the purpose of conducting certain commercial activities in India. All intercompany balances and transactions have been eliminated in consolidation.

**Reclassification**

Certain prior year amounts have been reclassified to conform to the current year presentation, including the reclassification of lease right-of-use assets into Right of Use Assets - Operating, Net and Right of Use Assets - Financing, Net and lease liabilities into Lease Liabilities - Operating, Current, Lease Liabilities - Financing, Current, Lease Liabilities - Operating, Long-Term, and Lease Liabilities - Financing, Long-Term. Additionally, amounts from the Changes in Lease Liabilities were reclassified to Payments on Financing Lease Liabilities on the statement of cash flows.

**Revenue Recognition**

The Company recognizes revenue under Accounting Standards Codification (“ASC”) 606, *Revenue from Contracts with Customers,* issued by the Financial Accounting Standards Board ("FASB"). 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. For a discussion of significant market segments and customers, see Note 6.

*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.

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 estimated at the time of sale. Customers typically pay for the product based on customary business practices with payment terms averaging 30 days, while a small subset of customers have payment terms averaging 60 days.

*Deferred License Revenue*

The Company received upfront fees under five distribution and license agreements that have been deferred as a contract liability and presented on the accompanying consolidated balance sheets as deferred license revenue. 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. During the year ended December 31, 2023, the amounts received from Wanbang were accelerated out of deferred license revenue and into revenue upon notice that the development effort was terminated. The amounts received from Baxter Healthcare Corporation ("Baxter") were deferred and recognized as revenue at the point in time the estimated product sales under the agreement occurred. During the year ended December 31, 2023, all remaining deferred revenue relating to the Baxter agreement was recognized as revenue. For additional information related to the Company's deferred license revenue, see Note 10.

*Product Purchase Agreements*

On September 18, 2023, the Company and its long-time partner, DaVita, Inc. ("DaVita"), a leading provider of kidney care, entered into an Amended and Restated Products Purchase Agreement (the "Amended Agreement"), which amends and restates the Product Purchase Agreement, dated July 1, 2019, as amended, under which the Company supplies DaVita with certain dialysis concentrates. Under the Amended Agreement, the Company and DaVita agreed to an increase in product pricing, effective September 1, 2023 and a one-time payment of $0.4 million to Rockwell on or after December 1, 2023, which was recorded as revenue recognized during the year ended December 31, 2023. The term of the Amended Agreement will expire on December 31, 2024. DaVita will have the right, in its sole discretion upon written notice to the Company given no later than September 30, 2024, to further extend the term through December 31, 2025. In the event of such an extension, product pricing will be increased for the extended term. In addition, DaVita is required to provide the Company with nine-month purchasing forecasts and a commitment to purchase at least the forecasted amounts. In the event that DaVita does not meet its forecasts, it is required to pay the Company for the amount forecasted, purchase additional product, or the Company

may terminate the Amended Agreement. Upon expiration or termination of the Amended Agreement, and upon request by DaVita, the Company has agreed to provide transition services to DaVita during a transition period.

***Disaggregation of revenue***

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

| *In thousands* | Year Ended December 31, 2023 | | |
|---|---|---|---|
| Products By Geographic Area | Total | U.S. | Rest of World |
| Drug Revenues | | | |
| Product Sales - Point-in-time | $ — | $ — | $ — |
| License Fee – Over time | 2,338 | — | 2,338 |
| Total Drug Products | 2,338 | — | 2,338 |
| Concentrate Products | | | |
| Product Sales – Point-in-time | 79,802 | 72,871 | 6,931 |
| License Fee – Over time | 1,472 | 1,472 | — |
| Total Concentrate Products | 81,274 | 74,343 | 6,931 |
| Net Revenue | $ 83,612 | $ 74,343 | $ 9,269 |

| *In thousands* | 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 |

***Contract balances***

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

| *In thousands* | December 31, 2023 | December 31, 2022 | January 1, 2022 |
|---|---|---|---|
| Accounts Receivable, net | $ 10,901 | $ 6,259 | $ 5,913 |
| Contract Liabilities, which are included in deferred license revenue | $ 521 | $ 4,331 | $ 8,157 |

There were no other material contract assets recorded on the consolidated balance sheets as of December 31, 2023 and 2022. 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, 2023 or 2022.

The contract liabilities primarily relate to upfront fees under distribution and license agreements with Baxter, Wanbang, Sun Pharma, Jeil Pharma, and Drogan Pharma.

***Transaction price allocated to remaining performance obligations***

For each of the years ended December 31, 2023 and 2022, the Company recognized $3.8 million as revenue from amounts classified as contract liabilities (i.e., deferred license revenue) as of December 31, 2022 and 2021, respectively.

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 $0.5 million and $2.9 million as of December 31, 2023 and 2022, 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.

**Use of Estimates**

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that may affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and reported amounts of expenses during the reporting period. Actual results could differ from those estimates. The most significant accounting estimates inherent in the preparation of the financial statements include estimates associated with fair value and classification of warrants, revenue recognition, allowance for credit losses, inventory reserves, accrued expenses, deferred license revenue, stock-based compensation, valuations and 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. 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 and 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 credit losses 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 based on future forecasts, historical loss information, and current economic conditions. All accounts or portions thereof deemed to be uncollectible are written off to the allowance for credit losses and credit loss expense.

**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 and Goodwill**

Long-lived assets, such as property and equipment and definite-lived intangible 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 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, 2023 and 2022, there were no impairments of long-lived assets.

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. Rockwell completed its annual impairment tests as of December 31, 2023 and 2022, and determined that no adjustment for impairment of goodwill or intangible assets was required during the years ended December 31, 2023 and 2022.

**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. Goodwill was $0.9 million as of December 31, 2023 and December 31, 2022.

Definite-lived intangible assets consist of our customer list associated with the Evoqua asset acquisition and license fees related to the technology, intellectual property and marketing rights for Triferic covered under certain issued patents. Definite-lived intangible assets have been capitalized and are being amortized over their useful life.

**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 $1.1 million and $3.1 million for the years ended December 31, 2023 and 2022, respectively.

**Stock-Based Compensation**

***Service-Based Stock Unit Awards***

The Company expenses stock-based compensation to employees and non-employees over the requisite service period based on the grant-date fair value of the awards. 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, 2023 and 2022, the Company recorded stock-based compensation expense on its options granted under the Company's equity compensation plans to its directors and officers, and its employees (See Note 13).

***Market and Performance-Based Stock Unit Awards***

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

The awards with performance conditions vest and result in issuance, at settlement, of common stock for each recipient based upon the recipient's continued employment with the Company through the settlement date of the award and the Company's achievement of specified milestones. The requisite service period of the awards with performance conditions is generally 1-2 years. In the case of awards with performance conditions, the Company recognizes stock-based compensation expense based on the grant date fair value of the award when achievement of the underlying performance-based targets become probable.

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

**Leases**

The Company accounts for its leases under ASC 842, *Leases*. Under this guidance, arrangements meeting the definition of a lease are classified as operating or financing leases and are recorded on the consolidated balance sheets as both a right-of-use asset and lease liability, calculated by discounting fixed lease payments over the lease term at the rate implicit in the lease or the Company's incremental borrowing rate. Lease liabilities are increased by interest and reduced by payments each period, and the right-of-use assets are amortized over the lease term. For operating leases, interest on the lease liability and the amortization of the right-of-use asset result in straight-line expense over the lease term. Variable lease expenses, if any, are recorded when incurred.

In calculating the right-of-use assets and lease liabilities, the Company elected the practical expedient to combine lease and non-lease components. Additionally, the Company excludes short-term leases having initial terms of 12 months or less as an accounting policy election and recognizes rent expense on a straight-line basis over the lease term.

**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.

**Restatement of Loss Per Share**

Loss per share for the year ended December 31, 2022 was recalculated and restated and is presented on a comparable basis with the year ended December 31, 2023. In the first quarter of 2023, the Company determined it should have included pre-funded warrants issued in the second quarter of 2022 in the loss per share calculation in accordance with ASC 260-10-45-13, which treats shares of common stock exercisable for little to no consideration as included in the denominator of both the basic and diluted earnings per share calculations. While the Company has determined the impact of including the pre-funded warrants in the loss per share calculations does not have a material impact on previously issued financial statements, the Company has recalculated and restated amounts presented on a comparative and consistent basis with current period results. The table below summarizes previously reported and restated amounts on a comparative basis.

| | Year Ended December 31, 2022 |
|---|---|
| **As Previously Reported:** | |
| Net Loss Per Share Attributable to Common Stockholders - Basic and Diluted | $ (1.89) |
| Weighted Average Number of Shares of Common Stock Outstanding - Basic and Diluted | 9,866,844 |
| | |
| **As Restated:** | |
| Net Loss Per Share Attributable to Common Stockholders - Basic and Diluted | $ (1.31) |
| Weighted Average Number of Shares of Common Stock Outstanding - Basic and Diluted | 14,304,512 |

**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, less accretion of the Series X Preferred Stock, 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.

The Company's potentially dilutive securities include stock options, restricted stock awards and units, convertible preferred stock and warrants. These securities were excluded from the computations of diluted net loss per share for the years ended December 31, 2023 and 2022, as the effect would be to reduce the net loss per share. The following table includes the potential shares of common stock, presented based on amounts outstanding at each period end, that were excluded from the computation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

| | As of December 31, | |
|---|---|---|
| | 2023 | 2022 |
| Warrants to purchase common stock | 3,793,388 | 10,196,268 |
| Convertible Preferred Stock | 1,363,636 | 1,363,636 |
| Options to purchase common stock | 1,328,621 | 1,206,905 |
| Unvested restricted stock units | 258,885 | 125,000 |
| Unvested restricted stock awards | 891 | 891 |
| Total | 6,745,421 | 12,892,700 |

Included within the weighted average shares of common stock outstanding for the year ended December 31, 2022 are 6,300,000 shares of common stock issuable upon the exercise of Pre-Funded Warrants (See Note 12), as the warrants were exercisable at any time for nominal consideration and, as such, the shares were considered outstanding for the purpose of calculating basic and diluted net loss per share attributable to common stockholders. There were no unexercised Pre-Funded Warrants as of December 31, 2023.

The following table presents the calculation of basic and diluted EPS:

| | Years Ended December 31, | |
|---|---|---|
| | 2023 | 2022 |
| Numerator: | | |
| Net Loss | $ (8,439) | $ (18,679) |
| Accretion of Series X Preferred Stock | (150) | — |
| Net Loss Attributable to Common Stockholders | $ (8,589) | $ (18,679) |
| Denominator | | |
| Weighted Average Number of Shares of Common Stock Outstanding - Basic and Diluted | 23,322,915 | 14,304,512 |
| Net Loss Per Share Attributable to Common Stockholders - Basic and Diluted | $ (0.37) | $ (1.31) |

**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 and New Accounting Pronouncements**

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

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments - Credit Losses (Topic 326)*, which introduced an impairment model that is based on expected credit losses, rather than incurred losses, to estimate credit losses on certain types of financial instruments (e.g., loan commitments). The expected credit losses should consider historical information, current information, and reasonable and supportable forecasts, including estimates of prepayments, over the contractual term. Financial instruments with similar risk characteristics may be grouped together when estimating expected credit losses. In addition, ASC 326 requires expected credit related losses for trade accounts receivable, as well as available-for-sale debt securities, which are to be recorded through an allowance for credit losses, while non-credit related losses will continue to be recognized through other comprehensive income. The Company adopted the new guidance, as of January 1, 2023, and it did not have a material impact on the consolidated financial statements.

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting - Improvements to Reportable Segment Disclosures*, which updates reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses and information used to assess segment performance. The amendments in this ASU are effective

for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted. The Company is in the process of determining the effect this ASU will have on the consolidated financial statements.

In December 2023, the FASB issued ASU 2023-09, *Improvements to Income Tax Disclosures*, which updates income tax disclosures primarily related to the rate reconciliation and income taxes paid information. This ASU also includes certain other amendments to improve the effectiveness of income tax disclosures. The amendments in this ASU are effective for annual periods beginning after December 15, 2024. Early adoption is permitted for annual financial statements that have not yet been issued or made available for issuance. The Company is in the process of determining the effect this ASU will have on the consolidated financial statements.

**Note 4. Asset Acquisition**

On July 10, 2023, the Company completed the Evoqua Asset Acquisition. At the Closing, the Company purchased customer relationships, equipment and inventory from Evoqua, which were related to manufacturing and selling of hemodialysis concentrates products, all of which are manufactured under a contract manufacturing agreement with a third-party organization.

Pursuant to the Purchase Agreement, total consideration was $17.4 million, comprising a cash payment at Closing of $12.4 million (inclusive of transaction costs) and two $2.5 million deferred payments, the first to be paid on the one-year anniversary of the Closing, which is included as a current liability on the Company's consolidated balance sheet, and the second to be paid on the second anniversary of the Closing (collectively, the "deferred consideration").

The transaction was accounted for as an asset acquisition, as the acquired assets did not meet the definition of a business as defined by ASC 805, *Business Combinations*.

The purchase price was allocated, on a relative fair value basis, to the assets acquired at the July 10, 2023 acquisition date as follows (table in thousands):

| | | |
|---|---|---|
| **Consideration** | | |
| Cash Payment | $ | 12,233 |
| Deferred Consideration | | 5,000 |
| Transaction Costs | | 128 |
| Total Consideration | $ | 17,361 |
| | | |
| **Assets Acquired** | | |
| Customer Relationships Intangible Asset | $ | 11,035 |
| Equipment | | 5,093 |
| Inventory | | 1,233 |
| Total Assets Acquired | $ | 17,361 |

The fair value of the customer relationships intangible asset was determined using a multi-period excess earnings method, a form of the income approach, which incorporates the estimated future cash flows to be generated from the customer base. Key assumptions included discounted cash flows, estimated life cycle and customer attrition rates. Customer relationships are being amortized over a period of 20 years. Given the recency of the purchase of the equipment in which the assets were recorded at relative fair value, the Company determined the fair value of the equipment using a cost approach, which considered assumptions over the equipment's current replacement cost and useful life. Inventory was purchased directly from the contract manufacturer holding the inventory, which approximated fair value.

During the year ended December 31, 2023, the Company recorded amortization of its customer relationship intangible asset of $0.3 million, resulting in a net intangible asset of $10.8 million as of December 31, 2023.

Estimated future amortization expense on the Company's customer relationships intangible asset as of December 31, 2023 is as follows (table in thousands):

| Year ended December 31: | |
|---|---|
| 2024 | $ 552 |
| 2025 | 552 |
| 2026 | 552 |
| 2027 | 552 |
| 2028 | 552 |
| Thereafter | 7,999 |
| **Total** | $ 10,759 |

**Note 5. Investments - Available-for-Sale**

Investments available-for-sale consisted of the following as of December 31, 2023 and 2022 (tables in thousands):

| | December 31, 2023 | | | | |
|---|---|---|---|---|---|
| | Amortized Cost | Unrealized Gain | Unrealized Loss | Accrued Interest Income | Fair Value |
| Available-for-Sale Securities | | | | | |
| Bonds | $ 1,948 | $ 4 | $ — | $ — | $ 1,952 |

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

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 a Level 1 measurement under ASC 820, *Fair Value Measurements*.

As of December 31, 2023 and 2022, our available-for-sale securities were due in one year or less.

**Note 6. 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. Rockwell's customer mix is diverse, with most customer sales concentrations under 10%, however, two customers, DaVita and Baxter, accounted for approximately 47% and nil, respectively, of Rockwell's total net product sales in 2023 and 46% and 29%, respectively, of its total net product sales in 2022. Rockwell's accounts receivable from DaVita and Baxter were $2.1 million and nil, respectively, as of December 31, 2023 and $1.9 million and $2.3 million, respectively, as of December 31, 2022. For additional information regarding the Company's contracts with DaVita and Baxter, see Notes 3 and 10, respectively.

DaVita is 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 current customer accounted for more than 10% of 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% of its total sales in each of 2023 and 2022.

**Note 7. Inventory**

Components of inventory, net of reserves as of December 31, 2023 and 2022 are as follows (table in thousands):

| | December 31, 2023 | December 31, 2022 |
|---|---|---|
| Inventory - Current Portion | | |
| Raw Materials | $ 2,250 | $ 3,351 |
| Work in Process | 351 | 351 |
| Finished Goods | 3,270 | 2,112 |
| Total Current Inventory | 5,871 | 5,814 |
| Inventory - Long Term[(1)] | 178 | 1,276 |
| Total Inventory | $ 6,049 | $ 7,090 |

1. Represents inventory related to Triferic raw materials. This Triferic inventory is expected to be utilized for the Company's international partnerships. In September 2022, the Company discontinued its New Drug Applications ("NDAs") for Triferic (dialysate) and Triferic AVNU in the United States. In 2023, the Company reserved $1.1 million of long-term inventory as a result of the termination of the Wanbang development effort.

As of December 31, 2023 and 2022, Rockwell had total Concentrate inventory aggregating $5.9 million and $5.8 million, respectively, against which Rockwell had reserved $25,000 and $25,000, respectively.

**Note 8. Property and Equipment**

As of December 31, 2023 and 2022, the Company’s property and equipment consisted of the following (table in thousands):

| | December 31, 2023 | December 31, 2022 |
|---|---|---|
| Leasehold Improvements | $ 1,423 | $ 1,256 |
| Machinery and Equipment | 11,131 | 5,922 |
| Information Technology & Office Equipment | 1,845 | 1,845 |
| Laboratory Equipment | 807 | 807 |
| | 15,206 | 9,830 |
| Accumulated Depreciation and Amortization | (8,804) | (7,636) |
| Net Property and Equipment | $ 6,402 | $ 2,194 |

Depreciation and amortization expense for the years ended December 31, 2023 and 2022 was $1.2 million and $0.6 million, respectively.

**Note 9. Accrued Liabilities**

Accrued liabilities as of December 31, 2023 and 2022 consisted of the following (table in thousands):

| | December 31, 2023 | December 31, 2022 |
|---|---|---|
| Accrued Compensation and Benefits | $ 2,413 | $ 2,568 |
| Accrued Unvouchered Receipts | 1,663 | 585 |
| Accrued Manufacturing Expense | 1,064 | — |
| Accrued Workers Compensation | 254 | 306 |
| Accrued Research & Development Expense | — | 43 |
| Other Accrued Liabilities | 1,755 | 4,200 |
| Total Accrued Liabilities | $ 7,149 | $ 7,702 |

**Note 10. Deferred License Revenue**

In October 2014, the Company entered into an exclusive distribution agreement with Baxter, which had a term of 10 years, and received an upfront fee of $20 million. Under the exclusive distribution agreement, Baxter distributed and commercialized Rockwell's hemodialysis concentrates products and provided customer service and order delivery to nearly all U.S. customers. The upfront fee was recorded as deferred license revenue and was 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 paid Baxter a fee, which was reflected as a reduction to revenue on the consolidated statements of operations, and was payable in two equal installments on January 1, 2023 and April 1, 2023, to reacquire 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 terminated December 31, 2022. To ensure that customer needs continued to be met after January 1, 2023, Rockwell agreed to provide certain services to a group of Baxter's customers until March 31, 2023, and Baxter and Rockwell worked together to transition customers' purchases of Rockwell's hemodialysis concentrates through that date. Following the reacquisition of these rights, Rockwell is now unrestricted in its ability to sell its hemodialysis concentrates products to dialysis clinics throughout the United States and around the world. The Company recognized $2.5 million of revenue associated with the upfront fee during the year ended December 31, 2022, and recognized the remaining revenue of $1.5 million during the year ended December 31, 2023.

