2025 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, 2025

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, 2025 (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 $28,688,982.

Number of shares outstanding of the registrant's Common Stock, par value $0.0001, as of March 23, 2026: 39,405,302 shares.

Documents Incorporated by Reference

Portions of the registrant's definitive Proxy Statement pertaining to the 2025 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, 2025, are herein incorporated by reference in Part III of this Annual Report on Form 10-K.

Table Of Contents

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,” "focus on," 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 and maintain 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:

- our ability to compete against other companies;
- 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 customers and obtain and/or retain major customers and distributors;
- any change in our customers’ interest in buying bundled products that include concentrates;
- the duration over which our cash balances will fund our operations;
- our ability to grow our business, and the future growth of our addressable market and the introduction of new therapies targeting CKD;
- 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 and Security Agreement (the "Loan Agreement") with Innovatus Life Sciences Lending Fund I, LP, (“Innovatus”);
- the effects of macroeconomic conditions (including as a result of tariffs), 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 estimates regarding the capacity of manufacturing and other facilities to support our products;
- 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; 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 Securities and Exchange Commission.

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 2026 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.

CitraPure®, Dri-Sate®, RenalPure®, and SteriLyte® are registered trademarks of Rockwell Medical. 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.

The Company is a supplier of liquid and dry, acid and bicarbonate concentrates for dialysis patients in the United States. Hemodialysis is the most common form of end-stage kidney disease treatment and is usually performed in freestanding outpatient dialysis centers, hospital-based outpatient centers, skilled nursing facilities, or 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 two facilities in Michigan and Texas and manufactures dry acid concentrate mixers at its facility in Iowa. The Company previously operated a manufacturing and warehouse facility in South Carolina, but the Company concluded manufacturing at that facility in the third quarter of 2025 as part of its ongoing efforts to streamline operations and improve efficiency.

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 2025 HIGHLIGHTS

Rockwell Medical's key developments from 2025 include:

- In February 2025, we added a single-use bicarbonate cartridge to our hemodialysis concentrates product portfolio that is 510(k) approved by the FDA and comes in two sizes, 720 grams and 900 grams.
- In February 2025, we achieved the 'Great Place to Work' certification from Great Place to Work® for the third year in a row.
- In June 2025, we maintained our membership on the Russell Microcap® Index for the third year in a row.
- In July 2025, we signed a multi-year product purchase agreement with Innovative Renal Care, one of the largest dialysis service providers in the United States.
- In September 2025, Heather Hunter was promoted to Chief Operating Officer.
- In September 2025, we were named a *Fortune* 'Best Workplaces in Manufacturing & Production' in the small & medium category for the second year in a row.
- In the fourth quarter of 2025, we added 30 new customers in the western portion of the United States. As a result, the western U.S. accounts for more than 10% of our customer clinic footprint.
- In November 2025, we named Rashad Brown as Vice President, Manufacturing and Supply Chain.
- In November 2025, we appointed Joe Dawson to the Company's board of directors.
- In December 2025, we amended our Amended and Restated Product Purchase Agreement (the "Amended Agreement") dated September 18, 2023 with DaVita, Inc. ("DaVita"), extending the term through December 31, 2026. As part of the amendment, product pricing will be increased for the extended term.

OUR STRATEGY

Rockwell Medical is focused on innovative, long-term growth strategies that deliver exceptional value to the healthcare system and provide a positive impact on the lives of patients.

Rockwell’s business strategy is centered on three core elements:

1) Create a profitable, leading hemodialysis concentrates business servicing hemodialysis centers in the United States and internationally;
2) Build a diversified portfolio of renal care or other medical products that integrate into our business infrastructure; and
3) Seek the next advancement in renal care to drive innovative treatments for patients.

Rockwell Medical continues to focus on driving growth and identifying opportunities that have the potential to improve the Company's performance so we can serve more patients, clinics, and major medical centers around the world.

OUR BUSINESS

Rockwell's core business 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 typically performed in freestanding outpatient dialysis centers, hospital-based outpatient centers, skilled nursing facilities, or 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

the 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. Rockwell currently provides a portfolio of hemodialysis concentrates products to 294 customers, including all five of the leading dialysis providers in the United States.

Our Products:

There are over 490,000 patients in the United States who undergo dialysis treatment each year, increasing 1% to 3% annually. Patients undergoing dialysis typically receive treatment three times per week, or approximately 156 times per year. Each treatment consumes approximately three gallons of concentrates which translates to 230 million gallons of concentrates used annually in the United States. 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

Rockwell Medical's CitraPure *c*oncentrate 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. CitraPure is also packaged as a dry powder acid concentrate to be used exclusively with Rockwell Medical's Dry Acid Concentrate Mixer. Each case of dry product produces 25 gallons of CitraPure liquid acid concentrate.

Dri-Sate Acid Concentrate

Rockwell Medical's Dri-Sate concentrate is an acetic acid-based product. Dri-Sate is packaged as a dry powder acetic acid concentrate to be used exclusively with Rockwell Medical's Dry Acid Concentrate Mixer. Each case of Dri-Sate dry product produces 25 gallons of RenalPure liquid acetic acid concentrate.

RenalPure Acid Concentrate

Rockwell Medical's RenalPure concentrate is an acetic acid-based product. RenalPure is packaged as a liquid acid concentrate in 55-gallon drums and in one-gallon jugs (sold in cases of two and four).

RenalPure Bicarbonate Concentrate

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

SteriLyte Bicarbonate Concentrate

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

Bicarbonate Cartridges

Rockwell Medical's single-use, premium grade bicarbonate cartridge contains sodium bicarbonate concentrate powder and is packaged in either 720 grams or 900 grams disposable canisters. Our bicarbonate cartridge is designed to be used for a single dialysis treatment on a compatible hemodialysis device and is packaged with ten cartridges in one case.

Dry Acid Concentrate Mix System

Rockwell Medical's Dry Acid Concentrate Mix System is 510(k) approved for exclusive use with Rockwell Medical's 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 essential ancillary products to select customers including 5% acetic acid cleaner, citric acid descaler, water softener salt pellets, and other supplies used by hemodialysis providers.

Market Opportunity:

Rockwell is the leading supplier of liquid bicarbonate concentrates and one of the largest suppliers of acid and dry bicarbonate concentrates for dialysis patients in the United States. Based on an independent research report that the Company commissioned from L.E.K. Consulting LLC in 2022, the hemodialysis concentrates market in the U.S. is projected to grow to approximately $560 million by 2028, up from $450 million in 2024. 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 a leading supplier that has the scalability to manufacture and deliver to 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:

Our commercial organization supports the Company's vision to focus its efforts on driving Rockwell Medical towards sustainable profitability. Our commercial team is focused on expanding revenue within our current customer base and seeking to grow revenue through the addition of new accounts to increase Rockwell's overall market share within the hemodialysis concentrates sector. We focus on creating long-term partnerships with customers, securing appropriate pricing for our products, and delivering high-quality product to our customers for use with their patients.

Customers:

Rockwell currently serves 294 customers, highlighted by all five of the leading dialysis providers in the United States, including Fresenius and DaVita. Rockwell's customer mix is diverse, with most customer sales concentrations under 10%. However, one customer, DaVita, accounted for 16% of our total net product sales in 2025 and 45% of our total net product sales in 2024. No other current customer accounted for more than 10% of sales in either of the last two years. Dialysate concentrates accounted for 100% of our revenue for the year ended December 31, 2025, of which approximately 88% of our sales was to distributors and customers for use in the United States.

On September 18, 2023, Rockwell and DaVita entered into an Amended Agreement, which amended and restated 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 the Company on or after December 1, 2023. The term of the Amended Agreement was scheduled to expire on December 31, 2024. Prior to the expiration, the Company received written notice from DaVita, notifying the Company that DaVita intended to extend the term of the Amended Agreement through December 31, 2025 (the "Extension Term"). Product pricing was increased for the Extension Term. DaVita subsequently indicated that it would completely transition to another supplier by mid-2025. While DaVita did significantly reduce its product purchases from Rockwell, DaVita did not completely transition its business to a different supplier. On December 31, 2025, the Company and DaVita entered into a second amendment (the "Second Amendment") to the Amended Agreement which extended the term by one additional year to December 31, 2026 (the "Second Extension Term"). The Second Amendment also provides for a price increase on the products sold under the Amended Agreement for the Second Extension Term. See "Material Agreements" below for more information on the Amended Agreement.

In 2025, Rockwell Medical signed several new long-term product purchase agreements with university medical centers, kidney centers and hospital systems. One notable new product purchase agreement was with Innovative Renal Care, one of the largest dialysis service providers in the United States, which will remain in effect for three years with the option to extend for an additional one-year period. Rockwell Medical also worked to renew and expand existing product purchase agreements. One notable expansion was with the largest provider of dialysis in skilled nursing facilities in the United States. This product purchase agreement is in effect for three years with the option to renew for one additional year and includes supply and purchasing minimums. The Company also added new customers in the western portion of the United States. As a result, the western U.S. now accounts for more than 10% of the Company's customer clinic footprint.

We supply dialysis concentrates to distributors serving over 30 foreign countries, primarily in the Americas and the Pacific Rim.

Our total international sales accounted for approximately 12% and 9% of our total sales in 2025 and 2024, respectively.

Our significant customers 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 and a discussion of certain risks related to our foreign sales.

Competition:

In the United States, our principal competitors for concentrate products are Fresenius Medical Care NA (“Fresenius”) and Nipro Medical Corporation, a subsidiary of Nipro Corporation Japan (“Nipro”).

Fresenius is 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 is also a Rockwell customer.

Nipro provides the dialysis marketplace with hemodialysis systems, dialyzers, AVF needles, bloodline tubing sets, concentrates and other renal accessories. Since it was established in 1996, Nipro has expanded its presence in the United States through acquisitions and organic growth.

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 both product quality requirements and FDA requirements. 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, services 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:

We deliver the majority of our hemodialysis concentrates products and mixers to dialysis clinics and hospitals throughout the United States via our subsidiary, Rockwell Transportation, Inc., which operates a fleet of trucks used to deliver products to our customers, with the remaining hemodialysis concentrates products and mixers being transported via other third-party carriers and distribution partners. We deliver our hemodialysis concentrates products and mixers internationally solely utilizing third-party carriers and distribution partners.

MATERIAL AGREEMENTS

Products Purchase Agreement with DaVita

On September 18, 2023, Rockwell and DaVita entered into the Amended Agreement, which amended and restated 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. The term of the Amended Agreement was scheduled to expire on December 31, 2024. Prior to the expiration, the Company received written notice from DaVita that DaVita intended to extend the term of the Amended Agreement through December 31, 2025 (the "Extension Term"). Product pricing was increased for the Extension Term. DaVita subsequently indicated that it would completely transition to another supplier by mid-2025. While DaVita did significantly reduce its product purchases from Rockwell, DaVita did not completely transition its business to a different supplier. On December 31, 2025, the Company and DaVita entered into the Second Amendment, which extended the term of the Amended Agreement by one additional year to December 31, 2026. The

Second Amendment also provides for a price increase on the products sold under the Amended Agreement for the Second Extension Term.

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 clearances for 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 regulatory control needed to provide reasonable assurances of safety and effectiveness.