The remaining agreements with Sun Pharam, Jeil Pharmaceutical, and Drogan Pharmaceuticals comprise the current and long-term portions of deferred license revenue on the consolidated balance sheet as of December 31, 2023.

**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 nine months, and the final payment was due on March 3, 2023. As of December 31, 2022, the Company's insurance note payable balance was $0.5 million and was paid fully in 2023.

On June 3, 2023, the Company entered into a new short-term note payable for $0.7 million, bearing interest at 9.59% per annum to finance various insurance policies. Principal and interest payments related to this note began on July 3, 2023 and are paid on a straight-line amortization over nine months with the final payment due on March 3, 2024. As of December 31, 2023, the Company's insurance note payable balance was $0.2 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. 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 consolidated financial statements and related notes hereto have been retroactively adjusted to account for the effect of the reverse stock split.

***Preferred Stock***

On April 6, 2022, the Company and DaVita entered into the Securities Purchase Agreement ("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. As of December 31, 2023, the Series X Preferred Stock accreted a total of $0.2 million.

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 and the sale of the assets that would allow for redemption is within the control of the Company, 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 mandatory redemption definition which could trigger liability classification.

As of December 31, 2023 and 2022, there were 2,000,000 shares of preferred stock, $0.0001 par value per share, authorized and 15,000 shares of preferred stock issued and outstanding.

***Common Stock***

As of December 31, 2023 and 2022, there were 170,000,000 shares of common stock, $0.0001 par value per share, authorized and 29,130,607 and 12,163,673 shares issued and outstanding, respectively.

As of December 31, 2023 and 2022, the Company 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 (collectively, "common stock equivalents"):

| | As of December 31, | |
|---|---|---|
| **Common stock and common stock equivalents:** | **2023** | **2022** |
| Common stock | 29,130,607 | 12,163,673 |
| Common stock issuable upon exercise of pre-funded warrants | — | 6,300,000 |
| Common stock and pre-funded stock warrants | 29,130,607 | 18,463,673 |
| Warrants to Purchase Common Stock | 3,793,388 | 10,196,268 |
| Convertible Preferred Stock | 1,363,636 | 1,363,636 |
| Options to Purchase Common Stock | 1,328,621 | 1,206,905 |
| Unvested Restricted Stock Units | 258,885 | 125,000 |
| Unvested Restricted Stock Awards | 891 | 891 |
| **Total** | 35,876,028 | 31,356,373 |

***Controlled Equity Offering***

On April 8, 2022, the Company entered into the Sales Agreement (the "ATM facility") with Cantor Fitzgerald & Co. as Agent, pursuant to which the Company may offer and sell from time to time up to $12.2 million of shares of Company's common stock through the Agent.

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.

During the quarter ended December 31, 2023, 640,944 shares were sold pursuant to the Sales Agreement for net proceeds of $1.1 million. Approximately $11.0 million remains available for sale under the ATM facility.

***Registered Direct Offering***

On May 30, 2022, the Company entered into the Registered Direct Purchase Agreement with the Purchaser, pursuant to which the Company issued and sold, 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 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 was $0.0001 per share. The Registered Direct Purchase Agreement contains customary representations and warranties and agreements of the Company and the Purchaser and customary indemnification rights and obligations of the parties.

During the year ended December 31, 2023, all of the remaining 6,300,000 Pre-Funded Warrants to purchase common stock were exercised at an exercise price of $0.0001 per share, which resulted in gross proceeds to the Company of $630. During the year ended December 31, 2022, 1,488,480 Pre-Funded Warrants to purchase common stock were exercised at an exercise price of $0.0001 per share, which resulted in gross proceeds to the Company of $149.

***Private Placement***

Also on May 30, 2022, concurrent with the Offering, the Company entered into the private investment in public equity "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 (the "PIPE Warrants") and pre-funded warrants to purchase up to a total of 1,267,897 shares of common stock (the "Pre-Funded PIPE Warrants"). Each warrant was sold at a price of $0.125 per underlying warrant share and was exercisable at an exercise price of $1.39 per share. The purchase price of each Pre-Funded PIPE 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 PIPE Warrant was $0.0001 per share. As of December 31, 2022, all Pre-Funded PIPE Warrants were exercised.

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 sheet 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.

On July 10, 2023, the Company entered into a letter agreement (the "Letter Agreement") with Armistice Capital Master Fund Ltd. ("Armistice"), which held a warrant (the "Prior Warrant") to purchase 9,900,990 shares of common stock of the Company (the "Common Stock") with an exercise price of $1.39 per share, offering Armistice the opportunity to exercise the Prior Warrant for cash, provided the Prior Warrant was exercised for cash on or prior to 5:00 P.M. Eastern Time on July 10, 2028 (the "End Date"). In addition, Armistice would receive a "reload" warrant (the "Reload Warrant") to purchase 3,750,000 shares of Common Stock with an exercise price of $5.13 per share, the closing price as reported by the Nasdaq Capital Market on July 7, 2023. The terms of the Reload Warrant and Letter Agreement provide for customary resale registration rights. The Reload Warrant may be exercised at all times prior to the 54 months month anniversary of its issuance date. The Prior Warrant and the Reload Warrant both provide that a holder (together with its affiliates) may not exercise any portion of the Prior Warrant or the Reload Warrant to the extent that 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 such warrant. To the extent the exercise of the Prior Warrant would result in Armistice holding more than 9.99% of the Company's outstanding Common Stock, such shares of Common Stock in excess of 9.99% will be held in abeyance. The Letter Agreement amended the Prior Warrant to extend the expiration date thereof to one year following the original expiration date set forth therein.

Armistice exercised the Prior Warrant on July 10, 2023, and the Company received gross proceeds of approximately $13.8 million.

**Note 13. Stock-Based Compensation**

The Board of Directors adopted the 2018 Long-Term Incentive Plan ("2018 LTIP") on January 29, 2018 as a replacement for the Company's prior 2007 Long Term Incentive Plan. As of December 31, 2023, the maximum number of shares of common stock with respect to which awards may be issued under the 2018 LTIP, as amended and restated, was 2,618,182. As of December 31, 2023, the 2018 LTIP had 1,403,325 shares of common stock available for grant. The Compensation Committee of the Board of Directors (the "Committee") is responsible for the administration of the 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 stock option agreements under the 2018 LTIP allow 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 2018 LTIP also allows 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 are retired.

The Company recognized total stock-based compensation expense during the years ended December 31, 2023 and 2022 as follows (table in thousands):

| | Year Ended December 31, | |
|---|---|---|
| | 2023 | 2022 |
| **Service based awards:** | | |
| Restricted stock units | $ 375 | $ 129 |
| Stock option awards | 557 | 576 |
| | 932 | 705 |
| **Performance based awards:** | | |
| Restricted stock awards | — | (390) |
| **Total** | $ 932 | $ 315 |

***Performance Based Restricted Stock Awards***

A summary of the Company's performance based restricted stock awards during the year ended December 31, 2023 is as follows:

| Performance Based Restricted Stock Awards | Number of Shares | Weighted Average Grant-Date Fair Value |
|---|---|---|
| Unvested at January 1, 2023 | 891 | $ 62.70 |
| Unvested at December 31, 2023 | 891 | $ 62.70 |

Performance-based 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, 2023, there is no unrecognized stock-based compensation expense related to performance-based 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, 2023 is as follows:

| Service Based Restricted Stock Units | Number of Shares | Weighted Average Grant-Date Fair Value |
|---|---|---|
| Unvested at January 1, 2023 | 125,000 | $ 1.47 |
| Granted | 313,065 | $ 1.87 |
| Forfeited | (54,180) | $ 1.37 |
| Vested | (125,000) | $ 1.47 |
| Unvested at December 31, 2023 | 258,885 | $ 1.83 |

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. As of December 31, 2023, the unrecognized stock-based compensation expense was $0.2 million which is expected to be recognized over the next 14 months.

***Service Based Stock Option Awards***

The fair value of the service based stock option awards granted for the years ended December 31, 2023 and 2022 were based on the following assumptions:

| | December 31, | |
|---|---|---|
| | 2023 | 2022 |
| Exercise price | $1.37 - $2.83 | $1.28 - $1.66 |
| Expected stock price volatility | 81.6% - 81.8% | 76.2% - 78.5% |
| Risk-free interest rate | 3.41% - 4.84% | 1.97% - 3.44% |
| Term (years) | 4.0 - 6.0 | 5.5 - 6.0 |

A summary of the Company's service based stock option activity for the year ended December 31, 2023 is as follows:

| Service Based Stock Option Awards | Shares Underlying Options | Weighted Average Exercise Price | Weighted Average Remaining Contractual Term | Aggregate Intrinsic Value *(in $1,000's)* |
|---|---|---|---|---|
| Outstanding at January 1, 2023 | 1,206,905 | $ 8.32 | | |
| Granted | 497,245 | $ 1.58 | | |
| Expired | (146,230) | $ 22.76 | | |
| Forfeited | (229,299) | $ 2.47 | | |
| Outstanding at December 31, 2023 | 1,328,621 | $ 5.22 | 8.5 | $ 450 |
| Exercisable at December 31, 2023 | 361,531 | $ 14.19 | 7.3 | $ 76 |

The aggregate intrinsic value in the table above is calculated as the difference between the closing price of the Company's common stock and the exercise price of the stock options that had strike prices below the closing price. The weighted average grant date fair value for service based stock option awards during the years ended December 31, 2023 and 2022 was $1.09 and $0.99, respectively.

As of December 31, 2023, total stock-based compensation expense related to 967,090 unvested options not yet recognized totaled approximately $0.7 million which is expected to be recognized over the next 3.0 years.

**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, 2023 and 2022, the Company has accrued $85,400 and $87,900, respectively, relating to certain IP reimbursement expenses and certain sublicense royalty fees as an accrued liability on the consolidated balance sheets.

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 is required to pay Charak a percentage of any sublicense income during the term of the agreement, which cannot 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, sub-licensable, 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 was 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, sub-licensable, 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, 2023.

**Note 15. Commitments and Contingencies**

**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 $618,000 in aggregate coverage for the policy year ending June 1, 2024. The total amount at December 31, 2023 by which retention limits exceed the claims paid and accrued is approximately $535,000 for the policy year ending July 1, 2023. Estimated loss and additional future claims of approximately $254,000 have been reserved and accrued for the year ended December 31, 2023.

As of December 31, 2023, approximately $0.4 million was held in cash collateral and escrow by the insurance carrier for workers' compensation insurance. At December 31, 2023, amounts held in cash collateral and escrow are included in prepaid expenses and other non-current assets in the consolidated financial statements.

**Litigation**

The Company may be involved in certain routine legal proceedings from time to time before various courts and governmental agencies. The Company cannot predict the final disposition of such proceedings. The Company regularly reviews 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 its operations or consolidated financial statements in the period in which they are resolved.

**Note 16. 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 and finance leases (dollars in thousands):

| | For the year ended December 31, | |
|---|---|---|
| | 2023 | 2022 |
| **Operating leases** | | |
| Operating lease cost | $ 1,672 | $ 1,710 |
| Variable lease cost | 497 | 388 |
| Operating lease expense | 2,169 | 2,098 |
| **Finance leases** | | |
| Amortization of right-of-use assets | 565 | 565 |
| Interest on lease obligations | 147 | 179 |
| Finance lease expense | 712 | 744 |
| Short-term lease rent expense | 17 | 17 |
| Total rent expense | $ 2,898 | $ 2,859 |
| | | |
| **Other information** | | |
| Operating cash flows from operating leases | $ 1,777 | $ 1,772 |
| Operating cash flows from finance leases | $ 147 | $ 179 |
| Financing cash flows from finance leases | $ 522 | $ 482 |
| Right of use assets obtained in exchange for operating lease liabilities | $ — | $ 768 |
| Weighted-average remaining lease term - operating leases | 2.3 | 3.0 |
| Weighted-average remaining lease term – finance leases | 3.5 | 4.4 |
| Weighted-average discount rate - operating leases | 6.5 % | 6.4 % |
| Weighted-average discount rate – finance leases | 6.4 % | 6.4 % |

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

| | Operating | Finance |
|---|---|---|
| Year ending December 31, 2024 | $ 1,511 | $ 672 |
| Year ending December 31, 2025 | 1,021 | 676 |
| Year Ended December 31, 2026 | 362 | 666 |
| Year Ended December 31, 2027 | 129 | 311 |
| Year Ended December 31, 2028 | 2 | — |
| Total | 3,025 | 2,325 |
| Less present value discount | (211) | (237) |
| Operating and Finance lease liabilities. | $ 2,814 | $ 2,088 |

**Note 17. 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 additional tranches, which were tied to the achievement of certain milestones. Net draw down proceeds were $21.2 million with closing costs of $1.3 million. The Company also owes an additional fee equal to 4.375% of the funded amount of the Term Loans, or $1.0 million (such additional fee, the “Final Fee”) at maturity. The Company is accreting up to this Final Fee premium with a charge against interest expense on the accompanying consolidated statements of operations.

In connection with each funding of the Term Loans, the Company was 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. In connection with the first tranche of the Term Loans, the Company issued a Warrant to Innovatus, exercisable for, after considering the impact of the reverse stock split as further described in Note 12, an aggregate of 43,388 shares of the Company’s common stock at an exercise price of $18.15 per share. The Warrant may be exercised on a cashless basis and is immediately exercisable through the seventh anniversary of the applicable funding date. The number of shares of common stock for which the Warrant is exercisable and the associated exercise price are subject to certain proportional adjustments as set forth in such Warrant. 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.

The Term Loan was scheduled to mature on March 16, 2025, and 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 12.50% as of December 31, 2023. The Company had 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, 2023, interest expense amounted to $1.2 million.

The Loan Agreement is secured by all assets of the Company and Rockwell Transportation, Inc. and contains customary representations and warranties and covenants, subject to customary carve outs, and initially included financial covenants related to liquidity and sales of Triferic. There can be no assurances that the Company can maintain compliance with the covenants under the Loan Agreement, which may result in an event of default. The Company's ability to comply with these covenants may be adversely affected by events beyond its control. For example, the Loan Agreement contains certain financial covenants relating to sales and, as a result of geopolitical and other factors, the Company 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, 2023 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 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 additional aggregate principal amount of $5.0 million in Term Loans in one installment on November 14, 2022; and (ii) paid interest only payments until September 2023, at which time it resumed scheduled debt payments. The financial covenant related to the sales of Triferic was replaced with the trailing 6 months revenue of our concentrates products. The Company's ability to comply with the covenants under the Loan Agreement may be adversely affected by events beyond its control. 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. 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. However, as of December 31, 2023, the Company was in compliance with its covenants under the Loan Agreement.

On January 2, 2024, the Company's Loan Agreement was amended to include, among other things, an interest-only period for 30 months, or up to 36 months if certain conditions are met, and extend the maturity date to January 1, 2029. (See Note 19 for further detail).

As of December 31, 2023, the outstanding balance of the Term Loan was $8.3 million, net of unamortized issuance costs, discount of $0.4 million, and including $0.7 million of premium accretion.

The following table reflects the schedule of principal payments on the Term Loan as of December 31, 2023 after giving effect to the January 2, 2024 amendment (in thousands):

| Year | Principal Payments |
|---|---|
| 2024 | $ — |
| 2025 | $ — |
| 2026 | $ 1,333 |
| 2027 | 3,200 |
| 2028 | 3,200 |
| 2029 | 267 |
| Total | $ 8,000 |

**Note 18. 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):

| | Year Ended December 31, | |
|---|---|---|
| | 2023 | 2022 |
| Tax Benefit Computed of Pretax Loss | $ (1,772) | $ (4,361) |
| Changes in Tax Laws | — | — |
| Foreign Income Tax Expense | — | — |
| Effect of Change in Valuation Allowance | 1,772 | 4,361 |
| Total Income Tax Expense | $ — | $ — |

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

| | December 31, | |
|---|---|---|
| | 2023 | 2022 |
| Deferred tax assets: | | |
| Net Operating Loss Carryforward | $ 72,612 | $ 70,686 |
| Stock Based Compensation | 7,856 | 7,792 |
| General Business Credit | 6,872 | 6,872 |
| Research & Experimental Expenses | 459 | 371 |
| Inventories | 398 | 234 |
| Accrued Expenses | 144 | 605 |
| Deferred License Revenue | 118 | 983 |
| Other Deferred Tax Assets | 1,989 | 1,274 |
| Total Deferred Tax Assets | 90,448 | 88,817 |
| Deferred Tax Liabilities: | | |
| Goodwill & Intangible Assets | 259 | 224 |
| Prepaid Expenses | 181 | 316 |
| Book over Tax Depreciation | 35 | 8 |
| Total Deferred Tax Liabilities | 475 | 548 |
| Subtotal | 89,973 | 88,269 |
| Valuation Allowance | (89,973) | (88,269) |
| Net Deferred Tax Asset | $ — | $ — |

Deferred tax assets result primarily from net operating loss carryforwards. For federal tax purposes, we have net operating loss carryforwards of approximately $321.4 million of which approximately $164.7 million began expiring in 2023 and will continue to expire through 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, 2023 and 2022. Considered together with the Company's limited history of operating income and its net losses in 2023 and 2022, management has placed a full valuation allowance against the net deferred tax assets as of December 31, 2023 and 2022.

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, 2023 and 2022. The Company has not been under tax examination in any jurisdiction for the years ended December 31, 2023 and 2022. A recent IRC Section 382 study has not been performed, which could limit the value of the Company's net operating losses.

**Note 19. Subsequent Events**

***Third Amendment to Loan Agreement***

On January 2, 2024, the Company and Rockwell Transportation, Inc. entered into the Third Amendment to and Restatement of the Loan and Security Agreement (the "A&R Loan Agreement") with Innovatus, dated January 1, 2024 (the "A&R Effective Date"). The A&R Loan Agreement provides for the continuation of term loans initially borrowed under the Loan Agreement amounting to $8.0 million as of the A&R Effective Date. The Company will make interest-only payments on the Term Loans for 30 months, or up to 36 months if certain conditions are met. The Term Loans will mature on the fifth anniversary of the A&R Effective Date, unless earlier repaid. The Term Loans will bear interest at the greater of (i) Prime Rate (as defined in the A&R Loan Agreement) and (ii) 7.50%, plus 3.50%. At the Company's option, 2.00% of the interest due on any applicable interest payment date during the interest-only period may be paid in-kind by adding such amount to the then outstanding principal balance of the Term Loans.

The Term Loans may be voluntarily prepaid in full (but not partially) at any time, upon at least seven business days' prior notice. In connection with any voluntary prepayment or satisfaction of the Term Loans prior to the maturity date

(including any acceleration), the Company will pay all accrued and unpaid interest and all other amounts due in connection with the Term Loans, together with (x) a prepayment fee (the "Prepayment Fee") equal to: (i) 6.0% of the principal amount of the Term Loans prepaid if the payment is made before the first anniversary of the A&R Effective Date; (ii) 2.0% of the principal amount of the Term Loans prepaid if the payment is made after the first anniversary of the A&R Effective Date but on or before the second anniversary of the A&R Effective Date; (iii) 1.0% of the principal amount of the Term Loans prepaid if the payment is made after the second anniversary of the A&R Effective Date but on or before the third anniversary of the A&R Effective Date; or (iv) 0% of the principal amount of the Term Loans prepaid if the payment is made after the third anniversary of the A&R Effective Date through maturity, and (y) an additional fee equal to 4.375% of the funded amount of the Term Loans Final Fee. The Term Loans will be mandatorily prepaid upon a change in control of the Company, or upon any early termination/ acceleration of the Term Loans. In the event of a mandatory prepayment of the Term Loans, the Company shall be required to pay the Prepayment Fee (if applicable), as well as the Final Fee. The Final Fee shall be due and payable at maturity if it has not previously been paid in full in connection with a prepayment of the Term Loans.

The A&R Loan Agreement is secured by all assets of the Company and Rockwell Transportation, Inc. Proceeds were used for working capital purposes. The A&R Loan Agreement contains customary representations and warranties and affirmative and negative covenants, subject to exceptions as described in the A&R Loan Agreement. The A&R Loan Agreement includes a financial covenant that requires actual consolidated revenue from the sale and supply of hemodialysis products for the trailing six-month period (ended on the date when tested), to be not less than 85.0% of the projections for the same period and, beginning with the quarter ending September 30, 2024, actual consolidated revenue from the sale and supply of hemodialysis products for the trailing six-month period (ended on the date when tested), to be not less than 80.0% of the projections for the same period. The A&R Loan Agreement also includes a financial covenant that requires that the Company to maintain minimum liquidity of the greater of (x) the Company's three-month cash burn or (y) the sum of $1.5 million and the aggregate amount of finance lease payments required to be made during the succeeding 12 months (or during a continuing event of default, the aggregate amount of finance lease payments required to be made during the entire term of such capital leases).

In connection with the execution of the A&R Loan Agreement, on January 2, 2024, the Company issued to Innovatus a warrant to purchase 191,096 shares of the Company's common stock with an exercise price of $1.83 per share. The warrant may be exercised on a cashless basis, and is immediately exercisable through the January 2, 2029. The number of shares of common stock for which the warrant is exercisable and the exercise price are subject to certain proportional adjustments as set forth in the warrant.

# ROCKWELL MEDICAL, INC.

## Corporate Information

### Annual Meeting

The Annual Meeting of the Stockholders will be held:

Tuesday May 21, 2024
At 10:00 am ET
Virtual Stockholder Meeting
www.virtualshareholdermeeting.com/RMTI2024

### 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, 2023 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: ir.rockwellmed.com

Reports and exhibits are available on-line through our website at ir.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".


# 2023 ANNUAL REPORT

www.rockwellmed.com

**ROCKWELL MEDICAL, INC.**
**NOTICE OF 2024 ANNUAL MEETING OF STOCKHOLDERS**
**To Be Held May 21, 2024**

To the Stockholders of Rockwell Medical, Inc.:

Notice is hereby given that the 2024 Annual Meeting of Stockholders (the ''Annual Meeting'') of Rockwell Medical, Inc. (the ''Company'') will be held as a virtual stockholder meeting at 10:00 a.m. Eastern Time, on May 21, 2024 to consider and take action upon the following matters:

(1) To elect the two Class III directors named in the proxy statement, each to serve for a three-year term expiring at the 2027 annual meeting of stockholders and until his successor has been duly elected and qualified;

(2) To approve, on an advisory basis, the compensation of the Company's named executive officers;

(3) To ratify the selection of EisnerAmper LLP as the Company's independent registered public accounting firm for 2024; and

(4) To transact any other business which may properly come before the Annual Meeting or any adjournment thereof.

Only stockholders of record at the close of business on March 25, 2024 will be entitled to notice of, and to vote at, the Annual Meeting or any adjournment or postponement of the Annual Meeting. You may attend the Annual Meeting, vote and submit a question during the meeting online at www.virtualshareholdermeeting.com/RMTI2024.

All stockholders as of the record date are cordially invited to attend the Annual Meeting. WHETHER OR NOT YOU INTEND TO BE PRESENT, PLEASE COMPLETE, DATE, SIGN AND RETURN THE ENCLOSED PROXY CARD IN THE STAMPED AND ADDRESSED ENVELOPE ENCLOSED FOR YOUR CONVENIENCE. Stockholders can help the Company avoid unnecessary expense and delay by promptly returning the enclosed proxy card. The business of the Annual Meeting to be acted upon by the stockholders cannot be transacted unless a majority of the outstanding shares of common stock of the Company is represented at the Annual Meeting.

By Order of the Board of Directors,
/s/ Megan Timmins
Megan Timmins
*Secretary*

Wixom, Michigan
April 15, 2024

**Important Notice Regarding the Availability of Proxy Materials for the Annual Meeting of Stockholders to Be Held on May 21, 2024**.

**This notice of meeting, the proxy statement, the proxy card and the Company's 2023 Annual Report to Stockholders, which includes the Annual Report on Form 10-K, are available online at www.virtualshareholdermeeting.com/RMTI2024. Stockholders may request a copy of the notice of meeting, the proxy statement, proxy card and 2023 Annual Report to Stockholders by contacting the Company at ir@rockwellmed.com or (800) 449-3353, or online at *http://www.rockwellmed.com.***

**ROCKWELL MEDICAL, INC.**
**30142 Wixom Road, Wixom, Michigan 48393**

# PROXY STATEMENT

## 2024 ANNUAL MEETING OF STOCKHOLDERS
**May 21, 2024**

## INTRODUCTION

This proxy statement (the ''Proxy Statement'') is being furnished to stockholders by the Board of Directors (the ''Board'') of Rockwell Medical, Inc. (the ''Company'') in connection with the solicitation of proxies by the Board for use at the 2024 annual meeting of stockholders of the Company to be held on May 21, 2024 at 10:00 a.m. Eastern Time, and all adjournments or postponements thereof (the ''Annual Meeting'') for the purposes set forth in the attached Notice of 2024 Annual Meeting of Stockholders. The Annual Meeting will be held as a virtual (online) meeting. You may attend the Annual Meeting, vote and submit a question during the meeting online at *www.virtualshareholdermeeting.com/RMTI2024.*

A proxy, in the enclosed form, which is properly executed, duly returned to the Company and not revoked, will be voted in accordance with the instructions contained therein. The shares represented by executed but unmarked proxies will be voted as follows:

(1) **FOR** the election of the two Class III directors nominated by our Board, each to serve for a three-year term expiring at the 2027 annual meeting of stockholders and until his successor has been duly elected and qualified (''Proposal 1'');

(2) **FOR** the approval, on an advisory basis, of the compensation of the Company's named executive officers (''Proposal 2''); and

(3) **FOR** the ratification of the selection of EisnerAmper LLP as the Company's independent registered public accounting firm for 2024 (''Proposal 3'').

With respect to such other business which may properly come before the Annual Meeting or any adjournment thereof, votes will be cast in the discretion of the appointed proxies.

These proxy materials are first being sent or made available to stockholders on or about April 15, 2024. References in this Proxy Statement to the "Company," "we," "our" and "us" are references to Rockwell Medical, Inc.

It is important that your shares are represented at the Annual Meeting. Whether or not you plan to attend the Annual Meeting, please sign and date the enclosed proxy card and return it to us. If you own your shares through a broker, bank or other nominee, please return your voting instruction form to your broker, bank or nominee, or use the electronic voting means described below to vote your shares.

**TABLE OF CONTENTS**


| | |
|---|---|
| QUESTIONS AND ANSWERS | 1 |
| PROPOSAL 1 ELECTION OF DIRECTORS | 5 |
| DIRECTORS CONTINUING IN OFFICE | 8 |
| CORPORATE GOVERNANCE | 10 |
| EXECUTIVE OFFICERS | 15 |
| COMPENSATION OF EXECUTIVE OFFICERS | 16 |
| PROPOSAL 2 ADVISORY VOTE ON THE COMPENSATION OF OUR NAMED EXECUTIVE OFFICERS | 28 |
| PROPOSAL 3 RATIFICATION OF SELECTION OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM FOR 2024 | 29 |
| SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT | 31 |
| CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS | 32 |
| OTHER MATTERS | 33 |

## QUESTIONS AND ANSWERS

***Why am I receiving these proxy materials?***

You are receiving these proxy materials, including this Proxy Statement, the Notice of the 2024 Annual Meeting of Stockholders, the 2023 Annual Report and the proxy card or voting instruction form, in connection with the solicitation of proxies by the Board for use at the Annual Meeting to be held on May 21, 2024 at 10:00 a.m. Eastern Time, and all adjournments or postponements thereof. The Annual Meeting will be held as a virtual (online) meeting. You may attend the Annual Meeting, vote and submit a question during the meeting by visiting *www.virtualshareholdermeeting.com/RMTI2024*.

***Who is entitled to vote at the Annual Meeting?***

Only stockholders of record of our common stock, par value $0.0001 per share, which we refer to as our common stock, at the close of business on March 25, 2024, the record date for the Annual Meeting, will be entitled to notice of, and to vote at, the Annual Meeting or any adjournment or postponement thereof. As of the close of business on the record date, we had 29,364,617 shares of common stock outstanding, the only class of stock outstanding and entitled to vote. Each share of common stock is entitled to one vote on each matter submitted for a vote at the Annual Meeting. The presence, in person or by proxy, of the holders of record of a majority of the outstanding shares of common stock entitled to vote is necessary to constitute a quorum for the transaction of business at the Annual Meeting or any adjournment or postponement thereof. Abstentions and broker non-votes will be counted toward the quorum requirement.

Valid proxies in the enclosed form which are timely returned and executed and dated in accordance with the instructions on the proxy will be voted as specified in the proxy. If no specification is made, the proxies will be voted ''**FOR**'' the director nominees listed in Proposal 1, and ''**FOR**'' Proposals 2 and 3.

***How do I vote if I hold my shares in "street name"?***

If your shares are held in a stock brokerage account or by a bank or other nominee, then you are **not** legally a stockholder of record but, rather, are considered to own your shares in ''street name'' and you will need to direct your broker, bank or nominee, who is considered the stockholder of record of your shares, how to vote your shares.

If you hold your shares in street name as of the record date, the notice of meeting, the Proxy Statement, the 2023 Annual Report and a voting instruction form have been forwarded to you by your broker, bank or nominee. As the beneficial or ''street name'' owner, you have the right to direct your broker, bank or nominee how to vote your shares by using the voting instruction form included in the mailing. If you are the beneficial owner and do not direct your broker, bank or nominee how to vote your shares, your broker, bank or nominee will only be able to vote your shares with respect to proposals considered to be ''routine''. Your broker, bank or nominee is not entitled to vote your shares with respect to ''non-routine'' proposals, which we refer to as a ''broker non-vote.'' Whether a proposal is considered routine or non-routine is subject to stock exchange rules and final determination by the stock exchange. Even with respect to routine matters, some brokers are choosing not to exercise discretionary voting authority. As a result, we urge you to direct your broker, bank or nominee how to vote your shares on all proposals to ensure that your vote is counted.

A ***street name holder*** may provide instructions to their broker, bank or nominee on how to vote their shares in any of the following ways:

- By completing, signing and dating each voting instruction form received and returning it in the envelope provided; or
- By Internet at *www.proxyvote.com* and following the instructions outlined on the secure website (have your 12-digit control number available).

***How do I vote if I am a stockholder of record?***

You are considered a stockholder of record if your shares are registered directly in your name with our transfer agent. If you are a stockholder of record, you may vote your shares in either of the following ways:

- By signing and dating each proxy card you received and returning it in the envelope provided; or
- By attending the virtual Annual Meeting by visiting *www.virtualshareholdermeeting.com/RMTI2024*.

***How Can I Participate in the Virtual Annual Meeting?***

Stockholders of record as of the close of business on the record date are entitled to participate in and vote at the Annual Meeting. To participate in the Annual Meeting, including to vote and ask questions during the meeting, stockholders of record should go to the meeting website at *www.virtualshareholdermeeting.com/RMTI2024*, enter the 16-digit control number found on your proxy card or notice, and follow the instructions on the website. If your shares are held in street name and your voting instruction form or notice indicates that you may vote those shares through *www.proxyvote.com*, then you may access, participate in and vote at the Annual Meeting with the 16-digit access code indicated on that voting instruction form or notice. Otherwise, stockholders who hold their shares in street name should contact their bank, broker or other nominee (preferably at least five days before the Annual Meeting) and obtain a ''legal proxy'' in order to be able to attend, participate in or vote at the Annual Meeting.

We will endeavor to answer as many stockholder-submitted questions as time permits that comply with the Annual Meeting rules of conduct. We reserve the right to edit profanity or other inappropriate language and to exclude questions regarding topics that are not pertinent to meeting matters or Company business. If we receive substantially similar questions, we may group such questions together and provide a single response to avoid repetition.

The meeting webcast will begin promptly at 10:00 a.m. Eastern Time. Online check-in will begin approximately 15 minutes before the meeting start time. We encourage you to allow ample time for check-in procedures. If you experience technical difficulties during the check-in process or during the meeting, please call the number listed on the meeting website for technical support. Additional information regarding the rules and procedures for participating in the Annual Meeting will be set forth in our meeting rules of conduct, which stockholders can view during the meeting at the meeting website.

***What am I voting on?***

The proposals to be voted on at the Annual Meeting are as follows:

(1) To elect the two Class III directors nominated by the Board, each to serve for a three-year term expiring at the 2027 annual meeting of stockholders and until his successor has been duly elected and qualified;

(2) To approve, on an advisory basis, the compensation of the Company's named executive officers;

(3) To ratify the selection of EisnerAmper LLP as the Company's independent registered public accounting firm for 2024.

***How does the Board recommend that I vote?***

The Board recommends that you vote your shares of common stock ''**FOR**'' the director nominees listed in Proposal 1 and ''**FOR**'' Proposals 2 and 3.

***What votes are required by our stockholders on the Board's proposals and how are votes counted?***

Votes will be counted by the Inspector of Elections appointed for the Annual Meeting.

*Proposal 1: Election of Class III Directors*

In an uncontested election (*i.e.*, an election where the number of director nominees equals the number of director positions up for election), such as the one taking place at the Annual Meeting, directors are elected by a majority of the votes cast, meaning each director nominee must receive a greater number of shares of common stock voted ''FOR'' his election than the number of shares of common stock voted ''AGAINST'' his election in order to be elected. Broker non-votes, if any, and abstentions will not be counted as votes cast on the matter and will have no effect on the outcome of this proposal.

*Proposal 2: Advisory Approval of Executive Compensation*

The affirmative vote of the holders of shares of common stock representing a majority of the votes cast on the matter is required for the advisory approval of executive compensation. Broker non-votes, if any, and abstentions will not be counted as votes cast on the matter and will have no effect on the outcome of this proposal.

*Proposal 3: Ratification of Selection of Independent Registered Public Accounting Firm*

The affirmative vote of the holders of shares of common stock representing a majority of the votes cast on the matter is required for the ratification of the selection of our independent registered public accounting firm for the year ended December 31, 2024. Broker non-votes, if any, and abstentions will not be counted as votes cast on the matter and will have no effect on the outcome of this proposal.

***Can I change my vote after I have mailed my proxy card?***

A stockholder who has submitted a completed proxy may revoke it at any time before it is voted at the Annual Meeting by giving written notice of such revocation to our Secretary or by executing and delivering to the Secretary a later dated proxy. Attendance at the Annual Meeting by a stockholder who has submitted a proxy will not have the effect of revoking it unless such stockholder votes at the Annual Meeting or submits written notice of revocation to the Company's Secretary before the proxy is voted.

Any written notice revoking a proxy, and any later dated proxy, must be received by the Company prior to the date of the Annual Meeting (unless delivered directly to the Company's Secretary at the Annual Meeting) and should be sent to Rockwell Medical, Inc., 30142 Wixom Road, Wixom, MI 48393, Attention: Secretary.

***What if another matter is properly brought before the Annual Meeting?***

As of the date of filing this Proxy Statement, the Board knows of no other matters that will be presented for consideration at the Annual Meeting. If any other matters are properly brought before the Annual Meeting, it is the intention of the persons named as proxies in the accompanying proxy card to vote on such matters in accordance with their best judgment.

***Who is paying for this proxy solicitation?***

We will pay the costs associated with the solicitation of proxies, including the preparation, assembly, printing and mailing of the proxy materials. We have retained InvestorCom LLC, at 19 Old Kings Highway S., Suite 130, Darien, CT 06820, to act as a proxy solicitor in connection with the Annual Meeting at a cost of $6,500 plus reasonable out-of-pocket expenses. If you have questions about the Annual Meeting, please contact InvestorCom at (203) 972-9300 or toll free at (877) 972-0090, or email them at info@investor-com.com.

In addition, our employees, officers and directors may solicit proxies in person or via telephone or the Internet. We will not pay additional compensation for any of these services. We may also reimburse brokers, fiduciaries or custodians for the cost of forwarding proxy materials to beneficial owners of shares of common stock held in ''street name.''

***How can I find out the voting results?***

We expect to announce preliminary voting results at the Annual Meeting. Final voting results will be published in a Current Report on Form 8-K to be filed with the U.S. Securities and Exchange Commission (the ''SEC'') within 4 business days after the Annual Meeting.