Class I includes devices with the lowest risk to the patient and consists of devices for which safety and effectiveness can be reasonably assured through adherence to General Controls. General Controls require compliance with the applicable portions of the FDA's Quality System Regulation ("QSR"), which is being transitioned to the Quality Management System Regulation, 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. However, 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, post market surveillance, patient registries, and FDA guidance documents. Most Class II devices are subject to premarket review and clearance by the FDA, which is accomplished through the 510(k) premarket notification process.

Class III devices include those deemed by the FDA to pose the greatest risk such as life-supporting or life-sustaining devices, or implantable devices, and devices found 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 Premarket Approval ("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 marketing authorization for certain Class II and some Class I medical devices, a manufacturer must submit a premarket notification to the FDA under Section 510(k) of the FD&C Act demonstrating that the proposed device is "substantially equivalent" to a legally marketed predicate device. A predicate device is a device that is legally marketed in the United States and is not subject to premarket approval, including (i) a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required, (ii) a device that has been reclassified from Class III to Class II or I, or (iii) a device that was found substantially equivalent through the 510(k) process.

To establish "substantial equivalence," the proposed device must have the same intended use as the predicate device, and either (i) the same technological characteristics as the predicate device or (ii) different technological characteristics that don't raise different questions of safety or effectiveness than the predicate device and are supported by appropriate data demonstrating that the device is at least as safe and effective as the predicate. Clinical data are not always required to support a determination of substantial equivalence.

Upon submission, the FDA conducts an administrative review to determine whether the 510(k) is sufficiently complete to permit substantive review. If the submission does not meet the applicable acceptance criteria, the FDA may refuse to accept ("RTA") the submission. If accepted, the FDA conducts a substantive review to determine whether the device is substantially equivalent to the identified predicate. By statute, the FDA is required to review a 510(k) within 90 days of receipt; however, the review timeline is frequently extended due to requests for additional information and the time required for the applicant to respond. As a result, the time to clearance can vary significantly and may extend well beyond the statutory review period. There can be no assurance that any 510(k) submission will be cleared by the FDA.

If the FDA determines that the device is not "substantially equivalent" to a predicate device, the device is automatically classified into Class III by operation of law, unless and until it is reclassified. In such case, the manufacturer must either submit and obtain approval of a PMA application or pursue reclassification of the device through the *de novo* classification process, if eligible.

After a device receives 510(k) clearance, the manufacturer must assess whether any modification to the device — including changes to design, materials, manufacturing processes, software, labeling, packaging, sterilization and intended use — requires submission of a new 510(k) or, in some circumstances, a PMA. FDA regulations require a new 510(k) if a modification could significantly affect its safety or effectiveness of the device or constitutes major change in the intended use of the device. Although manufacturers are responsible in the first instance for making this determination, the FDA may review and disagree with a manufacturer's conclusion. If the FDA determines that a new 510(k) clearance or PMA approval is required for a modified device that has already been marketed, the Company may be required to cease distribution, recall the device, or seek appropriate authorization, and could be subject to enforcement action, including warning letters, civil monetary penalties, or other sanctions.

Devices for which there is no legally marketed predicate device are automatically classified into Class III, regardless of risk. The de novo classification process provides a pathway for certain novel devices presenting low to moderate risk to be classified into Class I or Class II, rather than being subject to the PMA requirements applicable to Class III devices.

Under current law, a manufacturer may submit a de novo request either (i) after receiving a "not substantially equivalent" determination in response to a 510(k) submission or (ii) directly, without first submitting a 510(k), if the manufacturer determines that no legally marketed predicate device exists. The FDA is required by statute to classify the device within 120 days of receipt of the de novo request; however, the review process often exceeds this timeframe due to requests for additional information and interactive review. If the FDA grants a de novo request, the device is classified into Class I or Class II and may be subject to General Controls and, for Class II devices, Special Controls. The classification may also serve as a predicate for future 510(k)

submissions. If the FDA declines to grant the de novo request, the device remains classified in Class III and would require approval of a PMA application before marketing.

PMA Pathway

Class III medical devices—generally those that support or sustain human life, are of substantial importance in preventing impairment of human health, or present a potential unreasonable risk of illness or injury—are subject to the FDA's Premarket Approval ("PMA") process unless reclassified. A PMA is required when a device cannot be authorized for marketing through the 510(k) premarket notification or de novo classification pathways.

A PMA application must be supported by valid scientific evidence demonstrating reasonable assurance of safety and effectiveness of the device for its intended use. A PMA typically includes extensive technical, preclinical, and clinical data; information regarding the device's design and components; manufacturing information; proposed labeling; and other information required by the FDA. Clinical studies supporting a PMA must generally be conducted under an investigational device exemption ("IDE") and in compliance with applicable FDA regulations.

Following receipt of a PMA, the FDA conducts an initial administrative review to determine whether the application is sufficiently complete to permit a substantive review. If the FDA determines that the PMA is incomplete, it may refuse to file the PMA. If the application is filed, the FDA begins an in-depth substantive review. By statute the FDA has 180 days to review a filed PMA; however, the review process typically extends beyond this period, often significantly, due to the complexity of the submission, requests for additional information, and other factors. During this review period, the FDA may issue deficiency letters requesting additional data or clarification. If an applicant fails to adequately respond to an FDA request for additional information (*e.g.*, major deficiency letter) within the time specified by the FDA (generally up to 180 days per deficiency letter) the FDA may consider the PMA withdrawn. In connection with its review, the FDA may refer the PMA to an advisory panel of independent experts for review and recommendation at a public meeting. Although the FDA considers the panel's recommendation, it is not bound by it. The FDA also typically conducts inspections of clinical trial sites to verify data integrity and compliance with applicable regulations, as well as pre-approval inspections of manufacturing facilities to assess compliance with the Quality System Regulation.

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.

As a condition of PMA approval, the FDA may require post-approval studies or postmarket surveillance to gather additional long-term safety and effectiveness data. The FDA has authority to require postmarket surveillance for certain devices, including devices that are permanent implants, life-supporting or life-sustaining devices used outside a device user facility, or devices the failure of which would be reasonably likely to have serious adverse health consequences. The FDA may also impose other post-approval requirements, including restrictions on labeling, promotion, distribution, or use of the device. Failure to comply with PMA requirements or post-approval conditions may result in enforcement action, including withdrawal of approval, product recalls, civil monetary penalties, or other regulatory sanctions, which could materially adversely affect our business, financial condition, and results of operations.

Postmarket Requirements—U.S.

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

- 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 supplements or submission of a new 510(k) for certain production 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 or unscheduled 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, handling, storage, and distribution of finished devices intended for human use. The QSR also requires, among other things, maintenance of a device master record, device history file, and complaint files. Manufacturers are also subject to periodic scheduled 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, 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 maintain customer complaint files, record lot numbers of 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, any commercial sales and distribution of our product candidates.

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, among other things, authorizes CMS to negotiate prices of certain drugs and imposes inflation-based rebates on drug manufacturers. While these provisions to not directly apply to medical devices, broader healthcare cost containment efforts or changes in reimbursement policies that may result from the IRA or similar legislation could indirectly affect demand for our products or the pricing environment in which our customers operate.

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 knowingly and willfully soliciting, receiving, offering or paying remuneration, to induce, or in return for, either the referral of an individual, or the purchase or recommendation of an item or service for which payment may be made under any federal healthcare program, such as the Medicare and Medicaid programs. The term remuneration has been interpreted broadly to include anything of value. 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 items 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. In the European Union, medical devices are regulated under the EU Medical Device Regulation (EU) 2017/745, which imposes enhanced clinical evidence, post-market surveillance, and conformity assessment requirements. 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 foreign countries. Most such applications have resulted in registration of such trademarks and service marks.

As of December 31, 2025, we owned or had the rights to, patents that include claims to ferric pyrophosphate citrate ("FPC") in both dialysate and IV compositions, formulations and methods of making and parenteral nutritional compositions, including Triferic. None of these are material to our business. We have also allowed several patents and applications that are not material to our business to lapse.

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

Human Capital

As of December 31, 2025, we had 157 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 robust package of additional benefits that support the physical and mental health and wellness 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.

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. Moreover, some of the factors, events and contingencies discussed below may have occurred in the past, but the disclosures below are not representations as to whether or not the factors, events or contingencies have occurred in the past, and instead reflect our beliefs and opinions as to the factors, events or contingencies that could materially and adversely affect us in the future.

RISK FACTOR SUMMARY

- We face competition in the concentrates market and have large competitors with substantial resources.
- Newer treatment methods and newly available medications may decrease the need for concentrates. 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.
- Our A&R Loan Agreement (as defined below) 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 in the future and additional capital that we may need to operate or expand our business may not be available.
- 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.

RISKS RELATED TO OUR BUSINESS

We face competition in the concentrates market and have large competitors with substantial resources.

The primary competitors in the market for our concentrates products are Fresenius, a large, diversified healthcare company headquartered in Germany with global operations, and Nipro, a large medical equipment manufacturing company headquartered in Japan with U.S. operations, each of which has financial, technical, manufacturing, marketing, research and management resources substantially greater than ours. We may not be able to successfully compete with these companies. Both companies have historically used product bundling and low pricing for concentrates as a competitive strategy to capture market share for their broader renal product portfolios. We may be at a disadvantage in competing against these strategies to sell concentrates products since we do not have a broader renal product portfolio to use as leverage when negotiating contracts. 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, Nipro may be seeking to increase its market

share of the domestic concentrates market, which, if successful, could have an impact upon our market share and profitability. In addition, certain national medical products distributors have recently expanded their logistical capabilities to reach the outpatient dialysis space, which may also have an impact on the competitive landscape and threaten our business, which has historically focused on service as a differentiator.

A small group of 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 small group of customers. Prior to 2025, one customer accounted for nearly half of our sales and for a substantial number of the clinics we supplied. While we continue to sell to that customer, sales are now substantially reduced compared to before 2025. We now have a group of larger customers, both domestic and international, that account for a significant portion of our business. The loss of any of these significant customers could materially and adversely affect our business, results of operations, financial position and cash flows.

Advancements in treatment modalities for end stage kidney disease and the introduction of new pharmacologic therapies may reduce demand for our hemodialysis concentrate products.

The market for our hemodialysis concentrate products depends on the continued utilization of in-center hemodialysis as a primary treatment modality for patients with end stage kidney disease ("ESKD"). However, the treatment landscape for ESKD is evolving. Technological advances, alternative renal replacement therapies, and newly developed pharmacologic agents may reduce the number of patients requiring conventional hemodialysis or may decrease the frequency or intensity of hemodialysis treatments.

For example, increased adoption of home-based dialysis modalities, including peritoneal dialysis and home hemodialysis, as well as improvements in kidney transplantation outcomes, may reduce reliance on in-center hemodialysis services. In addition, the development and commercialization of innovative therapies and devices, including wearable or implantable artificial kidney technologies, regenerative medicine approaches, and other emerging treatment options, could further diminish the demand for traditional hemodialysis.