***Who can help answer my questions?***

If you have any questions about the Annual Meeting or how to vote or revoke your proxy, please contact Investor Com at:

InvestorCom LLC
19 Old Kings Highway S., Suite 130
Darien, CT 06820
Telephone: (203) 972-9300 or Toll Free (877) 972-0090
Fax: (203) 621-3333
E-mail: info@investor-com.com

You also can contact us at:

Rockwell Medical, Inc.
30142 Wixom Road
Wixom, MI 48393
Telephone: (800) 449-3353
E-mail: ir@rockwellmed.com

## PROPOSAL 1
## ELECTION OF DIRECTORS

### Background

Our Board is divided into three classes, designated Class I, Class II and Class III. Each year, on a rotating basis and until their successor has been elected and qualified, the terms of office of the directors in one of the three classes expire. Successors to the class of directors whose terms have expired will be elected for a three-year term. The terms of each of the Class III Directors will expire at the Annual Meeting, the terms of each of the Class I Directors will expire at the 2025 annual meeting of stockholders and the terms of each of the Class II Directors will expire at the 2026 annual meeting of stockholders, in each case upon the election and qualification of the applicable successors.

Set forth below are the names and certain information for each continuing member of the Board, including the nominees for election as Class III directors, as of March 1, 2024. The information presented includes each director's and nominee's principal occupation and business experience for the past five years, and the names of other public companies of which he or she has served as a director during the past five years. The information presented below regarding the specific experience, qualifications, attributes and skills of each director and nominee led our Nominating and Governance Committee and our Board to conclude that he or she should serve as a director. In addition, we believe that all of our directors and nominees possess the attributes or characteristics described in ''Corporate Governance—Governance and Nominating Committee'' that the Governance and Nominating Committee expects of each director. There are no family relationships among any of our directors, nominees for director, or executive officers.

| Name | Age | Position(s) |
|---|---|---|
| *Class III Directors:* | | |
| Mark Strobeck, Ph.D. | 53 | President and Chief Executive Officer, Director |
| Robert S. Radie | 60 | Chairman |
| *Class I Directors:* | | |
| Allen Nissenson, MD[(1)(3)] | 77 | Director |
| John G. Cooper[(1)(2)] | 65 | Director |
| *Class II Director Nominees:* | | |
| Joan Lau, Ph.D.[(1)(2)] | 53 | Director |
| Mark H. Ravich[(2)(3)] | 71 | Director |
| Andrea Heslin Smiley[(1)(3)] | 56 | Director |

(1) Member of the Compensation Committee.

(2) Member of the Audit Committee.

(3) Member of the Nominating and Governance Committee.

### Nominees For Reelection to Our Board

***Class III Directors (Terms Expiring 2027):***

*Mark Strobeck, Ph.D.* has served as our President, CEO and a director since July 2022. He served as Managing Director of Aquilo Partners, LP, a life sciences investment bank, from May 2021 to June 2022. He previously served as Executive Vice President and Chief Operating Officer of Assertio Holdings, Inc., a pharmaceutical company, from May 2020 to December 2020. Prior to that, Dr. Strobeck was Executive Vice President and Chief Operating Officer of Zyla Life Sciences, a pharmaceutical company, from September 2015 through its merger with Assertio Holdings, Inc. in May 2020, and previously served as Zyla's Chief Business Officer from January 2014 to September 2015. Before his employment at Zyla, he served as Zyla's advisor from June 2012 to December 2013. From January 2012 to December 2013, he served as President and Chief Executive Officer and a director of Corridor Pharmaceuticals, Inc., a pharmaceuticals company, which was acquired by AstraZeneca plc in 2014. From December 2010 to October 2011, Dr. Strobeck served as Chief Business Officer of Topaz Pharmaceuticals Inc., a specialty pharmaceutical company acquired by Sanofi Pasteur in the fourth quarter of 2011. From June 2010 to November 2010 and October 2011 to January 2012, Dr. Strobeck worked as a consultant. From January 2008 to May 2010, Dr. Strobeck served as Chief Business Officer of Trevena, Inc., a pharmaceutical company. Prior to joining Trevena, Dr. Strobeck held management roles at GlaxoSmithKline plc, a pharmaceuticals company, and

venture capital firms SR One Limited and EuclidSR Partners, L.P. Dr. Strobeck has served on the Board of Directors of Windtree Therapeutics, Inc. since June 2023. He also currently serves on the board of directors of Horse Power For Life, a nonprofit organization dedicated to improving the quality of life for individuals diagnosed with cancer, a position he has held since 2012. Dr. Strobeck received his B.S. in Biology from St. Lawrence University and his Ph.D. in Pharmacology and Biophysics from the University of Cincinnati, and completed his post-doctoral fellowship at the University of Pennsylvania.

We believe that Dr. Strobeck's role as Chief Executive Officer and President of our Company and his extensive scientific knowledge, coupled with his extensive management experience in the biopharmaceutical industry, and experience in the capital markets qualify him for service as a director of our Company.

*Robert S. Radie* has been a director since March 2020 and Chairman of the Board since April 2022. Mr. Radie has served as Chief Executive Officer and Chairman of the board of directors of Neuraptive Therapeutics, Inc., a private, clinical stage company focused on improving outcomes in traumatic peripheral nerve injury, since June 2020. He previously served as President and Chief Executive Officer and a member of the board of directors of Zyla Life Sciences, a life sciences company, from March 2012 to October 2019. From November 2010 to October 2011, Mr. Radie served as President and Chief Executive Officer of Topaz Pharmaceuticals Inc., a specialty pharmaceutical company. From March 2009 to November 2010, Mr. Radie served as President and Chief Executive Officer of Transmolecular, Inc., a biotechnology company, after serving as a consultant to Transmolecular from December 2008 through March 2009. From September 2007 to September 2008, Mr. Radie served as the Chief Business Officer of Prestwick Pharmaceuticals, Inc., a specialty pharmaceutical company. Before joining Prestwick, Mr. Radie served in senior management positions with a number of pharmaceutical and biotechnology companies, including Morphotek, Inc., Vicuron Pharmaceuticals, Inc. and Eli Lilly and Company. Mr. Radie has been a member of the board of directors ValSource Inc. since October 2020 and a member of the board of directors of Orcosa Inc since January 2024. He has also served as a director of Horse Power for Life, a nonprofit organization of to improving the quality of life for individuals diagnosed with cancer, since 2006. Mr. Radie previously served as a member of the board of directors of Paratek Pharmaceuticals from November 2014 to September 2023, Veloxis Pharmaceuticals A/S from June 2016 to February 2020 and Affinium Pharmaceuticals, Ltd. from July 2012 to March 2014. He also served as a Director for Life Science PA, an industry advocacy group in Pennsylvania. Mr. Radie received his B.S. in Chemistry from Boston College.

We believe that Mr. Radie's prior executive management, finance, commercialization, capital raising, investor relations and public company experience in the life sciences industry qualifies him for service as a director of our Company.

**Recommendation of the Board**

Upon the recommendation of the Nominating and Governance Committee of the Board, the Board has nominated each of Dr. Strobeck and Mr. Radie for election as directors. Each of Dr. Strobeck and Mr. Radie's terms as a director will expire at the 2027 Annual Meeting as a Class III Director and upon the election and qualification of his successor subject to prior death, resignation, retirement, disqualification or removal. Each of Dr. Strobeck and Mr. Radie currently serves as a Class III director and has indicated a willingness to continue to serve as a director.

Unless contrary instructions are given, the shares represented by a properly executed proxy will be voted FOR the election of each nominee. Should any of the nominees become unavailable to accept election as a director, the persons named in the enclosed proxy will vote the shares as they represent for the election of such other person as the Board may recommend or the Board may decrease the size of the Board. Management has no reason to believe that any nominee is unavailable or will not serve if elected.

Information regarding the remainder of our Board, along with corporate governance information, can be found starting on Page 10 of this Proxy Statement.

**Vote Required**

In an uncontested election (*i.e.*, an election where the number of director nominees equals the number of director positions up for election), such as the one taking place at the Annual Meeting, directors are elected by a majority of the votes cast, meaning each director nominee must receive a greater number of shares of common stock voted ''FOR'' his or her election than the number of shares of common stock voted ''AGAINST'' his election in order to be elected.

Under our Principles of Corporate Governance and Majority Voting Policy, any nominee who receives a greater number of votes ''AGAINST'' their election than votes ''FOR'' their election must tender their resignation to the Nominating and Governance Committee. The Nominating and Governance Committee will then recommend to the Board whether to accept or reject the resignation offer, or whether other action should be taken. In determining whether to recommend that the Board accept any resignation offer, the Nominating and Governance Committee may consider all factors that the committee's members believe are relevant. The Company will promptly disclose the Board's decision-making process and decision regarding whether to accept a resignation offer in a Current Report on Form 8-K filed with the SEC. Nominees generally will not participate in the Nominating and Governance Committee's or the Board's considerations of the appropriateness of their continued service, but may otherwise remain active and engaged in all other Board-related activities, deliberations and decisions while consideration of such director's resignation is ongoing.

Broker non-votes, if any, and abstentions will not be counted as votes cast on the matter and will have no effect on the outcome of this proposal.

**THE BOARD RECOMMENDS A VOTE "FOR"
THE NOMINEES FOR DIRECTOR**

## DIRECTORS CONTINUING IN OFFICE

### Information Relating to Our Continuing Directors

***Class I Director (Term Expiring 2025):***

*John G. Cooper* has been a director and Chair of the Audit Committee since September 2017. Mr. Cooper is currently principal of JGC Advisors, providing corporate development and financial advisory services to emerging life science companies, and serves on the strategic advisory board of IC Surgical, Inc. From 2001 to 2016, Mr. Cooper was a senior executive for Windtree Therapeutics Inc. (formerly Discovery Laboratories, Inc.), a publicly traded bio pharmaceutical company and the first to receive FDA approval for a synthetic peptide-containing surfactant to address premature infants with respiratory distress syndrome. At Discovery Labs, Mr. Cooper served as president, chief executive officer and a member of the board of directors from 2013 to 2016, president and chief financial officer from 2010 to 2013, executive vice president and chief financial officer from 2002 to 2010 and senior vice president and chief financial officer from 2001 to 2002. Previously, Mr. Cooper served as senior vice president and chief financial officer at Chrysalis International Corporation, a public company providing drug development services to the biopharmaceutical industry, and DNX Corporation, a public life sciences company pioneering transgenic technology for xenotransplantation and biotherapeutic development. Previously, Mr. Cooper served as a financial executive at ENI Diagnostics, Inc., a public life sciences company (acquired by Pharmacia AB) that developed and commercialized the second FDA-approved blood diagnostic test for HIV and a financial analyst at CR Bard, Inc., a public medical device company. Mr. Cooper earned a certified public accountant credential in 1985 and his B.S. in Commerce from Rider University.

We believe that Mr. Cooper's extensive executive management, finance and accounting, capital raising, strategic alliance, investor relations and governance experience with public companies in the life sciences industry qualifies him for service as a director and Chair of the Audit Committee of our Company.

*Allen Nissenson, MD* has been a director since June 2020. Dr. Nissenson served as Emeritus Chief Medical Officer of DaVita Kidney Care, a division of DaVita HealthCare Partners, a healthcare company, from January 2020 to January 2022. He previously served as Chief Medical Officer of DaVita Kidney Care from August 2008 to December 2019. Dr. Nissenson is also currently an Emeritus Professor of Medicine at the David Geffen School of Medicine at University California Los Angeles, a public research university, where he previously served as Director of the Dialysis Program and Associate Dean. He has served on the board of directors of Elicio Therapeutics (formerly Angion Biomedica Corp.), an early-stage cancer vaccine company, since January 2020. Dr. Nissenson has also served on the board of Diality, Inc. since 2021 and Innocura Nephrology since 2023. He is the immediate past Chair of Kidney Care Partners and immediate past Co-Chair of the Kidney Care Quality Alliance. He is a former president of the Renal Physicians Association and current member of the Government Affairs Committee. Dr. Nissenson also previously served as President of the Southern California End-Stage Renal Disease Network, as well as Chair of the Medical Review Board. Dr. Nissenson earned his B.S. from Northwestern University and his M.D. from Northwestern University Medical School.

We believe Dr. Nissenson's expertise in the renal health space and extensive experience as both a public company executive, clinician and professor, qualify him for service as a director of our Company.

***Class II Director Nominees (Terms Expiring 2026):***

*Mark H. Ravich* has been a director since June 2017. Mr. Ravich currently serves as president of Tri-Star Management, Inc., a commercial real estate management and syndication company that he co-founded in 1998. From October 2010 through December 2022, Mr. Ravich served as a director of Dilon Technologies, Inc., a designer and manufacturer of medical imaging solutions. In addition, from February 2019 to March 2023, Mr. Ravich served as a director of BioVentrix Inc., a manufacturer of devices to improve and expand the treatments available for congestive heart failure. Previously, from 1990 until its sale in 1998, Mr. Ravich served as the chief executive officer and a director of Universal International, Inc., a wholesale retail company, where he also led its IPO. From February 2013 to 2018, Mr. Ravich served as a director of Orchard Paper Products Company, a national supplier of high-quality consumer tissue products, as well as chairman of its governance committee and as a member of its audit committee. From June 2004 to 2018, Mr. Ravich served as a director of MR Instruments, Inc., an independent designer and

manufacturer of advanced MRI Radiofrequency coils. From 1978 to 1990, Mr. Ravich was a developer of commercial real estate where he was involved with all aspects of development, finance, construction, marketing, leasing and management of various commercial, industrial, office and multi-family real estate projects. Mr. Ravich began his career in 1975 as an account officer at Citibank N.A., where he made real estate construction loans to national real estate developers. Mr. Ravich also currently serves as a board advisor to Scidera Inc., a provider of clinical laboratory testing services, and is the chief manager of various real estate entities. Mr. Ravich graduated Magna Cum Laude from the Wharton School of the University of Pennsylvania with a B.S. and an M.B.A. degree with a major in finance.

We believe that Mr. Ravich's experience as a member of a board of directors of a public company, financial expertise and experience as a senior leader of his own company qualify him for service as a director of our Company.

*Andrea Heslin Smiley* has been a director since December 2020. Ms. Smiley currently serves as President and Chief Executive Officer of VMS BioMarketing, a provider of clinical educator solutions, which she joined in 2008 as Vice President, Strategic Marketing. Prior to joining VMS BioMarketing, Ms. Smiley held several executive positions running therapeutic business units at Eli Lilly and Company and has extensive commercialization expertise. She served as a member of the board of directors of Zyla Life Sciences, a life sciences company, from April 2018 to May 2020, when Zyla Life Sciences merged with Assertio Holdings, Inc., at which time she joined the board of directors of Assertio Holdings, Inc. and served on the Assertio Board until December 2020. Ms. Smiley serves as a member of the board of directors of ATAI Life Sciences B.V., clinical-stage biopharmaceutical company, and as an advisor to Agent Capital, a venture capital firm. Ms. Smiley earned her B.A. in Economics from DePauw University.

We believe that Ms. Smiley's more than 25 years of commercialization and management experience in the biopharmaceutical industry in both public and private companies qualify her for service as a director of our Company.

*Joan Lau, Ph.D.* has been a director since October 2023. Since 2016, Dr. Lau has served as Chief Executive Officer of Spirovant Sciences Inc. (formerly Talee Bio prior to its acquisition), a company focused on the discovery and development of gene therapies for respiratory diseases, which she founded. Since 2013, Dr. Lau has been co-founder and partner of Militia Hill Ventures, a firm that creates and builds innovative life science entities. Dr. Lau also serves as trustee of the Brandywine Realty Trust (BDN), a publicly-traded, full-service, integrated real estate company, Universal Display Corporation, a publicly-traded company, since March 2024, and as a director of RiboNova, Inc., a private company. She previously served as a director of Renovacor, Inc. Dr. Lau is also a trustee of the Philadelphia Orchestra and Kimmel Center, Inc. and the University of Pennsylvania. Dr. Lau earned an MBA from the Wharton School at the University of Pennsylvania, a PhD in Medical Neuroscience from the University of Cincinnati College of Medicine, and a BSE in Bioengineering from the University of Pennsylvania.

We believe that Dr. Lau's extensive scientific knowledge, management experience in the biopharmaceutical industry, financial experience, including with regard to capital markets, and regulatory expertise qualify her for service as a director of our Company.

**Board Diversity Matrix**

**Board Diversity Matrix (As of April 15, 2024)**

| **Total Number of Directors** | | | | |
|---|---|---|---|---|
| | **Female** | **Male** | **Non-Binary** | **Did Not Disclose Gender** |
| **Part I: Gender Identity** | | | | |
| Directors | 2 | 5 | | |
| **Part II: Demographic Background** | | | | |
| African American or Black | | | | |
| Alaskan Native or Native American | | | | |
| Asian | 1 | | | |
| Hispanic or Latinx | | | | |
| Native Hawaiian or Pacific Islander | | | | |
| White | 1 | 5 | | |
| Two or More Races or Ethnicities | | | | |
| LGBTQ+ | | | | |
| Did not disclose Demographic Background | | | | |

## CORPORATE GOVERNANCE

### Independence

Except as may otherwise be permitted by Nasdaq Stock Market rules, our Principles of Corporate Governance provide that a majority of the Board shall be independent directors. An ''independent'' director is a director who meets the Nasdaq Stock Market definition of independence, as determined by the Board. Based on the absence of any material relationship between each such director and the Company, other than in their capacities as directors and stockholders, the Board has determined that each of Messrs. Cooper, Radie and Ravich, and Drs. Lau and Nissenson and Ms. Smiley (representing all current directors other than Dr. Strobeck, who also serves as the Company's President and Chief Executive Officer) are independent, as independence is defined in the applicable Nasdaq Stock Market and SEC rules.

### Board Leadership Structure

Our Principles of Corporate Governance provide that the Board will elect a Chairman of the Board, who is not the CEO of the Company. In the event that there is a need for a lead independent director, the Board will appoint a lead independent director. Our Board believes that it is in the best interests of the Company and our stockholders to separate the role of Chairman of the Board from the role of Chief Executive Officer. Our Board believes that this separate leadership structure enhances the accountability of our Chief Executive Officer to our Board, strengthens our Board's independence from management and ensures a greater role for the independent directors in the oversight of the Company. In addition, our Board believes that separating these roles allows the Chief Executive Officer to focus his efforts on operating our business and managing our Company in the best interests of our stockholders, while the Chairman provides guidance to the Chief Executive Officer and, in consultation with management, helps to set the agenda for Board meetings and establishes priorities and procedures for the work of the full Board. The Chairman presides over meetings of the full Board. Mr. Radie serves as Chairman of the Board and Dr. Strobeck serves as the Company's President and CEO, as well as a Class III Director.

Our Board believes that the current Board leadership structure is in the best interests of the Company and its stockholders at this time. Our Board recognizes that no single leadership model is right for all companies and at all times and that, depending on the circumstances, other leadership models, such as combining the Chairperson and CEO roles, might be appropriate. Accordingly, our Board periodically reviews its leadership structure.