Moreover, recently approved or future pharmacologic therapies designed to treat diseases for which chronic kidney disease ("CKD") is a comorbidity, slow the progression of CKD or better manage complications associated with ESKD may delay or reduce the need for dialysis initiation. Emerging clinical evidence indicates that certain glucagon-like peptide-1 ("GLP-1") receptor agonists may effectively treat the diseases for which CKD is a comorbidity and may also slow the progression of CKD in some patient populations. Because diabetes and obesity are leading contributors to CKD and ESKD, broader adoption of GLP-1 therapies and other novel metabolic treatments could reduce the incidence of CKD or delay its progression to ESKD and therefore reduce the number of patients requiring dialysis. To the extent these therapies decrease the number of patients who progress to dialysis-dependent kidney failure, or meaningfully delay dialysis initiation, demand for in-center hemodialysis treatments may decline over time. In addition, broader clinical adoption of such therapies, changes in clinical practice guidelines, or shifts in reimbursement policies favoring alternative treatments could adversely affect the volume of hemodialysis treatments administered.

If the number of patients receiving in-center hemodialysis decreases, demand for our products could also decrease. Any significant reduction in demand for our hemodialysis concentrates would adversely affect our revenues, profitability, and cash flows, and could materially and adversely affect our business, results of operations, financial position and cash flows.

If our customers move back to entering into long-term bundled product contracts with suppliers, our business could suffer.

The hemodialysis business experiences market cycles of customers seeking bundled and unbundled product offerings. Several of our competitors offer broad renal product portfolios and utilize a bundling approach when contracting with dialysis providers and hospitals. While the dialysis customer base currently seems to be moving away from restrictive bundled contracts,

which has improved market access for Rockwell, there have been cycles in the past in which purchasing bundled products was in favor. We do not currently have a full renal product portfolio to leverage as a comprehensive or bundled offering to providers, as we do not sell dialysis machines, certain dialysis machine-related disposables, or certain pharmaceutical products used as part of dialysis treatments. If the current cycle shifts toward customers preferring bundled contracts across a wide range of dialysis-related products, our business could suffer due to lost sales.

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 contracts that limit price increases, and we may lose other customers due to price sensitivity.

A significant portion of our costs relate to chemicals and other raw materials and transportation and we have no control over the price of such materials and services. We may not be able to recover a portion of such costs due to provisions in our agreements with our customers that cap price increases. The costs of chemicals and other raw materials are subject to price volatility based on supply and demand (including any volume discounts based on our manufacturing needs) and are highly influenced by the overall level of economic activity in the United States and abroad, which may be affected by changes in U.S. trade policies, including tariffs and other trade restrictions or the threat of such actions. In addition, labor costs have been steadily rising, and our manufacturing process is labor intensive, which increases our costs to produce our products. Rising labor costs also impact our transportation division, where we have fixed sale prices with delivery commitments to customers and thus may be required to absorb increased shipping costs.

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 some regions, 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. In the past, we have been adversely affected by a general shortage in commercial truckers in the United States and significant increases in labor and fuel costs. The recent spike in global oil prices due to the conflict in the Middle East may further increase our fuel, shipping and input costs, particularly if the price increase is sustained. In addition, we have experienced a nationwide shortage of diesel fuel in the United States or a significant increase in the price of diesel fuel, which we use to run our delivery trucks. An increase in the cost of diesel fuel or lack of availability of diesel fuel could significantly increase our costs or require us to find another way to deliver our products to clinics, including through use of third-party freight. 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.

We expect that if we continue to be subject to the limitations on price increases in our contracts, increasing costs and decreasing volumes may continue to negatively impact our profit margins and materially and adversely affect our financial position and results of operations.

A portion of our customers do not have contracts with us and buy products strictly on a purchase order basis. Others are under contract, but the agreements may not contain purchasing minimums. In addition, if we do have contracts with our customers, some allow for price increases only once per year. In situations where we are able to increase prices to keep up with our costs, including through surcharges and other methods, we may lose customers if such customers are unwilling to pay higher prices. Any inability to pass along costs, decrease in demand or loss of customers would result in lost revenue for the Company and may negatively impact our financial position and results of operations.

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. Severe weather events have forced us to close our manufacturing facilities temporarily, which strains our

production. In addition, weather-related events may jeopardize our ability to deliver our products as required by our contracts. A weak or declining United States or global economy, or changes in U.S. trade policies, including tariffs and other trade restrictions or the threat of such actions, 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 we will continue being able to do so. 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.

Certain aspects of our production and other processes are manual, which introduces risk of error and may result in rising production costs.

Certain aspects of the production of our hemodialysis concentrates products are manual and involve 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 further 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 if they are unwilling to pay higher prices, which could negatively impact our financial position.

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.

We may seek to make acquisitions or enter into business development arrangements in our concentrates business to expand our customer base or geographic footprint. In addition, as part of our business strategy, 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 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 U.S. 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 or the executive branch 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, Centers for Medicare & Medicaid Services ("CMS") has continued to modify reimbursement policies for dialysis under the end-stage renal disease ("ESRD") prospective payment system, with reimbursements generally falling short of

covering the increasing cost of dialysis care, resulting in economic pressure on 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 could result in scrutiny and 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 customers 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.

Market dynamics in the 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 changes in patient census and cost saving measures implemented by our customers, including switching to single-use bicarbonate canisters and bags. If volumes decrease substantially, we may be forced to further consolidate our operations and curtail our activities to lower our fixed costs. While we expect that 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.

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, phishing, social engineering, ransomware or other cyber-attacks. Such cyber-security breaches may compromise our system infrastructure or lead to data leakage, either internally or at our customers or business partners. Cybersecurity incidents, including phishing attacks and attempts to misappropriate or compromise confidential or proprietary information or sabotage enterprise IT systems, are becoming increasingly frequent and more sophisticated. Cybersecurity incidents increasingly involve the use of artificial intelligence and machine learning to launch more automated, targeted, and coordinated attacks on targets. The information and data processed and stored in our technology systems, and those of our strategic partners, contract research organizations, contract manufacturers, suppliers, distributors or other third parties for

which we depend to operate our business, may be vulnerable to loss, damage, denial-of-service, unauthorized access or misappropriation.

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, sales, product development, and business development expertise of the principal members of our management, operations and sales team. We have hired executive-level employees who are leading our operational and functional 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, and functional 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 certain routes in our transportation division has also presented challenges for us in the past. There is similarly 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 OUR FINANCIAL POSITION

The reduction in sales to our largest customer required us to right size our operations and our inability to appropriately reduce our scale would have a negative impact on our results of operations and financial condition.

In the fall of 2024, we were notified by our largest customer that it would be moving a substantial portion of its business to another concentrates supplier in 2025. While we continue to sell to that customer, sales are now substantially reduced compared to before 2025. Because this customer represented approximately half of our sales volume, we reduced our cost structure to maintain our pricing and our profit margin. In August 2025, we ceased production in our South Carolina facility to reduce our overhead. We have also contracted a portion of our transportation operations to reduce costs. While we were able to cut our costs through these actions, we may seek to or be required to further reduce our costs or pass along cost increases to customers when contracts permit. We are also seeking to increase our sales to new and existing customers and expand our product portfolio to increase revenue in the wake of the decrease in sales from our largest customer. The recent restructuring of our operations could impact our ability to expand our business in the longer term should we be able to attract enough business to replace the revenue gap left by the loss of our largest customer.

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

In March 2020, we entered into the Loan Agreement with 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. On January 2, 2024, we amended and restated the Loan Agreement (the "A&R Loan Agreement") to provide for the continuation of term loans initially borrowed under the Loan Agreement, in an aggregate outstanding principal amount of $8.0 million as of the effective date and $8.8 million as of December 31, 2025.

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 A&R 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; and (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 requires that we make interest-only payments for thirty months, or up to thirty-six months if certain conditions are met. Those conditions were satisfied in 2024, and the Company may make interest only payments for thirty-six months. The loan will mature on January 1, 2029, unless repaid earlier. The A&R Loan Agreement includes a financial covenant that required 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. Those projections were amended to account for the lost revenue from DaVita when it moved to a different supplier. Our inability to satisfy this financial covenant or cure any breach would constitute an event of default. The A&R Loan Agreement also includes a liquidity covenant that requires 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.

We have limited capital resources and will likely need additional funding to 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 and a cumulative deficit of approximately $403.0 million since inception and we may incur further losses. As of December 31, 2025, we had approximately $25.0 million of cash, cash equivalents and investments available-for-sale, and working capital of $28.6 million. Net cash used in operating activities for the year ended December 31, 2025 was approximately $0.7 million. 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 acquire new customers or grow revenues from existing customers, execute on business development plans, 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 existing capital resources may not be adequate to finance our operating cash requirements in the future 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:

- our ability to enter into new contracts and negotiate favorable terms with current and future 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, we 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 financial projections are based on various assumptions that may not come to fruition.

Our financial projections, including without limitation those relating to profitability and operating cash flow, are subject to many assumptions regarding our future operations, including that we are successful in selectively automating our operations, that we successfully license, launch or acquire new product offerings, that we are able to add new profitable business, 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 financial projections.

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, distribution, sale and delivery of the products we manufacture directly, or that are manufactured by or for our distribution partners, are subject to extensive regulation by the U.S. Food and Drug Administration ("FDA") and by other federal, state and foreign authorities, including, with respect to our transportation operations, the U.S. Department of Transportation ("DOT"). Before medical devices, such as our concentrate products or the bicarbonate cartridge we distribute, 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 good manufacturing practices ("cGMP") and applicable state laws. As such, we and

our distribution partners are subject to continual review and periodic inspections to assess compliance with cGMP and state laws. For example, in 2025, the FDA conducted a routine cGMP inspection of one of our manufacturing facilities and issued observations, in response to which the Company performed corrective actions and resolved the issue. While the finding was not serious, management expended time and effort on 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 customer agreements. 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 industry involves numerous commercial relationships, complex contractual arrangements, uncertain intellectual property rights, potential product liability and other aspects that create heightened risks of disputes, claims, lawsuits and investigations. In particular, we may face claims related to the safety of our products, intellectual property matters, employment matters, tax matters, commercial or financial 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. If patients experience side effects from the use of our

hemodialysis concentrates or experienced side effects 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 intellectual property, it may sue us even if we or our manufacturer have received 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 intellectual property 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.

As is common in the medical device 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;
- the loss of key customers;
- 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.

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 this reverse stock split addressed the listing deficiency, there can be no assurance that we will be able to maintain compliance with the

minimum bid price requirement going forward. Our stock price has been volatile and has trended below the minimum closing bid price from time to time.
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.

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, 2025, there were 1,170,397 shares issuable upon the exercise of then-outstanding and exercisable stock options, 2,106,167 shares issuable upon the exercise of then-outstanding stock options that were not yet exercisable, and 3,984,484 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.

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 political and economic stability. 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, the conflict in the Middle East, trade disruptions due to tariffs and threats to global alliances 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 and significant cost increases. If we fail to maintain inventory or deliver product as a result of such delays or difficulties, we could breach our agreements. In addition, tariffs imposed on goods coming into the U.S., or tariffs imposed by other countries on goods coming into those countries, could adversely impact our ability to import the products we sell, or ability to sell our products internationally. 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.

The Company's management (the "Management") and the Company's board of directors (the "Board") recognize the critical importance of maintaining the trust and confidence of our investors, employees, customers, partners, and vendors. The Board is actively involved in the oversight of the Company's risk management program, and cybersecurity represents an important component of the Company's overall approach to enterprise risk management ("ERM"). The Company's cybersecurity policies, standards, processes, and practices are fully integrated into the Company's ERM program and are informed by recognized frameworks established by the National Institute of Standards and Technology ("NIST") and other applicable industry standards. In general, the Company seeks to address cybersecurity risks through a comprehensive, cross-functional approach that is focused on preserving the confidentiality, security, and availability of the information that the Company collects and stores by identifying, preventing, mitigating, and remediating cybersecurity threats and effectively responding to cybersecurity incidents when they occur.