### Meetings and Committees of the Board

During 2023, the Board held sixteen meetings. Each current director attended at least 75% of the total number of meetings of the Board and committees of which they were a member in 2023. It is the Board's policy that, absent any unusual circumstances, all director nominees standing for election will attend the Annual Meeting. Our 2023 annual meeting of stockholders was conducted virtually, with all of the then-sitting directors attending the meeting. In addition to formal Board meetings, the Board members have frequent informal discussions and conferences with management throughout the year.

#### *Audit Committee*

We have an Audit Committee which is currently comprised of Messrs. Cooper (Chair) and Ravich and Dr. Lau. Ms. Smiley served on the Audit Committee for all of 2023. The Audit Committee held seven meetings in 2023. The Board has determined that Mr. Cooper, who is the Chairman of the Audit Committee, is an ''audit committee financial expert,'' as defined by applicable SEC rules. In addition, the Board has determined that each member of the Audit Committee is independent as independence for audit committee members is defined in applicable Nasdaq Stock Market and SEC rules. The Audit Committee has a written charter setting forth the responsibilities of the committee, a copy of which is available on the ''Investors'' section of our website at *www.rockwellmed.com*. The charter provides that the Audit Committee will assist the Board in its oversight of the quality and integrity of the accounting, auditing and financial reporting practices of the Company.

The functions of the Audit Committee include, among other things, (1) monitoring the adequacy of the Company's internal controls, (2) engaging and overseeing the work of the registered public accounting firm engaged for the purpose of preparing or issuing an audit report or performing other audit, review or attest services for us, including the conduct of the annual audit and overseeing the independence of such firm, (3) overseeing our independent accountants' relationship with the Company, (4) reviewing the audited financial statements and the

matters required to be discussed by Auditing Standard No. 1301 with management and the independent accountants, including their judgments about the quality of our accounting principles, applications and practices, (5) recommending to the Board whether our current audited financial statements should be included in our Annual Report on Form 10-K, (6) reviewing with management and our independent accountants our quarterly financial information before we file our Forms 10-Q, (7) reviewing procedures for the receipt, retention and treatment of complaints received by us regarding accounting, internal accounting controls or auditing matters, and the confidential, anonymous submission by our employees of concerns regarding questionable accounting and compliance matters, (8) reviewing related party transactions required to be disclosed in our proxy statement for potential conflict of interest situations and, where appropriate, approving such transactions, (9) monitoring with management the status of pending litigation and investigations, and (10) overseeing the Company's compliance functions.

***Audit Committee Report***

Our Audit Committee has:

- Reviewed and discussed with management our audited financial statements for the year ended December 31, 2023;
- Discussed with our independent accountants the matters required to be discussed by the applicable requirements of the Public Company Accounting Oversight Board and the SEC;
- Received the written disclosures and the letter from our independent accountants required by applicable requirements of the Public Company Accounting Oversight Board regarding the independent accountant's communications with the Audit Committee concerning independence; and
- Discussed with our independent accountants the independent accountants' independence.

Based on its review and discussions described above, our Audit Committee recommended to our Board that our audited financial statements be included in our Annual Report on Form 10-K for the year ended December 31, 2023 as filed with the SEC.

Management is responsible for our financial reporting process, including its system of internal control, and for the preparation of consolidated financial statements in accordance with generally accepted accounting principles. Our independent accountants are responsible for auditing those financial statements. Our Audit Committee's responsibility is to monitor and review these processes. Our Audit Committee has relied, without independent verification, on management's representation that our financial statements have been prepared with integrity and objectivity and in conformity with accounting principles generally accepted in the United States of America and on the representations of our independent accountants included in their report on our financial statements.

By the Audit Committee:
John G. Cooper (Chairman)
Joan Lau, Ph.D.
Mark Ravich

***Compensation Committee***

We have a Compensation Committee which is currently comprised of Ms. Smiley (Chair), Mr. Cooper and Drs. Lau and Nissenson. Messrs. Radie and Ravich served on the Compensation Committee during all of 2023. The Compensation Committee held five meetings in 2023. The Compensation Committee has a written charter setting forth the responsibilities of the committee, a copy of which is posted on the ''Investors'' section of our website at *www.rockwellmed.com*. Pursuant to the charter, the Compensation Committee is generally responsible for (1) overseeing, reviewing and approving all compensation and benefits for executive officers, including the Chief Executive Officer, (2) assessing the performance of the Chief Executive Officer and reviewing the performance recommendations of the executive officers who report to the Chief Executive Officer, (3) establishing performance objectives of the Company, (4) making recommendations to the Board for director compensation, (5) overseeing and administering the stock compensation program, (6) overseeing the development and implementation of our compensation and employee benefit plans and discharging its responsibilities under such plans, (7) reporting to the Board on our compensation policies, programs and plans, (8) approving other employee compensation and benefit programs where Board action is necessary or appropriate, and (9) overseeing the assessment of risks related to the

Company's compensation policies and programs. Except to the extent prohibited by Nasdaq Stock Market rules and state law, our Compensation Committee may delegate its authority to subcommittees when it deems appropriate and in the best interests of the Company.

Pursuant to its authority under its charter to retain compensation consultants, the Compensation Committee engaged Compensia, Inc. (''Compensia''), an executive compensation consulting firm, to act as its independent advisor with respect to compensation decisions. We utilize Compensia to conduct a comprehensive review and benchmarking of overall executive and director compensation programs. All services provided by Compensia to the Compensation Committee are conducted under the direction and authority of the Compensation Committee, and all work performed by Compensia must be pre-approved by the Compensation Committee. Compensia does not provide any other services to the Company and does not own any shares of the Company's stock. There are no personal or business relationships between the Compensia consultants and any executive of the Company. In addition, there are no personal relationships between the Compensia consultants and any member of the Compensation Committee. Compensia maintains a detailed conflict of interest policy in order to ensure that the compensation committees for which it works receive conflict-free advice.

***Nominating and Governance Committee***

We have a Nominating and Governance Committee which is currently comprised of Dr. Nissenson (Chair), Mr. Ravich and Ms. Smiley. Mr. Radie served as a member of the Nominating and Governance Committee for all of 2023. The Nominating and Governance Committee held four meetings in 2023. The Nominating and Governance Committee has a written charter setting forth the responsibilities of the committee, a copy of which is posted on the ''Investors'' section of our website at *www.rockwellmed.com*. Pursuant to the charter, the Nominating and Governance Committee is generally responsible for (1) oversight of the corporate governance of the Company, (2) recommending appropriate corporate governance practices, (3) identifying individuals qualified to become directors and selecting, or recommending that the Board select, the candidates for all directorships to be filled by the Board or by the stockholders, (4) oversight of the evaluation of the Board and its committees, and (5) evaluating the charters of our Board's committees and the principles of our Board.

In identifying candidates for director, our Nominating and Governance Committee will consider suggestions from incumbent directors, management or others, including stockholders. Our Nominating and Governance Committee may retain the services of a consultant from time to time to identify qualified candidates for director. Our Nominating and Governance Committee reviews all candidates in the same manner without regard to who suggested the candidate. In selecting candidates, our Nominating and Governance Committee will consider all factors it believes appropriate, which may include (1) ensuring that the Board, as a whole, is diverse and consists of individuals with various and relevant career experience, technical skill, industry knowledge and experience, financial expertise, local or community ties, and (2) individual qualifications, including strength of character, mature judgment, familiarity with our business and industry, especially the life sciences industry, independence of thought and an ability to work collegially. Although it has no formal policy with regard to diversity, our Nominating and Governance Committee, with respect to diversity, considers such factors as differences of viewpoint, education, skill and other individual qualities and attributes that contribute to board heterogeneity, including characteristics such as race, gender and national origin. The Board and Nominating and Governance Committee assess their effectiveness in this regard annually. Our Nominating and Governance Committee is committed to seeking highly qualified candidates inclusive of all national origins, races and genders to include in the pool from which director nominees are chosen.

**Nominations of Directors**

Nominees for director that are proposed by stockholders must be proposed pursuant to timely notice in writing to our Secretary, at Rockwell Medical, Inc., 30142 Wixom Road, Wixom, MI 48393, as provided in our bylaws. The requirements for proposing director candidates, as set forth in our bylaws, are described below.

Stockholders proposing director nominees for election at the 2025 annual meeting of stockholders must provide written notice of such intention, along with the other information required by our bylaws, to our Secretary at our principal executive offices no earlier than the close of business on November 16, 2024 and no later than December 16, 2024. If the 2025 annual meeting of stockholders date is significantly advanced or delayed from the first anniversary of the date of the Annual Meeting, then the notice and information must be given not later than the 120th day before the meeting or, if later, the 10th day after the first public disclosure of the date of the 2025 annual meeting of stockholders. With respect to an election to be held at a special meeting of stockholders, such notice must

be given in accordance with the procedures set forth in our bylaws no earlier than the close of business on the 150th day before and not later than the close of business on the 120th day before the date of such special meeting or, if later, the 10th day after the first public disclosure of the date of such special meeting. A proponent must also update the information provided in or with the notice at the times specified by our bylaws. Nominees for director pursuant to a notice which is not timely given or does not contain the information required by our bylaws or which is not delivered in compliance with the procedures set forth in our bylaws will not be considered at the stockholders meeting. In addition to giving notice pursuant to the advance notice provisions of the Company's bylaws, a stockholder who intends to solicit proxies in support of nominees submitted under these advance notice provisions must also provide the notice required under Rule 14a-19, the SEC's universal proxy rule, to the Secretary of the Company regarding such intent no later than March 24, 2025.

Only persons who are stockholders both as of the giving of notice and the date of the stockholders meeting and who are eligible to vote at the stockholders meeting are eligible to nominate directors. The nominating stockholder (or his qualified representative) must attend the stockholders meeting and present the proposed nominee in order for the proposed nominee to be considered.

The Board has not established specific, minimum qualifications for recommended nominees or specific qualities or skills for one or more of our directors to possess. The Board uses a subjective process for identifying and evaluating candidates for nomination as a director, based on the information available to, and the subjective judgments of, the members of the Board and our then current needs. The Board does not believe there would be any difference in the manner in which it evaluates candidates based on whether the candidate is recommended by a stockholder.

**Board Role in Risk Oversight**

Our Board has an active role, as a whole and also at the committee level, in overseeing management of the Company's enterprise risks. While our Board oversees the Company's enterprise risk management and establishes policies, Company management is responsible for day-to-day enterprise risk management processes. The Board and its committees provide enterprise risk management oversight function through regular, periodic reporting from and discussions with management appropriate to the nature and magnitude of the particular enterprise risk. Our Audit Committee oversees management of financial risks, risks associated with conflicts of interest and cybersecurity risks. Our Compensation Committee oversees management of risks relating to executive compensation plans and arrangements. While each committee is responsible for evaluating certain risks and overseeing management of those risks, the entire Board is regularly informed about those risks. In addition, management's role is to evaluate and assess business risks and to inform the Board of its evaluation of such business risks periodically. Our Chief Compliance Officer is responsible for our internal compliance program and reports to our Audit Committee.

**Code of Business Conduct and Ethics**

Our Board has adopted a Code of Business Conduct and Ethics that applies to all of our employees, officers and directors, including our principal executive officer, principal financial officer and principal accounting officer or controller. Our Code of Business Conduct and Ethics contains written standards that we believe are reasonably designed to deter wrongdoing and to promote:

- Honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest between personal and professional relationships;
- Full, fair, accurate, timely and understandable disclosure in reports and documents that we file with, or submit to, the SEC and in other public communications we make;
- Compliance with applicable governmental laws, rules and regulations;
- The prompt internal reporting of violations of the Code of Business Conduct and Ethics to the appropriate person or persons or through the Company's anonymous whistleblower hotline; and
- Accountability for adherence to the Code of Business Conduct and Ethics.

**Principles of Corporate Governance**

Our Board has adopted our Principles of Corporate Governance, which are reviewed annually by our Board and the Nominating Committee. These Principles of Corporate Governance, along with our Certificate of Incorporation, Bylaws and the charters of our Board's committees, and our Disclosure Committee, form the framework for the

governance of our Company. These principles include principal board responsibilities, our Majority Voting Policy, Claw-back Policy, Lead Independent Director Charter (if a lead independent director is appointed), the Board's policy against hedging and pledging our shares of common stock, insider trading policy, and stock ownership guidelines. Our Principles of Corporate Governance, as currently in effect, are available on our website at *www.rockwellmed.com* through the ''Investors'' page.

**Compensation Committee Interlocks**

None of the members of our Compensation Committee has at any time during the prior three years been one of our officers or employees. None of our executive officers who served in 2023 currently serves, or in the past fiscal year has served, as a member of the board or compensation committee of any entity that has one or more executive officers serving on our Board or Compensation Committee.

**Stockholder Communications with the Board**

Our Board has a process for our stockholders to send communications to our Board or Audit Committee, including complaints regarding accounting, internal accounting controls or auditing matters. Communications may be sent to our Board, our Audit Committee or specific directors by regular mail to the attention of our Board, our Audit Committee or specific directors, at our principal executive offices at 30142 Wixom Road, Wixom, MI 48393. All of these communications will be initially reviewed by our Secretary (1) to filter out communications that the Secretary deems are not appropriate for the directors, such as communications offering to buy or sell products or services, and (2) to sort and relay the remainder (unedited) to the appropriate directors.

## EXECUTIVE OFFICERS

The executive officers of the Company are elected or appointed annually and serve as executive officers of the Company at the pleasure of our Board. Certain information regarding our executive officers who are not directors, as of March 1, 2024, is set forth below.

| Name | Age | Position(s) |
|---|---|---|
| Mark Strobeck, Ph.D.[(1)] | 53 | President and Chief Executive Officer, Director |
| Megan Timmins | 51 | Executive Vice President, Chief Legal Officer and Secretary |
| Jesse Neri | 46 | Senior Vice President, Finance |

(1) For Dr. Strobeck's biographical information, see "Nominees For Reelection to Our Board" above.

*Megan Timmins* has served as the Company's Executive Vice President, Chief Legal Officer and Secretary since September 2022 and previously served as our Senior Vice President, General Counsel and Secretary from August 2021 to September 2022. Prior to that, she was an independent consultant from February 2021 to August 2021 and from May 2020 to January 2021, she served as Senior Vice President, General Counsel and Secretary for Assertio Holdings, Inc. (successor by merger to Zyla Life Sciences), a commercial pharmaceutical company. From March 2018 to May 2020, she served as Senior Vice President and General Counsel of Zyla, a life sciences company, and as Zyla's Secretary from June 2018 to May 2020. From September 2017 to March 2018, she served as Zyla's Vice President and Acting General Counsel. From October 2016 to August 2018, Ms. Timmins served as Zyla's Deputy General Counsel and from April 2016 to October 2016, she served as a consultant at Zyla. Prior to that, she served in positions of increasing responsibility at Aramark, most recently as Vice President, Associate General Counsel and Assistant Secretary from January 2011 until March 2015. Ms. Timmins received her B.A. in Government and Economics from the University of Notre Dame and her J.D. from the William and Mary Law School.

*Jesse Neri* has been our Senior Vice President, Finance, since October 2023 and our principal accounting officer since January 2024. Prior to joining the Company, Mr. Neri was the Executive Director of Finance at Hemavant Sciences and Aruvant Sciences, clinical-stage biopharmaceutical companies that are members of the Roivant portfolio, from August 2021 to October 2023. From May 2020 to August 2021, Mr. Neri was a self-employed consultant. Mr. Neri served as Senior Vice President of Finance at Zyla Life Sciences, a pharmaceutical company, from January 2020 to May 2020, as Vice President of Finance of Zyla from March 2019 to January 2020 and prior to that, as Executive Director, Financial Planning and Analysis and prior to that, as Senior Director of Financial Planning and Analysis. Prior to Zyla, Mr. Neri served as Vice President of Financial Planning and Analysis at Symphony Health Solutions. He started his career at Ellucian, a leading ERP software provider for higher education institutions, where he held various roles of increasing responsibility. Mr. Neri received a B.S., Business Administration in Finance from Villanova University and an M.B.A. from Drexel University LeBow School of Business.

## COMPENSATION OF EXECUTIVE OFFICERS

### Overview

The following table sets forth the total compensation paid to or earned by Dr. Strobeck, our Chief Executive Officer, Ms. Timmins, our Chief Legal Officer and Secretary, Mr. Neri, our Senior Vice President, Finance, Dr. Hoffman, our former Chief Medical Officer and Mr. McGarry, our former Senior Vice President, Finance and Chief Accounting Officer (the ''NEOs'') during each of the last two years, or such shorter period during which they served as a named executive officer. Dr. Hoffman's employment with the Company terminated in August 2023 and Mr. McGarry's employment with the Company terminated in September 2023.

### Summary Compensation Table

| Name and Principal Position | Year | Salary ($) | Bonus ($) | Stock Awards ($)[(b)] | Option Awards ($)[(b)] | Non-Equity Incentive Plan Compensation ($)[(c)] | All Other Compensation ($)[(d)] | Total ($) |
|---|---|---|---|---|---|---|---|---|
| Mark Strobeck, Ph.D. | 2023 | 565,865 | — | 75,987 | 73,518 | 330,000 | 8,799 | 1,054,169 |
| *Chief Executive Officer*[(a)] | 2022 | 266,539 | — | — | 334,899 | 101,026 | 9,308 | 711,762 |
| Megan Timmins | 2023 | 412,000 | — | 39,065 | 35,479 | 164,800 | 8,944 | 660,288 |
| *Chief Legal Officer and Secretary* | 2022 | 400,000 | — | — | 89,199 | 106,400 | 11,692 | 607,291 |
| Jesse Neri[(e)] | 2023 | 57,652 | 84,000[(f)] | — | 93,542 | — | — | 235,194 |
| *Senior Vice President, Finance* | | | | | | | | |
| Marc Hoffman | 2023 | 260,226 | — | 35,161 | 31,455 | — | 159,940 | 486,782 |
| *Former Chief Medical Officer* | 2022 | 401,250 | — | — | 66,900 | 106,733 | 11,729 | 586,612 |
| Paul McGarry | 2023 | 239,952 | — | 39,065 | 35,479 | — | 9,622 | 324,118 |
| *Former Senior Vice President, Finance and CAO* | | | | | | | | |

(a) Dr. Strobeck was appointed as CEO on July 1, 2022.

(b) The amounts reported in this column represent grant date fair values of restricted stock unit grants computed in accordance with FASB ASC Topic 718 and stock option grants determined using the Black Scholes option pricing model, excluding any forfeiture reserves, in accordance with FASB ASC Topic 718. The assumptions used to determine fair value of the stock option grants for 2023 are:

| Options | Year Granted | Dividend Yield | Risk Free Rate | Volatility | Expected Term |
|---|---|---|---|---|---|
| Mark Strobeck | 2023 | 0.00% | 3.46% | 81.83% | 6 Years |
| Megan Timmins | 2023 | 0.00% | 3.46% | 81.83% | 6 Years |
| Jesse Neri | 2023 | 0.00% | 4.84% | 81.79% | 6 Years |
| Marc Hoffman | 2023 | 0.00% | 3.46% | 81.83% | 6 Years |
| Paul McGarry | 2023 | 0.00% | 3.46% | 81.83% | 6 Years |

(c) See ''Annual Incentive Compensation'' below for a description of the amounts included in this column.