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 ("IT") 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 IT 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 our Director of Technology and Information Systems and supported by our outsourced IT managed services provider, under the supervision of our Chief Operating 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.

Our Chief Operating Officer, who reports directly to the Chief Executive Officer, and our Director of Technology and Information Systems, together with our other executive officers, are responsible for assessing and managing cybersecurity risks. In the last fiscal year, the Company has 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.”

Risk Management and Strategy

Rockwell Medical believes that the Company maintains an IT and security program appropriate for a company its size, taking into account its operations and risks. As one of the critical elements of the Company's overall ERM approach, the Company's cybersecurity program is focused on the following key areas:

Governance

The Board's oversight of cybersecurity risk management is supported by the Audit Committee of the Board (the "Audit Committee"), which regularly interacts with the Company's Chief Operating Officer. The Board, as a whole and at the Audit Committee level, has oversight for the most significant risks facing the Company and for the Company's processes to identify, prioritize, assess, manage, and mitigate those risks. The Audit Committee, which is comprised solely of independent directors, has been designated by the Company's Board to oversee cybersecurity risks. The Audit Committee and the Board receive updates on cybersecurity and IT matters and related risk exposures from the Company's Chief Operating Officer and other members of Management on cybersecurity risks on at least a semi-annual basis.

Collaborative Approach

The Company has implemented a cross-functional approach intended to identify, prevent, and mitigate material cybersecurity threats and incidents, while also implementing controls and processes that provide for the prompt escalation of certain cybersecurity incidents so that decisions regarding the public disclosure and reporting of such incidents can be made by Management in a timely manner.

Information Security

The Company implements organizational, administrative, and technical measures based on commercially reasonable procedures using industry standard information security measures prescribed for use by NIST, the Sarbanes-Oxley Act, and other generally recognized industry standards, in each case, designed to safeguard the confidentiality, integrity, and availability of our infrastructure and data and the resiliency of our operations. Additionally, we perform information security maturity assessments and penetration testing quarterly for our IT infrastructure, and conduct vulnerability scans across key assets, core infrastructure, and endpoints to identify potential vulnerabilities and potential cybersecurity events. We assess and prioritize the remediation of vulnerabilities and other cybersecurity risks identified through these activities, using a risk-based approach.

Technical Safeguards

The Company deploys technical safeguards that are designed to protect the Company’s information systems from cybersecurity threats, including firewalls, intrusion prevention and detection systems, anti-malware functionality and access controls, which are evaluated and improved through vulnerability assessments and cybersecurity threat intelligence.

Incident Response and Recovery Planning

The Company has established and maintains a comprehensive cybersecurity incident response plan ("IRP") which establishes a framework designed to enable us to respond to cybersecurity incidents in a consistent, timely, and effective manner. Our IRP outlines procedures for identifying, reporting, investigating, assessing, and responding to cybersecurity incidents, including incident response team formation, roles and responsibilities by department, and communication and escalation protocols. Depending on the severity of the cybersecurity incident, the Company's IRP contemplates escalation to Management and the Audit Committee and/or the full Board, as well as periodic briefings on developments related to the incident response. We review and update our IRP annually and have conducted training of key team members regarding the IRP.

Third-Party Risk Management

The Company maintains a risk-based approach to identifying and overseeing cybersecurity risks presented by third parties, including vendors, service providers and other external users of the Company’s systems, as well as the systems of third parties that could adversely impact our business in the event of a cybersecurity incident affecting those third-party systems.

Education, Awareness and Training

The Company provides regular, mandatory cybersecurity training as a means to equip the Company’s personnel with effective tools to address cybersecurity threats, and to communicate the Company’s evolving information security policies, standards, processes and practices. We conduct automated phishing simulation campaigns which can trigger additional training for personnel on how to recognize social engineering attempts (e.g., phishing, smishing, vishing, etc.). We track performance on phishing exercises to help us monitor the awareness of our employees and inform future training priorities.

Risk and Readiness Assessments

The Company engages in the periodic assessment and testing of the Company's policies, standards, processes and practices that are designed to address cybersecurity threats and incidents. These efforts include a wide range of activities, including audits, assessments, tabletop exercises, threat modeling, vulnerability testing and other exercises focused on evaluating the effectiveness of our cybersecurity measures and planning. The Company regularly engages third parties to perform assessments on our cybersecurity measures, including information security maturity assessments, audits and independent reviews of our information security control environment and operating effectiveness. The results of such assessments, audits and reviews are reported to the Audit Committee and the Board, and the Company adjusts its cybersecurity policies, standards, processes and practices as necessary based on the information provided by these assessments, audits and reviews.

Insurance

We maintain information security risk insurance coverage to mitigate potential losses in the event of a business disruption.

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."

Item 2. Properties.

We lease a 51,000 square foot manufacturing, office and warehouse facility and an additional 17,500 square foot office and warehouse facility in Wixom, Michigan under a lease expiring in August 2027. We use the office space in Wixom, Michigan as our principal administrative office.

We lease a second 51,000 square foot manufacturing, office and warehouse facility in Grapevine, Texas under a lease that now expires in February 2031. Upon expiration of the original lease for this facility in December 2025, the Company extended the lease for an additional 62 months.

During the year ended December 31, 2025, we entered into a lease for a 16,800-square foot storage facility in Allentown, Pennsylvania, that expires in April 2030.

Previously, we leased a 57,000 square foot manufacturing and warehouse facility in Greer, South Carolina. In the third quarter of 2025, we concluded manufacturing in that facility in preparation for the lease expiry in February 2026 as part of the Company's ongoing efforts to streamline operations and improve efficiency.

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 14, Commitments and Contingencies, to the consolidated financial statements and is incorporated by reference herein.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information

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

Holders

As of February 28, 2026, there were 30 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.

You should read the following discussion of our financial condition and results of operations in conjunction with the consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K. The following discussion contains forward-looking statements that reflect our current plans, forecasts, estimates and beliefs and involve risks and uncertainties. Our historical results are not necessarily indicative of the results that may be expected for any period in the future. Our actual results, outcomes and the timing of events could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this Annual Report on Form 10-K, particularly in the section titled "Forward-Looking Statements" and "Risk Factors." We urge you to consider these factors carefully in evaluating the forward-looking statements contained in this Annual Report. Forward-looking statements are not historical facts, reflect our current views with respect to future events, and apply only as of the date made. We do not intend, and undertake no obligation, to update these forward-looking statements, except as required by law. Unless the context requires otherwise, references to "we," "our," "us," "the Company," "Rockwell," "Rockwell Medical," and other similar terms refer to Rockwell Medical, Inc., together with its consolidated subsidiaries.

Overview

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

The Company is a supplier of liquid and dry, acid and bicarbonate concentrates for dialysis patients in the United States. Hemodialysis is the most common form of end-stage kidney disease treatment and is usually performed in freestanding outpatient dialysis centers, hospital-based outpatient centers, skilled nursing facilities, or 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'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. 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 and Texas, and manufactures its dry acid concentrate mixers at its facility in Iowa. The Company previously operated a manufacturing and warehouse facility in South Carolina, but the Company concluded manufacturing at that facility in the third quarter of 2025 as part of its ongoing efforts to streamline operations and improve efficiency.

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.

Our commercial organization supports the Company's vision to focus its efforts on driving Rockwell Medical towards sustainable profitability. Our commercial team is focused on expanding revenue within our current customer base and seeking to grow revenue through the addition of new accounts to increase Rockwell's overall market share within the hemodialysis concentrates sector. We focus on creating long-term partnerships with customers, securing appropriate pricing for our products, and delivering high-quality product to our customers for use with their patients.

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

On September 18, 2023, Rockwell and DaVita, Inc. ("DaVita") entered into an Amended and Restated Products Purchase Agreement ("the Amended Agreement"), under which the Company supplies DaVita with certain dialysis concentrates. The term of the Amended Agreement was scheduled to expire on December 31, 2024. Prior to the expiration, the Company received written notice from DaVita that DaVita intended to extend the term of the Amended Agreement through December 31, 2025 (the "Extension Term"). Subsequently, DaVita indicated that it would completely transition to another supplier, subject to further discussions between Rockwell and DaVita. Product pricing was increased for the Extension Term. Additionally, DaVita agreed to quarterly, non-refundable payments totaling $2.0 million to ensure supply continuity for products purchased during the year ended December 31, 2025. These quarterly, non-refundable payments of $2.0 million were recorded as revenue during the year ended December 31, 2025. While DaVita did significantly reduce its product purchases from Rockwell, it did not completely transition its business to a different supplier. On December 31, 2025, the Company and DaVita entered into a second amendment (the "Second Amendment") to the Amended Agreement which extended the term of the Amended Agreement by one additional year to December 31, 2026 (the "Second Extension Term"). The Second Amendment also provides for a price increase on the products sold under the Amended Agreement for the Second Extension Term.

In 2024, Rockwell continued to upgrade its manufacturing equipment to streamline production and improve margins, renegotiated pricing with key suppliers, and entered into several multi-year customer purchase agreements.

In 2025, the Company continued to right-size the organization, including the closure of the Greer facility, to enhance operational efficiency and support long-term growth, while meeting customer demand. Throughout the year, Rockwell Medical signed several new long-term product purchasing agreements with university medical centers, kidney centers and hospital systems. One notable new product purchase agreement was with Innovative Renal Care, one of the largest dialysis service providers in the United States, which will remain in effect for three years with the option to extend for an additional one-year period. Rockwell Medical also worked to renew and expand existing product purchase agreements. One notable expansion was with the largest provider of dialysis in skilled nursing facilities in the United States. This product purchase agreement is in effect for three years with the option to renew for one additional year and includes supply and purchasing minimums. Additionally in 2025, the Company added new customers in the western portion of the United States. As a result, the western U.S. now accounts for more than 10% of the Company's customer clinic footprint.

Results of Operations

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

	For the Year Ended December 31,				
	2025	% of Revenue	2024	% of Revenue	% Change
Net Sales	**$ 69,258**		**$ 101,489**		**(31.8)%**
Cost of Sales	57,563	83.1 %	84,005	82.8 %	(31.5) %
Gross Profit	11,695	16.9 %	17,484	17.2 %	(33.1) %
Research and Product Development	—	— %	19	— %	(100.0) %
Selling and Marketing	2,354	3.4 %	2,749	2.7 %	(14.4) %
General and Administrative	14,032	20.3 %	14,108	13.9 %	(0.5) %
Operating (Loss) Income	**$ (4,691)**	**(6.8)%**	**$ 608**	**0.6 %**	**(871.5)%**

Net Sales

During the year ended December 31, 2025, our net sales were $69.3 million compared to net sales of $101.5 million during the year ended December 31, 2024. Product revenue for the year ended December 31, 2025 was $68.9 million compared to product revenue of $101.4 million for the year ended December 31, 2024. The decrease of $32.5 million was primarily due to a $34.6 million reduction in sales to DaVita, partially offset by an increase of $2.1 million from price increases to other existing customers and sales to new customers. DaVita represented 16% and 45% of net sales for the years ended December 31, 2025 and 2024, respectively.