(d) Represents matching contributions under our 401(k) plan. For Dr. Hoffman, also includes $151,009 in severance payments.

(e) Mr. Neri joined the Company on October 16, 2023. His annual base salary is $300,000. In 2023, his bonus target was 35%.

(f) Pursuant to Mr. Neri's Employment Agreement, he received a guaranteed bonus equal to 80% of his target bonus.

### Employment Agreements

#### *Employment Agreement with Mark Strobeck*

On June 21, 2022, in connection with Dr. Strobeck's commencement of employment, the Company entered into an employment agreement with Dr. Strobeck pursuant to which he serves as the Company's President and Chief Executive Officer (the ''Strobeck Agreement''). The Strobeck Agreement provides that Dr. Strobeck will serve as an at-will employee. Dr. Strobeck was entitled to receive an initial annualized base salary of $550,000. He is eligible to earn year-end performance bonuses with a target bonus opportunity of 60% of his base salary (the Board increased his target bonus percentage to 80% for 2024) and is eligible to participate in the employee benefit plans and programs generally available to the Company's similarly situated senior executives. Dr. Strobeck is also eligible

to receive annual long-term incentive grants consistent with similar practices for the Company's senior executives, awarded at the discretion of the Compensation Committee of the Board. In connection with his commencement of employment, he received an initial equity grant comprised of a time-based option to purchase up to 400,000 shares of the Company's common stock that vests in equal annual installments on each of the first four anniversaries of July 1, 2022 (the ''Strobeck Initial Time-Based Options'').

***Employment Agreement with Megan Timmins***

On July 21, 2021, in connection with Ms. Timmins' commencement of employment, the Company entered into an employment agreement with Ms. Timmins pursuant to which she was to serve as the Company's Senior Vice President, General Counsel and Secretary and currently serves as the Company's Executive Vice President, Chief Legal Officer and Secretary (the ''Timmins Agreement''). The Timmins Agreement provides that Ms. Timmins will serve as an at-will employee. Ms. Timmins was initially entitled to receive an annualized base salary of $400,000. She is eligible to earn year-end performance bonuses with a target bonus opportunity of 40% of her base salary (the Board increased her target bonus percentage to 45% for 2024) and is eligible to participate in the employee benefit plans and programs generally available to the Company's similarly situated senior executives. Ms. Timmins is also eligible to receive annual long-term incentive grants consistent with similar practices for the Company's senior executives, awarded at the discretion of the Compensation Committee of the Board. In connection with her commencement of employment, she received an initial equity grant comprised of a time-based option to purchase up to 350,000 shares of the Company's common stock that vests in equal installments on each of the second and fourth anniversaries of August 16, 2021 (the ''Timmins Initial Time-Based Options'').

***Employment Agreement with Jesse Neri***

On October 16, 2023, in connection with Mr. Neri's commencement of employment, the Company entered into an employment agreement with Mr. Neri pursuant to which he serves as the Company's Senior Vice President, Finance (the ''Neri Agreement''). The Neri Agreement provides that Mr. Neri will serve as an at-will employee. Mr. Neri receives an annualized base salary of $300,000. Under the Neri Agreement, for 2023, Mr. Neri was entitled to a guaranteed bonus equal to 80% of his target bonus (then 35% of his base salary), or $84,000. Commencing in 2024, he is eligible to earn year-end performance bonuses with a target bonus opportunity of 45% of his base salary and is eligible to participate in the employee benefit plans and programs generally available to the Company's similarly situated senior executives. Mr. Neri is also eligible to receive annual long-term incentive grants consistent with similar practices for the Company's senior executives, awarded at the discretion of the Compensation Committee of the Board. In connection with his commencement of employment, he received an initial equity grant comprised of a time-based option to purchase up to 75,000 shares of the Company's common stock that vests in equal installments on each of the first four anniversaries of October 16, 2023 (the ''Neri Initial Time-Based Options'').

***Employment Agreement with Marc Hoffman***

On September 24, 2019, in connection with Dr. Hoffman's commencement of employment, the Company entered into an employment agreement with Dr. Hoffman pursuant to which he served as the Company's Chief Medical Officer (the ''Hoffman Agreement''). The Hoffman Agreement provided that Dr. Hoffman served as an at-will employee. Dr. Hoffman received an annualized base salary of $400,000 ($413,288 at the time of his termination). He was eligible to earn year-end performance bonuses with a target bonus opportunity of 40% of his base salary and was eligible to participate in the employee benefit plans and programs generally available to the Company's similarly situated senior executives. Dr. Hoffman was also eligible to receive annual long-term incentive grants consistent with similar practices for the Company's senior executives, awarded at the discretion of the Compensation Committee of the Board. In connection with his commencement of employment, he received an initial equity grant comprised of a time-based option to purchase up to 250,000 shares of the Company's common stock that vested in equal annual installments on each of the first three anniversaries of November 25, 2019 (the ''Hoffman Initial Time-Based Options''). Dr. Hoffman's employment with the Company terminated in August 2023.

***Offer Letter with Paul McGarry***

On June 3, 2019, in connection with Mr. McGarry's commencement of employment, the Company entered into an offer letter with Mr. McGarry pursuant to which he served initially as the Company's Vice President, Corporate Controller and Principal Accounting Officer and later as the Company's Senior Vice President, Finance and Chief Accounting Officer (the ''McGarry Letter''). The McGarry Letter provided that Mr. McGarry would serve as

an at-will employee. Mr. McGarry received an initial annualized base salary of $265,000. He was eligible to earn year-end performance bonuses with a target bonus opportunity of 35% of his base salary and was eligible to participate in the employee benefit plans and programs generally available to the Company's similarly situated senior executives. Mr. McGarry was also eligible to receive annual long-term incentive grants consistent with similar practices for the Company's senior executives, awarded at the discretion of the Compensation Committee of the Board. In connection with his commencement of employment, he received an initial equity grant comprised of a time-based option to purchase up to 50,000 shares of the Company's common stock that vested in equal annual installments on each of the first three anniversaries of June 24, 2019 (the ''McGarry Initial Time-Based Options''). Mr. McGarry's employment with the Company terminated in September 2023.

***Annual Incentive Compensation***

For purposes of determining 2023 annual Non-Equity Incentive compensation for the eligible named executive officers, the Board, upon recommendation of the Compensation Committee, approved a set of corporate and individual goals for each executive that would determine their respective payout, subject to Board discretion. Dr. Strobeck's target bonus opportunity was 60% of base salary and Ms. Timmins's target bonus opportunity was 40% of base salary. Due to Dr. Hoffman's departure in August 2023 and Mr. McGarry's departure in September 2023, neither received an annual bonus for 2023. Mr. Neri received a fixed bonus pursuant to his contract equal to 80% of his 2023 target bonus.

The 2023 corporate goals focused on: (i) achieving certain financial objectives (including targets for GAAP revenue, gross margin, operating loss and ending cash on hand); (ii) extending the Company's agreement with its largest customer; and (iii) achieving certain operational objectives, including infrastructure improvements. The 2023 corporate goals also contained stretch objectives related to geographic and product expansion, as well as profitability.

The Compensation Committee assessed the eligible NEOs' performance in relation to the Company's corporate goals for 2023 and determined that such eligible NEOs achieved the following: (i) 90% of the financial objectives; (ii) 100% of the goal involving extending the Company's agreement with its largest customer; (iii) 85% of the operational objectives; and (iv) 50% of the stretch objectives. The Compensation Committee also determined that the eligible NEOs attained 100% of their individual goals. This individual and corporate goal attainment resulted in a total payout of 100% of their respective target bonus amounts.

***2023 Long-Term Equity Incentive Compensation***

In March 2023, Dr. Strobeck, Ms. Timmins, Dr. Hoffman and Mr. McGarry each received a grant of 55,465, 28,515, 25,665 and 28,515 restricted stock units, respectively. Also in March 2023, Dr. Strobeck, Ms. Timmins, Dr. Hoffman and Mr. McGarry also received grants of 77,105, 37,210, 32,990 and 37,210 stock options, respectively. In connection with his consulting arrangement after his termination of employment, Dr. Hoffman's equity continued to vest while he served in a consulting capacity with the Company, which terminated on February 15, 2024. In connection with his commencement of employment, in October 2023, Mr. Neri received the Neri Initial Time-Based Options. Mr. McGarry's unvested equity was cancelled upon his termination of employment and pursuant to the terms of the equity instruments, his vested equity was cancelled 90 days after his termination of employment.

### Outstanding Equity Awards at 2023 Year-End

The following table shows certain information regarding outstanding equity awards at December 31, 2023 for our NEOs:

| | | Option Awards | | | | Stock Awards | |
|---|---|---|---|---|---|---|---|
| Name | Grant Date | Number of Securities Underlying Unexercised Options Exercisable(#) | Number of Securities Underlying Unexercised Options Unexercisable(#) | Option Exercise Price($) | Option Expiration Date | Number of Shares or Units of Stock that Have Not Vested(#) | Market Value of Shares or Units of Stock that Have not Vested($) |
| Mark Strobeck | 3/17/2023 | — | 77,105[a] | 1.37 | 3/17/2033 | 55,465[d] | 104,829 |
| | 7/1/2022 | 100,000 | 300,000[b] | 1.28 | 7/1/2032 | — | — |
| Megan Timmins | 3/17/2023 | — | 37,210[a] | 1.37 | 3/17/2033 | 28,515[d] | 53,893 |
| | 9/9/2022 | 20,000 | 60,000[b] | 1.66 | 9/9/2032 | — | — |
| | 8/16/2021 | 15,909 | 15,909[c] | 6.71 | 8/16/2031 | — | — |
| Jesse Neri | 10/16/2023 | — | 75,000[b] | 1.88 | 10/16/2033 | | |
| Marc Hoffman | 3/17/2023 | — | 32,990[a] | 1.37 | 3/17/2033 | 25,665[d] | 48,507 |
| | 9/9/2022 | 15,000 | 45,000[b] | 1.66 | 9/9/2032 | — | — |
| | 5/3/2021 | 6,818 | 6,818[c] | 10.38 | 5/3/2031 | — | — |
| | 11/25/2019 | 22,727 | — | 23.98 | 11/25/2029 | — | — |
| Paul McGarry[e] | — | — | — | — | — | — | — |

(a) These options vest 25% on the first anniversary of the grant date, with the remainder vesting in equal monthly installments through the fourth anniversary of the grant date, subject to continued service through each such vesting date.

(b) These options vest 25% per year on each of the first four anniversaries of the grant date, subject to continued service through each such vesting date.

(c) These options vest in two equal installments on the second and fourth anniversaries of the grant date, subject to continued service through each such vesting date.

(d) These restricted stock units vest in two equal installments on the first and second anniversaries of March 17, 2023, subject to continued service through each such vesting date.

(e) Due to his termination of employment, Mr. McGarry's equity was cancelled prior to December 31, 2023.

### Other Compensation

The Company offers a 401(k) plan for individual retirement savings opportunities available to all of our salaried employees on a non-discriminatory basis. For the 2023 plan year, the Company provided matching contributions equal to 100% of the first 3% of compensation deferred and 50% of the next 2% of compensation deferred. All matching contributions under the 401(k) plan are fully vested. The Company does not have other pension or retirement plans or deferred compensation arrangements for our NEOs.

### Executive Stock Ownership Guidelines

In 2017, our Board established formal stock ownership guidelines to further align our executive's and stockholders' economic interests and discourage inappropriate or excessive risk-taking. The Board reviewed and amended the guidelines in February 2023. Under the amended guidelines, our Chief Executive Officer is required to hold shares with a value equal to at least 3x his base salary by the later of the fifth anniversary of the date the guidelines became effective or the fifth anniversary of the executive's first designation as an executive subject to the guidelines. Our Chief Executive Officer will be deemed to be in compliance with the guidelines if the value of shares he holds on any date during the calendar year equals or exceeds three times his base salary. After meeting the ownership guidelines, any subsequent decreases in the market value of shares will not be considered, as long as the executive remains at the same salary and/or title level and holds at least the same number of shares as they did when they met or exceeded the guidelines.

For purposes of these guidelines, the following securities will be counted in determining whether an executive owns the requisite number of shares: shares of common stock purchased by the executive, shares owned jointly with or separately by a member of the executive's immediate family, shares held indirectly by entities formed for the benefit of the executive or his or her immediate family members or over which the executive has the ability to

influence or direct investment decisions, outstanding shares held through the Company's equity plans (other than performance shares which have not yet vested), and shares issuable upon vesting of time-vested restricted stock units settleable in shares of common stock, whether vested or unvested. Our Chief Executive Officer intends to be in compliance with the stock ownership requirements by the deadline applicable to him as set forth above. We will continue to review the guidelines relative to market on a periodic basis and make adjustments as needed to executives covered and ownership requirements.

**Anti-Hedging and Anti-Pledging Policy**

Our Board has established an anti-hedging and anti-pledging policy as part of our Principles of Corporate Governance and Insider Trading Policy. This policy prohibits any of our directors or executive officers and certain of our employees from (a) pledging shares of common stock or derivative securities as collateral for a loan, (b) engaging in hedging transactions and other transactions involving derivative securities, and (c) placing standing and limit orders that will remain in place for longer than one trading day other than in compliance with Rule 10b5-1(c) of the Securities Exchange Act of 1934, as amended (the ''Exchange Act'').

**Incentive Compensation Clawback Policy**

In 2017, our Board adopted an incentive compensation recoupment, or ''clawback,'' policy applicable to our executive officers. The Board revised the clawback policy in 2023 in accordance with the Nasdaq rules. Under this policy, in the event the Company is required to prepare an accounting restatement of the Company's financial statements due to material non-compliance with any financial reporting requirement under the federal securities laws (including any such correction that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period), the Company will recover on a reasonably prompt basis the amount of any incentive-based compensation received by an executive officer during the recovery period that exceeds the amount that otherwise would have been received had it been determined based on the restated financial statements. ''Incentive-Based Compensation'' means any compensation granted, earned, or vested based in whole or in part on the Company's attainment of a financial reporting measure that was received by a person (i) on or after October 2, 2023 and after the person began service as an executive officer, and (ii) who served as an executive officer at any time during the performance period for the incentive-based compensation. A financial reporting measure is (i) any measure that is determined and presented in accordance with the accounting principles used in preparing the Company's financial statements and any measure derived wholly or in part from such a measure, and (ii) any measure based in whole or in part on the Company's stock price or total shareholder return.

**Payments Upon Termination or Change in Control**

***Mark Strobeck***

Under the Strobeck Agreement, upon a termination of Dr. Strobeck's employment due to death or Disability (as defined therein), any equity awards held by Dr. Strobeck subject to time-based vesting conditions will accelerate and become fully vested. All stock options held by Dr. Strobeck that are exercisable as of the date of such termination, including any stock options that accelerate in connection with such termination, will remain exercisable until the earlier of one year following such termination and the expiration date of the stock options. Under the Strobeck Agreement, upon a termination of Dr. Strobeck's employment by the Company without Cause or by Dr. Strobeck for Good Reason (each as defined therein), Dr. Strobeck will be entitled to receive, subject to his execution and non-revocation of a separation agreement and release of claims in favor of the Company and compliance with certain restrictive covenants, (i) an amount equal to his base salary then in effect, payable in equal installments for a one-year period, (ii) a pro-rated bonus for the year of termination, based on achievement of actual performance for the full performance period and pro-rated based on the portion of the performance period Dr. Strobeck was employed prior to termination, payable in a lump sum after the completion of the full performance, (iii) reimbursement of COBRA coverage for up to one year (or, if sooner, until he receives substantially similar coverage from another employer), and (iv) the Strobeck Initial Time-Based Options will continue to vest for a period of one year and all stock options held by Dr. Strobeck that are exercisable as of the date of such termination and all stock options that become exercisable over the one-year period following such termination, will remain exercisable until the earlier of one year following such termination and the expiration date of the stock options. Under the Strobeck Agreement, in the event of a Change of Control (as defined therein), upon a termination of Dr. Strobeck's employment by the Company without Cause or by Executive for Good Reason during the Effective Period (as defined therein), subject to his

compliance with certain restrictive covenants, Dr. Strobeck will be entitled to receive (i) an amount equal to the sum of (A) 1.5 times his base salary then in effect plus (B) 100% of his annual target bonus, (ii) reimbursement of COBRA coverage for up to two years (or, if sooner, until he receives substantially similar coverage from another employer or is no longer eligible for COBRA coverage) and (iii) any equity awards held by Dr. Strobeck subject to time-based vesting conditions will accelerate and become fully vested and all stock options held by Dr. Strobeck that are exercisable as of the date of such termination, including any stock options that accelerate in connection with such termination, will remain exercisable until the expiration date of the stock options.

In connection with the Strobeck Agreement, Dr. Strobeck also entered into the Company's form of Employee Confidentiality, Assignment of Inventions, Non-Interference and Non-Competition Agreement.

***Megan Timmins***

Under the Timmins Agreement, upon a termination of Ms. Timmins' employment due to death or Disability (as defined therein), any equity awards held by Ms. Timmins subject to time-based vesting conditions (the ''Time-Based Awards'') will accelerate and become fully vested. All stock options held by Ms. Timmins that are exercisable as of the date of such termination, including any stock options that accelerate in connection with such termination, will remain exercisable until the earlier of one year following such termination and the expiration date of the stock options. Under the Timmins Agreement, upon a termination of Ms. Timmins' employment by the Company without Cause or by Ms. Timmins for Good Reason (each as defined therein), Ms. Timmins will be entitled to receive, subject to her execution and non-revocation of a separation agreement and release of claims in favor of the Company and compliance with certain restrictive covenants, (i) an amount equal to her base salary then in effect, payable in equal installments for a one-year period, (ii) reimbursement of COBRA coverage for up to one year (or, if sooner, until she receives substantially similar coverage from another employer), and (iii) the Time-Based Awards will continue to vest for a period of one year and all stock options held by Ms. Timmins that are exercisable as of the date of such termination and all stock options that become exercisable over the one-year period following such termination, will remain exercisable until the earlier of one year following such termination and the expiration date of the stock options. Under the Timmins Agreement, in the event of a Change of Control (as defined therein), upon a termination of Ms. Timmins' employment by the Company without Cause or by Ms. Timmins for Good Reason during the Effective Period (as defined therein), subject to her compliance with certain restrictive covenants, Ms. Timmins will be entitled to receive (i) an amount equal to the sum of (A) 1.5 times her base salary then in effect plus (B) 100% of her annual target bonus, (ii) reimbursement of COBRA coverage for up to one year (or, if sooner, until she receives substantially similar coverage from another employer or is no longer eligible for COBRA coverage) and (iii) any Time-Based Awards will accelerate and become fully vested and all stock options held by Ms. Timmins that are exercisable as of the date of such termination, including any stock options that accelerate in connection with such termination, will remain exercisable until the expiration date of the stock options.