Net sales of non-product revenue were $0.3 million for the year ended December 31, 2025 from the recognition of the remaining deferred license revenue associated with Sun Pharmaceutical Industries Ltd. ("Sun Pharma"), Jeil Pharmaceutical Co., Ltd. ("Jeil Pharma") and Drogsan Pharmaceuticals ("Drogsan Pharma"). Net sales of non-product revenue were not material during the year ended December 31, 2024.

Cost of Sales and Gross Profit

Cost of sales during the year ended December 31, 2025 was $57.6 million, resulting in gross profit of $11.7 million, compared to cost of sales of $84.0 million and a gross profit of $17.5 million during the year ended December 31, 2024. Gross profit decreased by $5.8 million during the year ended December 31, 2025 compared to the year ended December 31, 2024 driven by (i) a $6.7 million decrease in product sales, which includes $1.8 million from a special large order of premium-priced product to DaVita during the year ended December 31, 2024 that did not repeat in 2025, (ii) an increase of $1.0 million in additional manufacturing costs and (iii) an increase of $0.4 million in severance expense, partially offset by a price adjustment of $2.0 million for DaVita purchases for the year ended December 31, 2025 and a $0.3 million decrease in facility transition costs.

Selling and Marketing Expense

Selling and marketing expenses were $2.4 million during the year ended December 31, 2025 compared with $2.7 million during the year ended December 31, 2024. The decrease of $0.4 million is due to $0.2 million of lower marketing costs and a $0.2 million decrease in employee compensation and recruiting expense.

General and Administrative Expense

General and administrative expenses were $14.0 million during the year ended December 31, 2025 compared with $14.1 million during the year ended December 31, 2024. The $0.1 million decrease was primarily due to increases of $0.5 million of stock-based compensation expense and $0.3 million of employee compensation, offset by decreases of $0.6 million of administrative expense and $0.3 million of professional fees.

Other Expense

Total other expense for the years ended December 31, 2025 and December 31, 2024 was $0.6 million and $1.1 million, respectively, which was driven by interest expense of $1.1 million and $1.3 million, respectively, related to our debt facility (See Note 16 in the consolidated financial statements included in this Annual Report on Form 10-K), partially offset by $0.2 million and $0.1 million of interest income, respectively, as well as realized gains on available-for-sale of investments of $0.3 million and $0.1 million, respectively.

Liquidity and Capital Resources

Since inception, we have incurred significant net losses and have funded our operations primarily through revenue from commercial products, proceeds from the issuance of debt and equity securities and payments from partnerships. On December 31, 2025, we had an accumulated deficit of approximately $403.0 million and stockholders' equity of $37.0 million. As of December 31, 2025, we had approximately $25.0 million of cash, cash equivalents and investments available-for-sale, and net working capital of $28.6 million. Net cash used in operating activities for the year ended December 31, 2025 was approximately $0.7 million.

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 ability to meet our revenue forecasts, as well as 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/or 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 holds less than 50% of its original investment in the Company's Convertible Series X Preferred Stock, the Company may only incur additional debt in the form of a purchase money loan, a working capital line of up to $5.0 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 and maintain sales with existing customers, (ii) our ability to achieve sustained profitability and (iii) our ability to identify, develop, in-license, or acquire new products in developing our 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 its 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 may include raising capital, if needed, by using the $13.1 million remaining under our at-the-market facility ("ATM Facility"), which provides for the offer and sale of up to an aggregate of $25.0 million of shares of the Company's common stock through the sales agent, or other methods or forms of financings, subject to existing limitations. For further information on our ATM Facility, see Note 11 to our consolidated financial statements in this Annual Report on Form 10-K.

On January 2, 2024, we amended our Loan and Security Agreement (the "Loan Agreement") with Innovatus Life Sciences Lending Fund I, LP (“Innovatus”) to include, among other things, an interest only period of 30 months, or up to 36 months if certain conditions are met, and to extend the maturity date to January 1, 2029. The Company is subject to certain covenants and cure provisions under the Loan Agreement. As of December 31, 2025, the Company is in compliance with all covenants. See Note 16 to our consolidated financial statements included in this Annual Report on Form 10-K for additional information.

On July 4, 2025, the U.S. enacted P.L. 119-21, a U.S. federal statute passed by the 119th United States Congress that includes tax and spending policies (the “Act”), which contains a broad range of tax reform provisions affecting businesses, including extending or reinstating certain provisions of the 2017 Tax Cuts and Jobs Act, tax relief measures, modifications of certain energy tax credits granted under the Inflation Reduction Act and limits on various tax deductions, among other key provisions. The Company evaluated the Act and concluded it will not have a material impact on its consolidated financial statements.

Global Economic Considerations

The global macroeconomic environment is uncertain and could be negatively affected by, among other things, changes in U.S. trade policies, including tariffs and other trade restrictions or the threat of such actions, 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 Middle East conflicts 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.

Net Cash (Used In) Provided by Operating Activities

Net cash used in operating activities was $0.7 million for the year ended December 31, 2025 compared to net cash provided by operating activities of $4.2 million for the year ended December 31, 2024. The change in cash used in operating activities during the current period as compared to cash provided by operating activities in the prior period was primarily due to (i) an increase in net loss of approximately $4.8 million and (ii) an increase in cash used from non-cash adjustments, partially offset by (iii) a decrease in cash used by changes in current balance sheet accounts in the ordinary course of business of approximately $0.1 million, primarily due to decreases of $3.1 million from inventory and $0.8 million from accounts payable, partially offset by increases of $2.7 million from accounts receivable, net, $0.6 million from accrued and other liabilities and $0.4 million from deferred license revenue.

Net Cash Used In Investing Activities

Net cash used in investing activities was $8.5 million during the year ended December 31, 2025. The net cash used in investing activities was due to $24.2 million in purchases of our available-for-sale investments and $0.5 million for the purchase of equipment, partially offset by proceeds from the sale of our available-for-sale investments of $16.2 million.

Net cash used in investing activities was $4.9 million during the year ended December 31, 2024. The net cash used in investing activities was due to $5.9 million in purchases of our available-for-sale investments and $1.0 million for the purchase of equipment, offset by proceeds from the sale of our available-for-sale investments of $2.0 million.

Net Cash Provided By Financing Activities

Net cash provided by financing activities was $4.3 million during the year ended December 31, 2025. The net cash provided by financing activities was primarily due to the net proceeds from the issuance of common stock in connection with the ATM facility of $7.8 million, partially offset by $2.4 million of earn-out payments in connection with the Company's 2023 acquisition of certain customer relationships, equipment, and inventory from Evoqua Water Technologies LLC ("Evoqua") (the "Evoqua Asset Acquisition") during the year ended December 31, 2025.

Net cash provided by financing activities was $7.3 million during the year ended December 31, 2024. The net cash provided by financing activities was primarily due to the gross proceeds from the issuance of common stock in connection with the ATM facility of $10.2 million, partially offset by the cash paid in connection with the Evoqua Asset Acquisition of $1.6 million during the year ended December 31, 2024.

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 13, 14, 15, and 16 to the consolidated financial statements included elsewhere in this Form 10-K for further details.

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, impairments of long-lived assets, goodwill, and deferred consideration 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 in this Annual Report on Form 10-K.

Revenue Recognition

The Company recognizes revenue under Accounting Standards Codification ("ASC") 606, *Revenue from Contracts with Customers.* The core principle of the 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.

Certain distributors deduct distribution service fees from amounts due to the Company. These fees, along with chargebacks arising from contracted pricing arrangements with certain end customers, are recorded as reductions of revenue. Chargebacks represent the difference between the distributor's acquisition cost and the lower contracted price offered to the end customer, and are estimated and recorded as a reduction of revenue at the time of the initial sale to the distributor.

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.

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, 2025 and 2024, 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 Asset Acquisition, which is being amortized over 20 years.

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 to our consolidated financial statements included in this Annual Report on Form 10-K for additional information.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk.

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

Item 8. Financial Statements and Supplementary Data.

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

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

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

Under the supervision of and with the participation of our management, including the Company's Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31, 2025. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2025. Additionally, the Company's management, including the Chief Executive Officer and Chief Financial Officer, has concluded that the consolidated financial statements included in this Annual Report are fairly stated, in all material respects, in accordance with generally accepted accounting principles in the United States for each of the periods presented herein.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. We maintain internal control over financial reporting designed to provide reasonable, but not absolute, assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Therefore, internal control over financial reporting determined to be effective provides only reasonable assurance regarding the reliability of

financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

Under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, our management evaluated the effectiveness of our internal control over financial reporting as of December 31, 2025. 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, 2025.

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, 2025, that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

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

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Except as set forth below, the information required by this Item 10 is incorporated herein by reference to information in our proxy statement for our 2026 Annual Meeting of Stockholders (the "2026 Proxy Statement"), which we expect to be filed with the SEC within 120 days of the end of our fiscal year ended December 31, 2025, 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.

Except as set forth below, the information required by this Item 11 is incorporated herein by reference to information in our 2026 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 2026 Proxy Statement, including under heading "Security Ownership of Certain Beneficial Owners and Management" and "Securities Authorized for Issuance Under Equity Compensation Plans."

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, 2025:

Plan Category	Number of securities to be issued upon exercise of outstanding options and restricted stock units and awards	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]	4,537,911	$ 2.67	1,944,938
Equity compensation plans not approved by security holders[2]	613,204	$ 2.52	—
Total	5,151,115	$ 2.64	1,944,938

(1) Consists of 2,663,360 stock options with a weighted average exercise price of $2.67, 1,156,660 restricted stock units issued at $1.11, 717,000 restricted stock units - market condition issued at $0.86 and 891 restricted stock awards issued at $62.70.

(2) Consists of 613,204 stock options with a weighted average exercise price of $2.52.

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 2026 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 2026 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	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).
10.9	Amendment No. 1 to Asset Purchase Agreement, dated July 12, 2024, by and between Rockwell Medical, Inc., and Evoqua Water Technologies LLC (Exhibit 10.1 to the Company's Form 8-K filed on July 15, 2024).
10.10+	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).

10.11*	Form of Performance Share Award Agreement March 2017 (Director Version) (Exhibit 10.65 to the Company's Form 10-O filed May 9, 2017).
10.12*	Rockwell Medical, Inc. Amended and Restated 2018 Long Term Incentive Plan (Exhibit 10.1 to the Company's Form 10-Q filed on August 14, 2025).
10.13*	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).
10.14*	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).
10.15*	Form of Restricted Stock Unit Award Agreement Employee Version (2018 Long Term Incentive Plan).
10.16*	Form of Restricted Stock Unit Award Agreement Director Version (2018 Long Term Incentive Plan).
10.17*	Performance Stock Unit Award Agreement (Exhibit 10.2 to the Company's Form 10-Q filed on August 14, 2025).
10.18*	Rockwell Medical, Inc. Short Term Incentive Plan (Exhibit 10.1 to the Company's Form 10-Q filed on November 14, 2022).
10.19*	Form of Indemnification Agreement (Exhibit 10.1 to the Company's Form 8-K filed August 30, 2019).
10.20*	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-O filed November 8, 2017).
10.21*	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).
10.22*	Employment Agreement dated July 21, 2021 between Rockwell Medical, Inc. and Megan Timmins (Exhibit 10.30 to the Company's Form 10-K filed on March 21, 2024).
10.23*	Employment Agreement, dated as of October 16, 2023, between the Company and Jesse Neri (Exhibit 10.1 to Form 8-K filed on December 12, 2024)
10.24*	Employment Agreement, dated as of August 31, 2022, as amended, between the Company and Heather Hunter (incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed on September 29, 2025).
10.25*#	Consulting Agreement dated as of February 1, 2026 between the Company and Joseph Dawson.
19.1	Rockwell Medical, Inc. Statement of Company Policy Prohibiting Insider Trading (Exhibit 10.32 to the Company's Form 10-K filed on March 21, 2024)
21.1	List of Subsidiaries (Company's Form 10-K filed on March 31, 2021).
23.1#	Consent of EisnerAmper LLP.
31.1#	Certification of Chief Executive Officer Pursuant to Rule 13a-14(a).
31.2#	Certification of Chief Financial Officer Pursuant to Rule 13a-14(a).
32.1#	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1	Rockwell Medical, Inc. Amended and Restated Clawback Policy (Exhibit 10.31 to the Company's Form 10-K filed on March 21, 2024).
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, Ph.D.

President and Chief Executive Officer

Date: March 26, 2026

POWER OF ATTORNEY

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

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons on behalf of registrant and in the capacities and on the dates indicated.

SIGNATURE	TITLE	DATE
/s/ Mark Strobeck Mark Strobeck, Ph.D.	President, Chief Executive Officer and Director (Principal Executive Officer)	March 26, 2026
/s/ Jesse Neri Jesse Neri	Senior Vice President, Chief Financial Officer (Principal Financial Officer)	March 26, 2026
/s/ Nicholas Fanslau Nicholas Fanslau	Controller (Principal Accounting Officer)	March 26, 2026
/s/ Robert S. Radie Robert S. Radie	Director and Chairman of the Board	March 26, 2026
/s/ John G. Cooper John G. Cooper	Director	March 26, 2026
/s/ Joseph Dawson Joseph Dawson	Director	March 26, 2026
/s/ Joan Lau Joan Lau, Ph.D.	Director	March 26, 2026
/s/ Allen R. Nissenson Allen R. Nissenson, M.D.	Director	March 26, 2026
/s/ Mark H. Ravich Mark H. Ravich	Director	March 26, 2026

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Rockwell Medical, Inc. and Subsidiaries (the "Company") as of December 31, 2025 and 2024, and the related consolidated statements of operations, comprehensive loss, changes in stockholders' equity, and cash flows for each of the years 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, 2025 and 2024, and the consolidated results of their operations and their cash flows for each of the years 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 audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB. We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the 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 audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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

Critical Audit 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.

Revenue – Chargeback Accrual

As disclosed in Note 3 to the financial statements, the Company records variable consideration estimated at the time of sale, for chargebacks in connection with new distributor relationships in 2025. The amount accrued for chargebacks as of December 31, 2025 is approximately $1.0 million. Management's estimate of the chargeback accrual is based on estimated inventory levels held by the distributor in the channel that are expected to be sold through to specific customers, impacted by the contractual end customer selling price for each product versus the distributor acquisition cost.

We identified the chargeback accrual as a critical audit matter due to the significant judgment and estimation required by management to determine the accrual. As a result there is especially challenging auditor judgment required with respect to measurement uncertainty, in connection with the calculation of the chargeback accrual given certain assumptions used including sell through trends of the distributor and the lack of significant historical evidence available to predict future activity in 2026. This in turn led to a high degree of auditor subjectivity and significant audit effort was required in performing our procedures and evaluating audit evidence relating to estimates made by management.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the financial statements. These procedures included assessing the design and implementation of controls relating to the chargeback accrual. We evaluated the estimated inventory levels in the distribution channel expected to be sold through to specific customers, considered the underlying contracts for the distributor acquisition cost, and inspected external information from the distributor including the contractual end customer selling price for each product as well as the sell through activity to date. We performed an analysis of the Company's accrual using our independent assumptions. We further evaluated the chargeback accrual by analyzing actual monthly sale and chargeback trends and by comparing the recorded accrual to subsequent amounts ultimately charged back by the distributor.

/s/ EisnerAmper LLP

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

EISNERAMPER LLP
Iselin, New Jersey
March 26, 2026

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(In thousands, except share and par value amounts)

	December 31, 2025	December 31, 2024
ASSETS		
Cash and Cash Equivalents	$ 10,711	$ 15,662
Investments Available-for-Sale	14,286	5,940
Accounts Receivable, net	8,143	8,291
Inventory, net	3,424	5,778
Prepaid and Other Current Assets	1,599	1,359
Total Current Assets	**38,163**	**37,030**
Property and Equipment, net	4,629	5,785
Inventory - Non-Current	—	178
Right of Use Assets - Operating, net	2,569	3,215
Right of Use Assets - Finance, net	651	1,344
Intangible Assets, net	9,656	10,207
Goodwill	921	921
Other Non-Current Assets	556	528
Total Assets	**$ 57,145**	**$ 59,208**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts Payable	$ 1,999	$ 2,869
Accrued Liabilities	4,337	6,275
Deferred Consideration - Current	1,000	2,371
Lease Liabilities - Operating - Current	1,155	1,566
Lease Liabilities - Finance - Current	469	599
Deferred License Revenue - Current	—	46
Insurance Financing Note Payable	264	268
Customer Deposits	356	97
Total Current Liabilities	**9,580**	**14,091**
Lease Liabilities - Operating - Long-Term	1,454	1,699
Lease Liabilities - Finance - Long-Term	304	931
Term Loans - Long-Term, Net of Issuance Costs	8,826	8,472
Deferred License Revenue - Long-Term	—	429
Deferred Consideration - Long-Term	—	1,000
Total Liabilities	**20,164**	**26,622**
Commitments and Contingencies (See Note 14)		
Stockholders' Equity:		
Preferred Stock, $0.0001 par value, 2,000,000 shares authorized, 15,000 shares issued and outstanding at both December 31, 2025 and 2024	—	—
Common Stock, $0.0001 par value, 170,000,000 shares authorized, 39,405,302 and 34,056,920 shares issued and outstanding at December 31, 2025 and 2024, respectively	4	3
Additional Paid-in Capital	439,838	430,207
Accumulated Deficit	(402,992)	(397,678)
Accumulated Other Comprehensive Income	131	54
Total Stockholders' Equity	**36,981**	**32,586**
Total Liabilities and Stockholders' Equity	**$ 57,145**	**$ 59,208**

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,	
	2025	**2024**
Net Sales	$ 69,258	$ 101,489
Cost of Sales	57,563	84,005
Gross Profit	11,695	17,484
Research and Product Development	—	19
Selling and Marketing	2,354	2,749
General and Administrative	14,032	14,108
Operating (Loss) Income	**(4,691)**	**608**
Other Income (Expense):		
Realized Gain on Available-for-Sale Investments	267	74
Interest Expense	(1,124)	(1,254)
Interest Income	234	92
Total Other Expense, net	**(623)**	**(1,088)**
Net Loss	**$ (5,314)**	**$ (480)**
Net Loss Per Share Attributable to Common Stockholders - Basic and Diluted	**$ (0.15)**	**$ (0.03)**
Weighted Average Number of Shares of Common Stock Outstanding - Basic and Diluted	**35,974,231**	**31,058,539**

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,	
	2025	2024
Net Loss	**$ (5,314)**	**$ (480)**
Reclassification of Realized Gain on Available-for-Sale Investments Included in Net Loss	(267)	(25)
Unrealized Gain on Available-for-Sale Investments	344	85
Foreign Currency Translation Adjustments	—	(5)
Comprehensive Loss	**$ (5,237)**	**$ (425)**

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, 2024	**15,000**	**$ —**	**29,130,607**	**$ 3**	**$ 418,487**	**$ (397,198)**	**$ (1)**	**$ 21,291**
Net Loss	—	—	—	—	—	(480)	—	(480)
Reclassification of Realized Gains on Available-for-Sale Debt Instrument Investments	—	—	—	—	—	—	(25)	(25)
Unrealized Gain on Available-for-Sale Investments	—	—	—	—	—	—	85	85
Foreign Currency Translation Adjustments	—	—	—	—	—	—	(5)	(5)
Fair Value of Warrant Related to Debt Financing	—	—	—	—	247	—	—	247
Issuance of Common Stock, net of Offering Costs/At-the-Market Offering	—	—	4,718,923	—	10,172	—	—	10,172
Vesting of Restricted Stock Units Issued, net of Taxes Withheld	—	—	201,348	—	—	—	—	—
Issuance of Common Stock Upon Exercise of Options	—	—	6,042	—	9	—	—	9
Stock-based Compensation	—	—	—	—	1,292	—	—	1,292
Balance as of December 31, 2024	**15,000**	**—**	**34,056,920**	**3**	**430,207**	**(397,678)**	**54**	**32,586**
Net Loss	—	—	—	—	—	(5,314)	—	(5,314)
Reclassification of Realized Gain on Available-for-Sale Investments	—	—	—	—	—	—	(267)	(267)
Unrealized Gain on Available-for-Sale Investments	—	—	—	—	—	—	344	344
Issuance of Common Stock, net of Offering Costs/At-the-Market Offering	—	—	4,964,636	1	7,799	—	—	7,800
Vesting of Restricted Stock Units Issued, net of Taxes Withheld	—	—	373,433	—	—	—	—	—
Issuance of Common Stock Upon Exercise of Options	—	—	10,313		16	—	—	16
Stock-based Compensation	—	—	—	—	1,816	—	—	1,816
Balance as of December 31, 2025	**15,000**	**$ —**	**39,405,302**	**$ 4**	**$ 439,838**	**$ (402,992)**	**$ 131**	**$ 36,981**

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,	
	2025	**2024**
Cash Flows From Operating Activities:		
Net Loss	**$ (5,314)**	**$ (480)**
Adjustments To Reconcile Net Loss To Net Cash (Used In) Provided By Operating Activities:		
Depreciation and Amortization	2,192	2,180
Stock-based Compensation	1,816	1,292
Write-off of Inventory	178	—
Change in Inventory Reserves	(425)	425
Non-cash Lease Expense from Right of Use Assets	2,141	1,960
Amortization of Debt Financing Costs and Accretion of Debt Discount and Premium	354	426
Loss on Disposal of Assets	57	—
Realized Gain on Sale of Investments	(267)	(74)
Gain on Early Termination of Lease Liability	(24)	—
Provision for Credit Losses	246	—
Changes in Assets and Liabilities:		
Accounts Receivable	(98)	2,610
Inventory	2,779	(332)
Prepaid and Other Assets	392	374
Accounts Payable	(870)	(1,647)
Lease Liabilities	(1,662)	(1,452)
Accrued and Other Liabilities	(1,679)	(1,034)
Deferred License Revenue	(475)	(46)
Changes in Operating Assets and Liabilities	(1,613)	(1,527)
Net Cash (Used In) Provided by Operating Activities	**(659)**	**4,202**
Cash Flows From Investing Activities:		
Purchases of Investments Available-for-Sale	(24,202)	(5,858)
Proceeds from Sales of Investments Available-for-Sale	16,200	2,003
Purchases of Equipment	(542)	(1,011)
Net Cash Used In Investing Activities	**(8,544)**	**(4,866)**
Cash Flows From Financing Activities:		
Payments on Insurance Financing Note Payable	(664)	(646)
Payments on Finance Lease Liabilities	(529)	(558)
Proceeds from Issuance of Common Stock	7,816	10,181
Deferred Consideration Paid in Connection with Evoqua Asset Acquisition	(2,371)	(1,629)
Net Cash Provided By Financing Activities	**4,252**	**7,348**
Effect of Exchange Rate Changes on Cash and Cash Equivalents	—	(5)
Net (Decrease) Increase in Cash and Cash Equivalents	(4,951)	6,679
Cash and Cash Equivalents at Beginning of Year	15,662	8,983
Cash and Cash Equivalents at End of Year	**$ 10,711**	**$ 15,662**
Supplemental Disclosure of Cash Flow Information:		
Cash Paid for Interest	$ 772	$ 847
Supplemental Disclosure of Noncash Investing and Financing Activities:		
Issuance of Warrant in Connection with the Third Amendment as Debt Issuance Costs	$ —	$ 247
Right of Use Assets - Operating Obtained in Exchange for Lease Liabilities - Operating	$ 1,006	$ 2,012
De-recognition of Lease Liability - Finance and Right of Use Asset - Finance Upon Early Termination	$ 228	$ —
Change in Unrealized Gain on Investments Available-for-Sale	$ 77	$ 60
Increase in Prepaid Assets from Insurance Financing Note Payable	$ 660	$ 670

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

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1. Description of Business

Rockwell Medical, Inc. (the "Company", "Rockwell", or "Rockwell Medical") is a healthcare company that develops, manufactures, commercializes, and distributes a portfolio of hemodialysis products for dialysis providers worldwide.