In connection with the Timmins Agreement, Ms. Timmins also entered into the Company's form of Employee Confidentiality, Assignment of Inventions, Non-Interference and Non-Competition Agreement.

***Jesse Neri***

Under the Neri Agreement, upon a termination of Mr. Neri's employment due to death or Disability (as defined therein), any equity awards held by Mr. Neri subject to time-based vesting conditions (the ''Time-Based Awards'') will accelerate and become fully vested. All stock options held by Mr. Neri that are exercisable as of the date of such termination, including any stock options that accelerate in connection with such termination, will remain exercisable until the earlier of one year following such termination and the expiration date of the stock options. Under the Neri Agreement, upon a termination of Mr. Neri's employment by the Company without Cause or by Mr. Neri for Good Reason (each as defined therein), Mr. Neri will be entitled to receive, subject to his execution and non-revocation of a separation agreement and release of claims in favor of the Company and compliance with certain restrictive covenants, (i) an amount equal to his base salary then in effect, payable in equal installments for a one-year period, (ii) reimbursement of COBRA coverage for up to one year (or, if sooner, until he receives substantially similar coverage from another employer), and (iii) the Time-Based Awards will continue to vest for a period of one year and all stock options held by Mr. Neri that are exercisable as of the date of such termination and all stock options that become exercisable over the one-year period following such termination, will remain exercisable until the earlier of one year following such termination and the expiration date of the stock options. Under the Neri Agreement, in the event of a Change of Control (as defined therein), upon a termination of Mr. Neri's employment by the Company without Cause or by Mr. Neri for Good Reason during the Effective Period (as defined therein), subject to his

compliance with certain restrictive covenants, Mr. Neri will be entitled to receive (i) an amount equal to the sum of (A) 1.5 times his base salary then in effect plus (B) 100% of his annual target bonus, (ii) reimbursement of COBRA coverage for up to one year (or, if sooner, until he receives substantially similar coverage from another employer or is no longer eligible for COBRA coverage) and (iii) any Time-Based Awards will accelerate and become fully vested and all stock options held by Mr. Neri that are exercisable as of the date of such termination, including any stock options that accelerate in connection with such termination, will remain exercisable until the expiration date of the stock options.

In connection with the Neri Agreement, Mr. Neri also entered into the Company's form of Employee Confidentiality, Assignment of Inventions, Non-Interference and Non-Competition Agreement.

***Marc Hoffman***

Under the Hoffman Agreement, upon Dr. Hoffman's termination of employment by the Company without Cause (as defined therein) in August 2023, Dr. Hoffman became entitled to receive, subject to his execution and non-revocation of a separation agreement and release of claims in favor of the Company and compliance with certain restrictive covenants, (i) an amount equal to the sum of (A) his base salary then in effect plus (B) 100% of his annual target bonus, payable in equal installments for a one-year period (ii) reimbursement of COBRA coverage for up to one year (or, if sooner, until he receives substantially similar coverage from another employer). Following his termination, Dr. Hoffman provided consulting services to the Company until February 15, 2024 and his outstanding equity awards continued to vest during his consulting period.

In connection with the Hoffman Agreement, Dr. Hoffman also entered into the Company's form of Employee Confidentiality, Assignment of Inventions, Non-Interference and Non-Competition Agreement.

***Paul McGarry***

Under the McGarry Letter, upon a termination of Mr. McGarry's employment by the Company without cause, Mr. McGarry would have been entitled to receive, subject to his execution and non-revocation of a separation agreement and release of claims in favor of the Company, an amount equal to three months of his base salary then in effect.

In connection with the McGarry Letter, Mr. McGarry also entered into the Company's form of Employee Confidentiality, Assignment of Inventions, Non-Interference and Non-Competition Agreement. Mr. McGarry voluntarily terminated his employment with the Company in September 2023 and did not become entitled to any severance benefits.

***Long Term Incentive Plans***

In addition to the severance benefits discussed above, the NEOs would receive certain benefits upon termination of employment that are provided to all salaried employees on a nondiscriminatory basis-accrued salary and 401(k) plan distributions.

In the event of a change of control, all unvested awards under the 2018 Plan do not accelerate automatically. However, if a participant's employment terminates under certain qualifying circumstances (as described above for each NEO) after a change in control or if the surviving corporation does not assume our unvested awards, then the vesting of unvested awards will accelerate and be considered fully vested, provided that performance awards will only vest either to the extent the performance is met or assuming target performance, but pro-rated to reflect only the portion of the performance period that has lapsed, whichever is greater.

## Pay Versus Performance

As required by Section 953(a) of the Dodd-Frank Wall Street Reform and Consumer Protection Act, and Item 402(v) of Regulation S-K, we are providing the following information about the relationship between executive ''compensation actually paid'' and certain financial performance of the Company. For further information concerning the Company's pay for performance philosophy and how the Company aligns executive compensation with the Company's performance, refer to ''Compensation of Executive Officers.''

| Year (a) | Summary Compensation Table Total for Strobeck[1] (b) | Summary Compensation Table Total for Ellison[1] (c) | Compensation Actually Paid to Strobeck[2] (d) | Compensation Actually Paid to Ellison[2] (e) | Average Summary Compensation Table Total for Non-PEO NEOs[3] (f) | Average Compensation Actually Paid to Non-PEO NEOs[4] (g) | Value of Initial Fixed $100 Investment Based On Total Shareholder Return[5] (h) | Net Loss[6] (i) (in 000's) |
|---|---|---|---|---|---|---|---|---|
| 2023 . . . | $1,054,169 | — | $1,760,113 | — | $426,596 | $464,365 | $17.01 | ($ 8,439) |
| 2022 . . . | $ 711,762 | $712,128 | $ 641,120 | $619,576 | $660,702 | $569,351 | $ 8.91 | ($18,679) |
| 2021 . . . | — | $627,537 | — | ($349,420) | $626,452 | $349,121 | $39.81 | ($32,674) |

(1) The dollar amounts reported in columns (b) and (c) are the amounts reported for Dr. Strobeck (the Company's Chief Executive Officer) and Dr. Ellison (the Company's former Chief Executive Officer) for each of the corresponding years in the ''Total'' column in our Summary Compensation Table. Refer to the ''Summary Compensation Table''.

(2) The dollar amounts reported in columns (d) and (e) represent the amount of ''compensation actually paid'' to Dr. Strobeck and Dr. Ellison, as computed in accordance with Item 402(v) of Regulation S-K. In accordance with these rules, these amounts reflect ''Total Compensation'' as set forth in the Summary Compensation Table for each year, adjusted as shown below. Equity values are calculated in accordance with FASB ASC Topic 718 and, other than with respect to 2023 volatility, which increased approximately 13%, the valuation assumptions used to calculate fair values did not materially differ from those disclosed at the time of grant.

| **Compensation Actually Paid to PEO** | **2023** |
|---|---|
| Summary Compensation Table Total | $1,054,169 |
| Less, value of ''Stock Awards'' and ''Option Awards'' reported in Summary Compensation Table | ($ 149,505) |
| Plus, year-end fair value of outstanding and unvested equity awards granted in the year | $ 215,137 |
| Plus, fair value as of vesting date of equity awards granted and vested in the year. | — |
| Plus, year over year change in fair value of outstanding and unvested equity awards granted in prior years | $ 227,872 |
| Plus, year over year change in fair value of equity awards granted in prior years that vested in the year | $ 412,440 |
| Less, prior year-end fair value for any equity awards forfeited in the year | — |
| **Compensation Actually Paid to PEO** | $1,760,113 |

(3) The dollar amounts reported in column (f) represent the average of the amounts reported for the Company's named executive officers (NEOs) as a group (excluding Drs. Strobeck and Ellison) in the ''Total'' column of the Summary Compensation Table in each applicable year. The names of each of the NEOs included for these purposes in each applicable year are as follows: (i) for 2023, Megan Timmins, Jesse Neri (3 months), Marc Hoffman (8 months) and Paul McGarry (9 months); (ii) for 2022, Russell Skibsted (11 months), Megan Timmins and Marc Hoffman; and (iii) for 2021, Russell Skibsted and Raymond Pratt. Unless otherwise indicated, the average amounts for each fiscal year are based on a full year of service for each NEO.

(4) The dollar amounts reported in column (g) represent the average amount of ''compensation actually paid'' to the NEOs as a group (excluding Drs. Strobeck and Ellison), as computed in accordance with Item 402(v) of Regulation S-K. In accordance with these rules, these amounts reflect average ''Total Compensation'' as set forth in the Summary Compensation Table for each year, adjusted as shown below. Equity values are calculated in accordance with FASB ASC Topic 718 and, other than with respect to 2023 volatility, which increased approximately 13%, the valuation assumptions used to calculate fair values did not materially differ from those disclosed at the time of the grant.

| **Average Compensation Actually Paid to Non-PEO NEOs** | **2023** |
|---|---|
| Average Summary Compensation Table Total | $426,596 |
| Less, average value of ''Stock Awards'' and ''Option Awards'' reported in Summary Compensation Table | ($ 77,312) |
| Plus, average year-end fair value of outstanding and unvested equity awards granted in the year | $ 64,447 |
| Plus, average fair value as of vesting date of equity awards granted and vested in the year | — |
| Plus, average year over year change in fair value of outstanding and unvested equity awards granted in prior years | $ 31,224 |
| Plus, average year over year change in fair value of equity awards granted in prior years that vested in the year | $ 19,410 |
| Less, prior year-end fair value for any equity awards forfeited in the year | — |
| **Average Compensation Actually Paid to Non-PEO NEOs** | $464,365 |

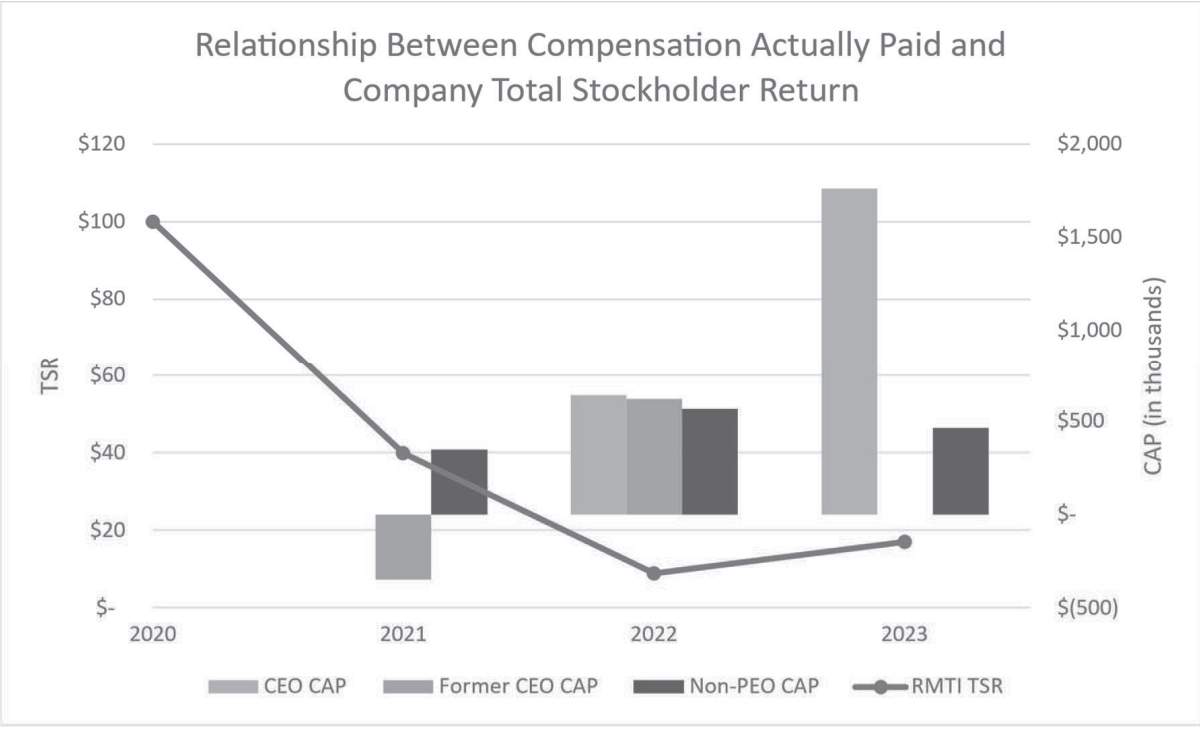
(5) Total Shareholder Return ("TSR") is calculated by dividing (a) the sum of (i) the cumulative amount of dividends for the measurement period, assuming dividend reinvestment, and (ii) the difference between the Company's share price at the end of each fiscal year shown and the beginning of the measurement period, by (b) the Company's share price at the beginning of the measurement period. The beginning of the measurement period for each year in the table is December 31, 2020.

(6) The dollar amounts reported represent the amount of net income reflected in the Company's audited financial statements for the applicable year.

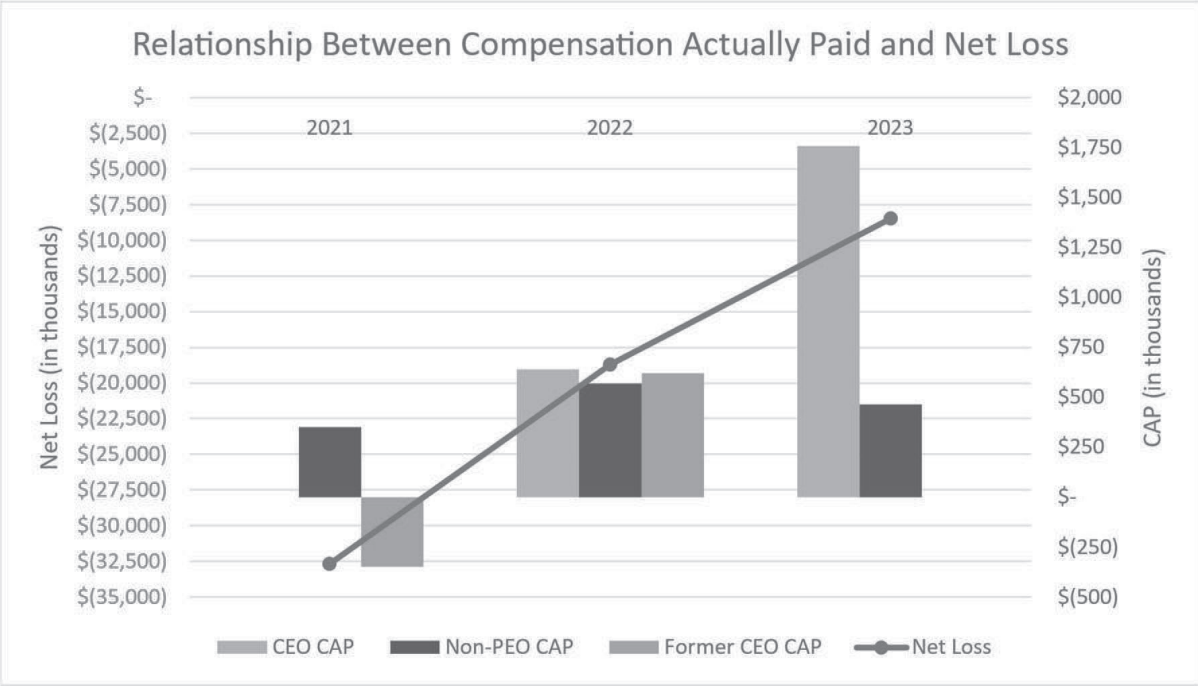
***Description of Certain Relationships between Information Presented in the Pay versus Performance Table***

While the Company utilizes several performance measures to align executive compensation with Company performance, all of those Company measures are not presented in the Pay versus Performance table. Moreover, the Company generally seeks to incentivize long-term performance, and therefore does not specifically align the Company's performance measures with compensation that is actually paid (as computed in accordance with SEC rules) for a particular year. In accordance with SEC rules, the Company is providing the following descriptions of the relationships between information presented in the Pay versus Performance table.

*Compensation Actually Paid and Cumulative TSR*



*Compensation Actually Paid and Net Loss*



## DIRECTOR COMPENSATION

### 2023 Director Compensation

In considering the Company's need to attract and retain qualified directors and to ensure that the Company compensates non-employee directors in line with market practice, we regularly review our director compensation program with our independent compensation consultant. Based on market benchmarking completed in 2023 by Compensia, the Compensation Committee adjusted our director compensation program effective for the second half of 2023 and for 2024. As described below, the Company compensates non-employee directors through a mix of cash retainer fees and equity grants that are subject to vesting.

(1) Annual Board Service Cash Retainer: $45,000

(2) Additional Annual Cash Retainer for Chairman of the Board: $40,000

(3) Additional Annual Cash Retainers for Committee Chair Service: $20,000 for Audit, $15,000 for Compensation and $10,000 for Governance and Nominating

(4) Additional Annual Cash Retainers for Committee Member Service (excluding Chairs): $10,000 ($12,000 for the first half of 2023) for Audit, $7,500 for Compensation and $5,000 for Governance and Nominating

(5) Annual Equity Grant: $100,000 in grant value, awarded 50% in stock options and 50% in restricted stock units (subject to adjustment based on share pool constraints)

In 2023, due to limited availability in the pool of shares reserved for issuance under the Company's 2018 Long Term Incentive Plan and the low stock price, the Board determined to award each of our non-employee directors 24,715 restricted stock units. The restricted stock units, which had a grant date value of $65,000 on May 23, 2023, vest in full one year from the date of grant. The amounts in the table below reflect the aggregate compensation received under each of the director compensation programs as in effect for 2023. Dr. Lau joined our Board on October 16, 2023, and received a grant of 25,000 stock options and 25,000 restricted stock units on that date, each of which will vest on the first anniversary of the grant date.

The following table sets forth certain information relating to the compensation for our non-employee directors for the last year:

### 2023 Director Compensation

| Name | Fees Earned or Paid in cash ($) | Option Awards ($)[a] | Restricted Stock Unit Awards ($)[b] | Total ($) |
|---|---|---|---|---|
| John Cooper | 77,267 | — | 65,000 | 142,267 |
| Joan Lau, Ph.D.[c] | 9,375 | 33,132 | 47,000 | 89,507 |
| Allen Nissenson, MD | 62,944 | — | 65,000 | 127,944 |
| Robert Radie | 105,000 | — | 65,000 | 170,000 |
| Mark H. Ravich | 63,294 | — | 65,000 | 128,294 |
| Andrea Heslin Smiley | 65,561 | — | 65,000 | 130,561 |

(a) The amount in the table represents the grant-date fair value of such stock options determined in accordance with FASB ASC Topic 718.