Rockwell is a leading supplier of liquid and dry, acid and bicarbonate concentrates for dialysis patients in the United States. Hemodialysis is the most common form of end-stage kidney disease treatment and is usually performed at freestanding outpatient dialysis centers, at hospital-based outpatient centers, at skilled nursing facilities, or in a patient’s home.

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 and Texas, and manufactures its dry acid concentrate mixers at its facility in Iowa. The Company previously operated a manufacturing and warehouse facility in South Carolina, but the Company concluded manufacturing at that facility in the third quarter of 2025 as part of its ongoing efforts to streamline operations and improve efficiency. Rockwell delivers 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 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

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, 2025, Rockwell had an accumulated deficit of approximately $403.0 million and stockholders' equity of $37.0 million. As of December 31, 2025, Rockwell had approximately $25.0 million of cash, cash equivalents and investments available-for sale, and working capital of $28.6 million. Net cash used in operating activities for the year ended December 31, 2025 was $0.7 million.

Management evaluated its going concern by reviewing the Company's operational plans which include executing on projected financial performance, 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 may include raising capital, if needed, by using the $13.1 million remaining on its at-the-market ("ATM") facility or other methods or forms of financings, subject to existing limitations. If the Company attempts to obtain additional debt or equity financing, the Company cannot assume such financing will be available on favorable terms, if at all.

The Company is subject to certain covenants and cure provisions under its Loan Agreement (as defined below in Note 16) with Innovatus Life Sciences Lending Fund I, LP ("Innovatus"), which, on January 2, 2024, 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 to extend the maturity date to January 1, 2029 (See Note 16 for further detail). The Company satisfied those conditions and will now make interest-only payments for the full 36 months. As of December 31, 2025, the Company is in compliance with all covenants.

Global Economic Conditions - Risks and Uncertainties

The global macroeconomic environment is uncertain, and could be negatively affected by, among other things, changes in U.S. trade policies, including tariffs and other trade restrictions or the threat of such actions, 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 Middle East 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, if any, of this economic and political instability on its 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. Basis of Presentation, Summary of Significant Accounting Policies and Recent Accounting Pronouncements

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 2020 for the purpose of conducting certain commercial activities in India. All intercompany balances and transactions have been eliminated in consolidation.

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 revenues and expenses during the reporting period. Actual results could differ from those estimates.

Restructuring and Other Charges

During the year ended December 31, 2025, the Company concluded manufacturing at its facility in Greer, South Carolina as part of its ongoing efforts to streamline operations and improve efficiency. As a result, the Company incurred severance expense and other closure-related costs during the year ended December 31, 2025 of $1.0 million which were included in cost of sales on the accompanying consolidated statements of operations. No impairment losses were recorded, as the plant's assets were either fully depreciated or transferred to other operating locations. The closure is not expected to have a significant impact on the Company's future operations, and the restructuring costs associated with these activities were substantially completed by December 31, 2025.

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 Rockwell from a customer, are excluded from revenue.

Certain distributors deduct distribution service fees from amounts due to the Company. These fees, along with chargebacks arising from contracted pricing arrangements with certain end customers, are recorded as reductions of revenue. Chargebacks represent the difference between the distributor's acquisition cost and the lower contracted price offered to the end customer, and are estimated and recorded as a reduction of revenue at the time of the initial sale to the distributor. Chargeback estimates represent variable consideration and are determined based on contractual pricing arrangements, historical chargeback activity and expected sales to eligible end customers.

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 when the customer takes control at the shipping point, which is generally the Company's plant or warehouse. For other customers, the Company recognizes revenue based on when the customer takes control of the product upon delivery. 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 three distribution and license agreements, which were 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 to determine that regulatory approval was probable as of the execution of the agreement. During the year ended December 31, 2025, all remaining deferred revenue relating to the distribution and license agreements was recognized, resulting in $0.3 million of revenue recorded. All license agreements have been terminated.

Product Purchase Agreement

On September 18, 2023, Rockwell and DaVita, Inc. ("DaVita") entered into an Amended and Restated Products Purchase Agreement (the "Amended Agreement"), 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. Prior to the expiration of the Amended Agreement on December 31, 2024, the Company received written notice, notifying the Company that DaVita intended to extend the term of the Amended Agreement through December 31, 2025 with an increase in product pricing. DaVita subsequently indicated that it planned to transition to another supplier by mid-2025, subject to further discussions between Rockwell and DaVita. DaVita agreed to quarterly, non-refundable payments totaling $2.0 million during the year ended December 31, 2025 to ensure supply continuity during the transition period for products purchased. These quarterly, non-refundable payments totaled $2.0 million and were recorded as revenue during the year ended December 31, 2025. On December 23, 2025, DaVita and the Company extended the term of the Amended Agreement through December 31, 2026 (the "Extension Term") with an increase in product pricing during the Extension Term.

Disaggregation of revenue

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

In thousands	Year Ended December 31, 2025		
Products By Geographic Area	Total	U.S.	Rest of World
License Fee – Over Time	$ 325	$ —	$ 325
Concentrate Product Sales - Point-in-Time	68,933	60,358	8,575
Net Revenue	$ 69,258	$ 60,358	$ 8,900

In thousands	Year Ended December 31, 2024		
Products By Geographic Area	Total	U.S.	Rest of World
License Fee – Over Time	$ 46	$ —	$ 46
Concentrate Product Sales - Point-in-Time	101,443	92,258	9,185
Net Revenue	$ 101,489	$ 92,258	$ 9,231

Contract balances

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

In thousands	December 31, 2025	December 31, 2024	January 1, 2024
Accounts Receivable, net	$ 8,143	$ 8,291	$ 10,901
Contract Liabilities, which are included in deferred license revenue	$ —	$ 475	$ 521

There were no other material contract assets recorded on the consolidated balance sheets as of December 31, 2025 and 2024. The Company does not generally accept returns of its concentrate products and no material reserve for returns of concentrates products was established as of December 31, 2025 or 2024.

Transaction price allocated to remaining performance obligations

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 nil as of both December 31, 2025 and 2024. 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.

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 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.

The Company may be exposed to credit losses through its available-for-sale debt securities. Unrealized losses resulting from the amortized cost basis of any available-for-sale debt security exceeding its fair value are evaluated for identification of credit and non-credit related factors. Any difference between the fair value of the debt security and the amortized cost basis not attributable to credit related factors are reported in other comprehensive income. A credit-related impairment is recognized as an allowance on the balance sheet with a corresponding adjustment to earnings. When evaluating the investments for impairment at each reporting period, the Company reviews factors such as the extent of the unrealized loss, current and future economic market conditions and the economic and financial condition of the issuer and any changes thereto.
Realized gains or losses resulting from the sale of these securities are determined based on the specific identification of the securities sold.

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, and is presented net of estimated chargebacks. 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 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 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, 2025 and 2024, 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, 2025 and 2024, and determined that no adjustment for impairment of goodwill or indefinite lived assets was required during the years ended December 31, 2025 and 2024.

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 at both December 31, 2025 and 2024.

Definite-lived intangible assets consist of our customer list associated with the Evoqua Asset Acquisition. 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 Company accounts for uncertain tax positions in accordance with ASC 740, Income Taxes. The Company evaluates its tax positions for all open tax years and recognizes tax benefits when it is more likely than not (i.e., a likelihood of greater than 50 percent), based on the technical merits, that the position will be sustained upon examination by the applicable taxing authority. Tax positions that meet the more-likely-than-not recognition threshold are measured as the largest amount of tax benefit that is greater than 50 percent likely of being realized upon ultimate settlement. Tax positions that do not meet the recognition threshold are not recognized in the financial statements. The Company recognizes interest and penalties related to uncertain tax positions in income tax expense. Accrued interest and penalties are included in the related tax liability on the balance sheet.

Research and Product Development

The Company recognizes research and product development expenses as incurred. The Company did not incur any product development and research costs in 2025 and minimal product development and research costs in 2024.

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, 2025 and 2024, the Company recorded stock-based compensation expense on its options granted under the Company's equity compensation plans to its directors and officers, and its employees (See Note 12).

Market and Performance-Based Stock Unit Awards

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

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

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 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.

Basic income (loss) per share is computed by dividing net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding during the period, excluding the effects of any potentially dilutive securities. Diluted EPS gives effect to the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock, using the more dilutive of the two-class method and the if-converted method in the period of earnings. The two-class method is an earnings allocation method that determines income (loss) per share (when there are earnings) for common stock and participating securities. The if-converted method assumes all convertible securities are converted into common stock. Diluted EPS excludes all dilutive potential shares of common stock if their effect is anti-dilutive.

The Company's potentially dilutive securities include stock options, restricted stock awards and units, convertible preferred stock and warrants. The following table includes the potential shares of common stock that were excluded from the computation of diluted EPS per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	As of December 31,	
	2025	2024
Warrants to Purchase Common Stock	3,984,484	3,984,484
Options to Purchase Common Stock	3,276,564	1,886,247
Convertible Preferred Stock	1,405,001	1,391,045
Unvested Restricted Stock Units	1,156,660	584,309
Unvested Restricted Stock Units - Market Condition	717,000	—
Unvested Restricted Stock Awards	891	891
Total	10,540,600	7,846,976

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

	Years Ended December 31,	
	2025	2024
Numerator:		
Net Loss	$ (5,314)	$ (480)
Accretion of Series X Preferred Stock	(153)	(302)
Net Loss Attributable to Common Stockholders	$ (5,467)	$ (782)
Denominator		
Weighted Average Number of Shares of Common Stock Outstanding - Basic and Diluted	35,974,231	31,058,539
Net Loss Per Share Attributable to Common Stockholders - Basic and Diluted	$ (0.15)	$ (0.03)

Accumulated Other Comprehensive Loss

Accumulated other comprehensive loss includes all changes in equity during a period except those that resulted from investments by or distributions to the Company's stockholders. Accumulated other comprehensive loss refers to revenues, expenses, gains and losses that are included in comprehensive income, but excluded from net loss as these amounts are recorded directly as an adjustment to stockholders' equity. As of December 31, 2025, accumulated other comprehensive loss consists of (i) unrealized gain on available-for-sale investments of $0.1 and (ii) foreign currency translation adjustments of nil.