(b) The amount in the table represents the grant-date fair value of such restricted stock units determined in accordance with FASB ASC Topic 718.

(c) Dr. Lau joined the Board on October 16, 2023. On that date, she received a grant of 25,000 stock options and 25,000 restricted stock units, each of which will vest on the first anniversary of the grant date.

The table below shows the number of unexercised options and stock appreciation rights and the number of shares of unvested restricted stock units and unvested restricted stock awards held by each of the non-employee directors at December 31, 2023.

| Name | Options Held | Restricted Stock Units Held | Restricted Stock Awards Held | Stock Appreciation Rights Held |
|---|---|---|---|---|
| John Cooper | 15,378 | 24,715 | — | 2,090 |
| Joan Lau, Ph.D | 25,000 | 25,000 | — | — |
| Allen Nissenson, MD | 9,772 | 24,715 | — | — |
| Robert Radie | 10,092 | 24,715 | — | — |
| Mark H. Ravich | 15,794 | 24,715 | — | — |
| Andrea Heslin Smiley | 8,990 | 24,715 | — | — |

### *Director Stock Ownership Guidelines*

The Board adopted formal stock ownership guidelines for its non-employee directors in 2017. In February 2023, the Compensation Committee engaged with Compensia to review the guidelines against market best practices. To better align with market and the Company's shareholders, the committee amended the guidelines to increase the ownership requirement from 1x to a value equal to 3x the annual Board service cash retainer. Non-employee directors must satisfy the applicable guidelines by the later of the fifth anniversary of when they joined the Board, or the fifth anniversary of when the guidelines were amended, which occurred in February 2023. Shares are counted toward the guideline in the same manner as described under ''Compensation of Executive Officers-Executive Stock Ownership Guidelines.''

### *Anti-Hedging and Anti-Pledging Policy*

We have an anti-hedging and anti-pledging policy that applies to our directors. See ''Compensation of Executive Officers–Anti-Hedging and Anti-Pledging Policy'' for more information.

## PROPOSAL 2
## ADVISORY VOTE ON THE COMPENSATION OF OUR NAMED EXECUTIVE OFFICERS

In accordance with Section 14A of the Exchange Act and related rules of the SEC, we are providing stockholders with an opportunity to vote on an advisory or non-binding resolution to approve the 2023 compensation of our NEOs as described in this Proxy Statement (sometimes referred to as ''say on pay''). Consistent with the advisory vote of the stockholders in 2023, the Board has determined that the opportunity for such a vote will occur at every annual meeting of stockholders.

The Compensation Committee, comprised solely of independent directors, is responsible for our compensation policies and practices and has established a process for the review and approval of compensation programs and amounts awarded to our executive officers without encouraging excessive risk-taking. One of the key principles underlying our Compensation Committee's compensation philosophy is pay for performance. We will continue to emphasize compensation arrangements that align the financial interests of our executives with the interests of long-term stockholders. We urge you to read the section of this Proxy Statement entitled ''Compensation of Executive Officers and Directors'' for a detailed discussion of our executive compensation practices and philosophy.

The Compensation Committee believes that the policies and procedures described in that section are effective in implementing our compensation philosophy. Therefore, we ask that you indicate your support for our executive compensation policies and practices as described in the tables and related narrative contained in this Proxy Statement by voting FOR the following resolution:

RESOLVED, that the stockholders approve, on an advisory basis, the compensation paid to the Company's NEOs as disclosed in ''Compensation of Executive Officers,'' including the compensation tables, and the related narrative disclosure in this Proxy Statement.

### Vote Required

Approval of the compensation of our named executive officers in an advisory vote requires the affirmative vote of a majority of the votes cast by the holders of common stock entitled to vote on the matter. Your vote is advisory and so will not be binding on the Board. However, the Board and the Compensation Committee value the opinion of stockholders and expect to take into account the outcome of the vote when considering future executive compensation decisions to the extent they can determine the cause or causes of a negative vote.

Broker non-votes, if any, and abstentions will not be counted as votes cast on the matter and will have no effect on the outcome of this proposal.

**THE BOARD RECOMMENDS A VOTE "FOR"**
**THE APPROVAL, ON AN ADVISORY BASIS, OF THE COMPENSATION OF THE COMPANY'S NAMED EXECUTIVE OFFICERS.**

## PROPOSAL 3
## RATIFICATION OF SELECTION OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM FOR 2024

### Proposal to Ratify Selection of Auditors for 2024

Our Board has engaged EisnerAmper LLP as our independent registered public accounting firm for the year ending December 31, 2024 and is seeking ratification of such selection by our stockholders at the Annual Meeting. EisnerAmper LLP was appointed by our Board effective April 10, 2023, following the termination of our prior firm, Marcum LLP (''Marcum''). Representatives of EisnerAmper LLP are expected to be present at the Annual Meeting. They will have an opportunity to make a statement if they so desire and will be available to respond to appropriate questions.

### Independent Accountants

EisnerAmper LLP served as our independent registered public accounting firm for the year ended December 31, 2023, and Marcum served as our independent registered public accounting firm for the year ended December 31, 2022. The following table summarizes the total fees EisnerAmper LLP and Marcum billed and expected to be billed to us for each of the last two fiscal years.

| | 2022 | 2023 |
|---|---|---|
| Audit Fees[(a)] | $678,300 | $639,320 |
| Audit-Related Fees | — | — |
| Tax Fees | — | — |
| All Other Fees | — | — |

(a) Consists of fees for the audit of our annual financial statements and internal control over financial reporting, review of our Form 10-K, review of our quarterly financial statements included in our Forms 10-Q, services provided in connection with our proxy statement and services in connection with other SEC filings (including comfort letters).

The Audit Committee of the Board does not consider the provision of the services described above by EisnerAmper LLP to be incompatible with the maintenance of EisnerAmper LLP's independence.

Before EisnerAmper LLP is engaged by us to render audit or non-audit services, the engagement is approved by our Audit Committee. All of the services performed by Marcum and EisnerAmper LLP for the Company during 2023 were pre-approved by the Audit Committee.

### Recent Changes in Independent Registered Public Accounting Firm

#### *Dismissal of Marcum LLP*

Our Board conducted a competitive process to determine the Company's independent registered public accounting firm for the fiscal year ending December 31, 2023. Our Board invited several independent registered public accounting firms to participate in the process.

Following the review of proposals from the independent registered public accounting firms that participated in this process, on April 7, 2023, the Board, upon recommendation of the Audit Committee, dismissed Marcum as the Company's independent registered public accounting firm, effective April 10, 2023.

The audit reports of Marcum on the consolidated financial statements of the Company as of and for the years ended December 31, 2022 and 2021, did not contain an adverse opinion or a disclaimer of opinion, and were not qualified or modified as to uncertainty, audit scope or accounting principles.

During the fiscal years ended December 31, 2021 and December 31, 2022, and the subsequent interim period preceding Marcum's dismissal, there were (i) no ''disagreements'' as that term is defined in Item 304(a)(1)(iv) of Regulation S-K, between the Company and Marcum on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, any of which that, if not resolved to Marcum's satisfaction, would have caused Marcum to make reference to the subject matter of any such disagreement in connection with its reports for such years and interim period and (ii) no reportable events within the meaning of Item 304(a)(1)(v) of Regulation S-K during the two most recent fiscal years or the subsequent interim period.

***Appointment of EisnerAmper LLP***

On April 7, 2023, our Board appointed EisnerAmper LLP as its new independent registered public accounting firm for the year ended December 31, 2023, effective April 10, 2023. During the fiscal years ended December 31, 2021 and December 31, 2022, and the subsequent interim period through April 10, 2023, neither the Company nor anyone on its behalf consulted with EisnerAmper LLP regarding (i) the application of accounting principles to a specific transaction, either completed or proposed, or the type of audit opinion that might be rendered on the Company's financial statements and neither a written report nor oral advice was provided to the Company that EisnerAmper LLP concluded was an important factor considered by the Company in reaching a decision as to any accounting, auditing, or financial reporting issue, (ii) any matter that was the subject of a disagreement within the meaning of Item 304(a)(1)(iv) of Regulation S-K, or (iii) any reportable event within the meaning of Item 304(a)(1)(v) of Regulation S-K.

**Vote Required**

Approval of the proposal to ratify the selection of EisnerAmper LLP as our independent registered public accounting firm requires the affirmative vote of a majority of the votes cast by the holders of common stock entitled to vote on the matter. We are not required to have stockholders ratify the selection of our independent registered public accounting firm. However, the Audit Committee is submitting its selection of EisnerAmper LLP to our stockholders for ratification as a matter of good corporate practice and to help ensure that we will have the necessary quorum at our Annual Meeting. If our stockholders fail to ratify the selection, the Audit Committee will reconsider whether or not to retain EisnerAmper LLP. Even if the selection is ratified, the Audit Committee in its discretion may direct the appointment of a different independent registered public accounting firm at any time during the year if they determine that such a change would be in the best interests of the Company and our stockholders.

Broker non-votes, if any, and abstentions will not be counted as votes cast on the matter and will have no effect on the outcome of this proposal.

**THE BOARD RECOMMENDS A VOTE "FOR"**
**THE RATIFICATION OF EISNERAMPER LLP AS THE COMPANY'S INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM FOR 2024.**

## SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth information regarding the ownership of shares of common stock as of March 25, 2024 (unless otherwise indicated) with respect to:

- each director and each of the Company's NEOs;
- all current directors and executive officers as a group; and
- each person known to us to be the beneficial owner of more than 5% of the shares of common stock outstanding on March 25, 2024.

As of March 25, 2024, 29,364,617 shares of Company common stock were outstanding. The number of shares beneficially owned is determined under rules of the SEC and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any shares as to which the individual has sole or shared voting power or investment power and also any shares which the individual has the right to acquire on the March 25, 2024 or within sixty days thereafter through the exercise of any stock option or other right. The persons named in the table have sole voting power and sole dispositive power with respect to the shares of common stock beneficially owned, except as otherwise noted below.

| Name of Beneficial Owner | Amount and Nature of Beneficial Ownership[a] | Percent of Class |
|---|---|---|
| **Directors and Named Executive Officers[b]** | | |
| John G. Cooper | 71,406 | * |
| Joan Lau, Ph.D. | 2,000 | * |
| Allen Nissenson, M.D. | 62,947 | * |
| Robert S. Radie | 64,194 | * |
| Mark H. Ravich[d] | 107,242 | * |
| Andrea Heslin Smiley | 61,629 | * |
| Mark Strobeck, Ph.D. | 144,121 | * |
| Megan Timmins | 57,882 | * |
| Jesse Neri | — | * |
| Marc Hoffman, MD | 44,545 | * |
| Paul McGarry | — | * |
| *All directors and current executive officers as a group (9 persons)* | 571,421 | 1.9% |
| **Greater than 5% Beneficial Holders** | | |
| Armistice Capital Master Fund, Ltd.[c] | 3,380,534 | 9.9% |

* Less than 1%.

(a) Includes shares that may be acquired upon exercise of restricted stock units and stock options within 60 days from March 25, 2024, as set forth in the table below.

| Name | RSUs | Option Shares |
|---|---|---|
| John G. Cooper | 24,715 | 12,066 |
| Joan Lau, Ph.D. | — | — |
| Allen Nissenson, M.D. | 24,715 | 6,461 |
| Robert S. Radie | 24,715 | 6,780 |
| Mark H. Ravich[d] | 24,715 | 12,210 |
| Andrea Heslin Smiley | 24,715 | 5,678 |
| Mark Strobeck, Ph.D. | — | 122,489 |
| Megan Timmins | — | 46,761 |
| Marc Hoffman, M.D.. | — | 44,545 |
| *All directors and current executive officers as a group (9 persons)* | 123,575 | 256,990 |

(b) The address of all current directors and officers is c/o Rockwell Medical, Inc., 30142 Wixom Road, Wixom, Michigan 48393.

(c) Based on Company records and the Schedule 13G/A filed with the SEC on February 14, 2024 reflecting ownership as of December 31, 2023. Consists of shares, shares underlying warrants and prefunded warrants, the exercise of which is subject to a beneficial ownership limitation of 9.99% of the outstanding common stock. By virtue of their Joint Filing Agreement, dated February 14, 2023, Armistice Capital, LLC and Steven Boyd affirm their membership in a group under SEC Rule 13d-5(b) and the group is deemed to beneficially own all of the shares beneficially owned by the group members. The address for Armistice Capital, LLC and Steven Boyd is 510 Madison Avenue, 7th Floor, New York, New York 10022.

(d) Includes (i) 48,054 shares of common stock owned by Mr. Ravich and (ii) 22,263 shares of common stock beneficially owned by Mr. Ravich as the trustee of trusts.

## CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

### Related Party Transactions

We have described below each transaction or series of similar transactions since January 1, 2022, or any currently proposed transaction, to which we were or are a party in which:

- the amount involved exceeded or exceeds the lesser of $120,000 or one percent of the average of our total assets at year end for the last two years; and
- any of our directors or executive officers, any beneficial owner of more than 5% of any class of our voting securities or any member of their immediate family had or will have a direct or indirect material interest.

Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to such securities.

*DaVita Product Purchase Agreement*

In August 2019, we entered into a Products Purchase Agreement (as amended and restated on September 18, 2023, the ''Products Purchase Agreement'') with DaVita Inc. (''DaVita''), pursuant to which 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). On April 6, 2022, the Company and DaVita entered into a Securities Purchase Agreement, pursuant to which the Company issued an aggregate of $15 million of Series X Convertible Preferred Stock to DaVita in two separate tranches. During the years ended December 31, 2023 and 2022, the Company recognized $38.4 million and $33.2 million of revenue related to the Product Purchase Agreement.

The Products Purchase Agreement may be considered a related party transaction because DaVita was (although no longer is) a 5% or greater stockholder of the Company (on an as-converted basis, assuming that only the shares of Series X Convertible Preferred Stock held by DaVita are converted into shares of common stock). The Products Purchase Agreement was negotiated on an arm's-length basis and is a market rate transaction on terms that the Company believes are no less favorable than would have been reached with an unrelated third party.

### Related Party Transactions Policies

Pursuant to its charter, our Audit Committee is charged with monitoring and reviewing transactions and relationships involving independence and potential conflicts of interest with respect to our directors and executive officers. To the extent any such transactions are proposed, they would be subject to approval by our Audit Committee in accordance with applicable law and the Nasdaq Stock Market rules, which require that any such transactions required to be disclosed in our proxy statement be approved by a committee of independent directors of our Board. In addition, our Code of Business Conduct and Ethics generally requires directors and employees to avoid conflicts of interest. Our Related Party Transactions Policy sets forth the process by which a related party transaction is disclosed, considered and approved.

## OTHER MATTERS

### Annual Report

A copy of our Annual Report to Stockholders for the year ended December 31, 2023, which includes our Annual Report Form 10-K, accompanies this Proxy Statement. We have filed an Annual Report on Form 10-K with the SEC. **We will provide, without charge, to each person being solicited by this Proxy Statement, upon the written request of any such person, a copy of our Annual Report on Form 10-K for the year ended December 31, 2023.** All such requests should be directed to Rockwell Medical's Investor Relations Department via email at IR@rockwellmed.com or via postal mail at Rockwell Medical, Inc, Attention: Investor Relations, 30142 Wixom Road, Wixom, MI 48393.

### Stockholder Proposals

Any proposal by a stockholder of the Company to be considered for inclusion in the proxy statement for the 2025 annual meeting of stockholders must be received by our Secretary by the close of business on December 16, 2024. Such proposals should be addressed to him or her at our principal executive offices and should satisfy the informational requirements applicable to stockholder proposals contained in the relevant SEC rules and our bylaws. If the date for the 2025 annual meeting of stockholders is significantly different than the first anniversary of the Annual Meeting, Rule 14a-8 of the SEC provides for an adjustment to the notice period described above.

For stockholder proposals not sought to be included in our proxy statement, our bylaws provide that, in order to be properly brought before the 2025 annual meeting of stockholders, written notice of such proposal, along with the information required by our bylaws, must be received by our Secretary at our principal executive offices no earlier than the close of business on November 16, 2024 and no later than December 16, 2024. If the 2025 annual meeting of stockholders date has been significantly advanced or delayed from the first anniversary of the date of the Annual Meeting, then notice of such proposal must be given not later than the 120th day before the meeting or, if later, the 10th day after the first public disclosure of the date of the Annual Meeting. A proponent must also update the information provided in or with the notice at the times specified in our bylaws.

Only persons who are stockholders both as of the giving of notice and the date of the stockholders meeting and who are eligible to vote at the stockholders meeting are eligible to propose business to be brought before a stockholders meeting. The proposing stockholder (or the stockholder's qualified representative) must attend the stockholders meeting in person and present the proposed business in order for the proposed business to be considered.

### Householding

We have adopted a procedure approved by the SEC called "householding." Under this procedure, certain stockholders of record who have the same address and last name will receive only one copy of our notice of annual meeting of stockholders, proxy statement, and accompanying documents, unless one or more of these stockholders notifies us that they wish to continue receiving individual copies. This procedure is intended to reduce our printing costs and postage fees.

Stockholders who participate in householding will continue to receive separate proxy cards. Also, householding will not in any way affect other mailings.

If you are eligible for householding, but you and other stockholders of record with whom you share an address currently receive multiple copies of the notice of annual meeting of stockholders, proxy statement and accompanying documents, or if you hold shares of common stock in more than one account, and in either case you wish to receive only a single copy of each of these documents for your household, please contact the Company's Secretary at 30142 Wixom Road, Wixom, MI 48393, or by telephone at (248) 960-9009.

If you participate in householding and wish to receive a separate copy of the notice of annual meeting of stockholders, proxy statement and the accompanying documents (or if you do not wish to participate in householding and prefer to receive separate copies of these documents in the future), please contact the Company's Secretary as indicated above and we will promptly them provide them to you.

Beneficial owners can request information about householding from their banks, brokers or other holders of record.

**Other Business**

Neither we nor the members of our Board intend to bring before the Annual Meeting any matters other than those set forth in the notice of Annual Meeting, and we and they have no present knowledge that any other matters will be presented for action at the Annual Meeting by others. If any other matters properly come before such Annual Meeting in accordance with our Bylaws, however, it is the intention of the persons named in the enclosed form of proxy to vote in accordance with their best judgment.

By Order of the Board of Directors,

/s/ Megan Timmins

*Megan Timmins*
*Secretary*

Wixom, Michigan
April 15, 2024