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.

Recently Adopted Accounting Pronouncements

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. The Company adopted ASU 2023-09 for the year ended December 31, 2025 and applied the new disclosure requirements prospectively to the current annual period. Prior period disclosures have not been adjusted to reflect the new disclosure requirements. For additional information, see Note 17.

New Accounting Pronouncements

In November 2024, the FASB issued ASC 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expense*s, which is intended to provide more detailed information about specified categories of expenses (purchases of inventory, employee compensation, depreciation and amortization) included in certain expense captions presented on the consolidated statement of operations. This new standard is effective for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027. Early adoption is permitted. The amendments may be applied either (1) prospectively to financial statements issued for periods after the effective date of this ASU or (2) retrospectively to all prior periods presented in the consolidated financial statements. The Company is currently assessing the impact this ASU will have on the consolidated financial statements and footnote disclosures.

In July 2025, the FASB issued ASU 2025-05, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses for Accounts Receivable and Contract Assets*, which simplifies the estimation of credit losses on current accounts receivable and contract assets by allowing the election of a practical expedient to assume that the current conditions as of the consolidated balance sheet date will remain unchanged for the remaining life of the asset when developing a reasonable and supportable forecast as part of estimating expected credit losses on these assets. The guidance in this ASU is effective for fiscal years beginning after December 15, 2025 and for interim periods within those fiscal years. Early adoption is permitted. If adopted in an interim period, entities are required to apply the new guidance as of the beginning of the annual reporting period that includes such interim period. The Company is currently assessing the impact this ASU will have on the consolidated financial statements and footnote disclosures.

Note 4. Intangible Assets and Deferred Consideration

Intangible Assets

Our customer relationship intangible asset relates to customer relationships acquired in connection with an acquisition (the "Evoqua Asset Acquisition") executed on July 10, 2023 with Evoqua Water Technologies LLC ("Evoqua").

The details of our intangible assets subject to amortization are set forth below (in thousands):

	December 31, 2025			
	Useful Life	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Customer Relationships	20 years	$ 11,035	$ (1,379)	$ 9,656

	December 31, 2024			
	Useful Life	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Customer Relationships	20 years	$ 11,035	$ (828)	$ 10,207

During the year ended December 31, 2025, the Company recorded amortization of its customer relationship intangible asset of $0.6 million, resulting in a net intangible asset of $9.7 million as of December 31, 2025. During the year ended December 31, 2024, the Company recorded amortization of its customer relationship intangible asset of $0.6 million.

Estimated future amortization expense on the Company's customer relationships intangible asset as of December 31, 2025 is as follows (table in thousands):

Year ending December 31:	
2026	$ 552
2027	552
2028	552
2029	552
2030	552
Thereafter	6,896
Total	$ 9,656

Deferred Consideration

A portion of the purchase price of the Evoqua Asset Acquisition was deferred on the acquisition date, with payment terms extending through April 2026. The Company made payments totaling $2.4 million and $1.3 million for during the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, a deferred consideration liability of $1.0 million is presented in Deferred Consideration - Current on the accompanying consolidated balance sheets.

Note 5. Investments - Available-for-Sale

Investments available-for-sale consisted of the following as of December 31, 2025 and 2024 (table in thousands):

	December 31, 2025				
	Amortized Cost	Unrealized Gain	Unrealized Loss	Accrued Interest	Fair Value
Available-for-Sale Securities					
Debt Securities	$ 14,149	$ 137	$ —	$ —	$ 14,286

	December 31, 2024				
	Amortized Cost	Unrealized Gain	Unrealized Loss	Accrued Interest	Fair Value
Available-for-Sale Securities					
Debt Securities	$ 5,880	$ 60	$ —	$ —	$ 5,940

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, 2025 and 2024, the Company's remaining available-for-sale securities are U.S. Department of the Treasury bonds and are all due within one year.

Note 6. Segment Reporting, Significant Market Segments and Customers

Operating segments are defined as components of an entity about which discrete financial information is evaluated regularly by the Company's Chief Operating Decision Maker ("CODM") in deciding how to allocate resources and assess performance. 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. Accordingly, the Company has one reportable segment. The Company has a

single management team that reports to its Chief Executive Officer, the Company's CODM, who comprehensively manages the entire Company. The accounting policies of the segment are the same as those described in the summary of significant accounting policies.

The CODM assesses performance for the segment and decides how to allocate resources based on net loss that also is reported on the statements of operations and comprehensive loss as net loss. The CODM uses net loss to monitor budget and forecast versus actual results in assessing segment performance, as well as cash forecast models, in order to evaluate operating results and performance in deciding how to allocate resources. The measure of segment assets is reported on the consolidated balance sheets as total assets.

The Company’s significant segment expenses for its one segment for the years ended December 31, 2025 and 2024 consisted of the following (table in thousands):

	Year Ended December 31,	
	2025	2024
Net Sales	$ 69,258	$ 101,489
Cost of Sales	57,563	84,005
Gross Profit	11,695	17,484
Employee Compensation	10,140	9,452
Administrative Costs	6,246	7,424
Operating (Loss) Income	**(4,691)**	**608**
Other Income (Expense):		
Realized Gain on Available-for-Sale Investments	267	74
Interest Expense	(1,124)	(1,254)
Interest Income	234	92
Total Other Expense, net	**(623)**	**(1,088)**
Net Loss	**$ (5,314)**	**$ (480)**

Significant Market Segments and Customers

Rockwell's customer mix is diverse, with most customer sales concentrations under 10%, however, one customer, DaVita, accounted for approximately 16% of Rockwell's total net product sales in 2025 and 45% of its total net product sales in 2024. Rockwell's accounts receivable from DaVita were approximately 14% and 20% of the total net consolidated accounts receivable balance as of December 31, 2025 and 2024, respectively. For additional information regarding the Company's contracts with DaVita, see Note 3. No other current customer accounted for more than 10% of sales in any of the last two years, however one other customer accounted for 17% of the Company's total net consolidated account receivable balance as of December 31, 2025.

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 12% and 9% of its total sales in 2025 and 2024, respectively.

Note 7. Inventory

Components of inventory, net of reserves as of December 31, 2025 and 2024 were as follows (table in thousands):

	December 31, 2025	December 31, 2024
Inventory - Current Portion		
Raw Materials	$ 1,848	$ 3,010
Work in Process	199	367
Finished Goods	1,377	2,401
Total Current Inventory	3,424	5,778
Inventory - Long Term[(1)]	—	178
Total Inventory	$ 3,424	$ 5,956

(1) Represents inventory related to Triferic raw materials, which was expected to be utilized for the Company's international partnerships. During the year ended December 31, 2025, the Company wrote off this remaining inventory balance, resulting in an expense of $0.2 million recorded within cost of sales in the consolidated statement of operations.

As of December 31, 2025 and 2024, Rockwell had total current concentrate inventory aggregating $3.4 million and $6.2 million, respectively, against which Rockwell had reserved $25.0 thousand and $0.5 million, respectively.

Note 8. Property and Equipment

As of December 31, 2025 and 2024, the Company’s property and equipment consisted of the following (table in thousands):

	December 31, 2025	December 31, 2024
Machinery and Equipment	$ 11,340	$ 11,973
Information Technology & Office Equipment	1,717	1,845
Leasehold Improvements	1,567	1,562
Laboratory Equipment	726	807
Total Property and Equipment	15,350	16,187
Accumulated Depreciation and Amortization	(10,721)	(10,402)
Property and Equipment, net	$ 4,629	$ 5,785

Depreciation and amortization expense for both of the years ended December 31, 2025 and 2024 was $1.6 million.

Note 9. Accrued Liabilities

Accrued liabilities as of December 31, 2025 and 2024 consisted of the following (table in thousands):

	December 31, 2025	December 31, 2024
Accrued Compensation and Benefits	$ 2,558	$ 2,744
Accrued Unvouchered Receipts	814	1,417
Accrued Manufacturing Expense	—	602
Accrued Workers Compensation	84	176
Other Accrued Liabilities	881	1,336
Total Accrued Liabilities	$ 4,337	$ 6,275

Note 10. Insurance Financing Note Payable

On June 3, 2025, the Company entered into a short-term note payable with a principal amount of $0.7 million, bearing interest at a rate of 7.14% per annum to finance various insurance policies, which required an upfront payment of $0.2 million. Principal and interest payments related to this note began on July 3, 2025 and are being paid in 10 equal monthly payments of $0.1 million, with the final payment due on April 3, 2026. As of December 31, 2025, the Company's insurance financing note payable balance was $0.3 million.

On June 4, 2024, the Company entered into a short-term note payable with a principal amount of $0.7 million, bearing interest at a rate of 7.89% per annum to finance various insurance policies. Principal and interest payments related to this note began on July 3, 2024 and were paid on a straight-line amortization over 10 months, with the final payment due on April 3, 2025. As of December 31, 2024, the Company's insurance note payable balance was $0.3 million. During the year ended December 31, 2025, the Company's insurance financing note payable balance was paid in full.

Note 11. Stockholders' Equity

Preferred Stock

On April 6, 2022, the Company and DaVita entered into the Securities Purchase Agreement (the "SPA"), which provided for the issuance by the Company of up to $15 million of preferred stock to DaVita, which was issued to DaVita during 2022 as Series X Preferred Stock and, by virtue, made DaVita a 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, 2025, a total of $0.5 million of the Series X Preferred Stock had been accreted.

The Series X Convertible Preferred Stock is convertible to common stock at a 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 SPA with DaVita. Specifically, until DaVita holds less than 50% of its original investment in the Company's Series X Convertible Preferred Stock, 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 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 as 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, 2025 and 2024, 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, 2025 and 2024, there were 170,000,000 shares of common stock, $0.0001 par value per share, authorized and 39,405,302 and 34,056,920 shares issued and outstanding, respectively.

As of December 31, 2025 and 2024, 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, and warrants (collectively, "common stock equivalents"):

	As of December 31,	
Common Stock and Common Stock Equivalents:	2025	2024
Common Stock	39,405,302	34,056,920
Options to Purchase Common Stock	3,276,564	1,886,247
Unvested Restricted Stock Awards	891	891
Unvested Restricted Stock Units	1,156,660	584,309
Convertible Preferred Stock	1,405,001	1,391,045
Unvested Restricted Stock Units - Market Condition	717,000	—
Warrants to Purchase Common Stock	3,984,484	3,984,484
Total	49,945,902	41,903,896

Controlled Equity Offering

On April 8, 2022, the Company entered into a Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co. (the "Agent"), pursuant to which the Company may offer and sell from time to time shares of Company’s common stock through the Agent pursuant to the Company’s shelf registration statement on Form S-3 (No. 333-259923) filed with the SEC on September 30, 2021 (the “Prior Registration Statement”).

This Prior Registration Statement expired on October 8, 2024 and, upon the effectiveness of the new registration statement on October 21, 2024, was deemed terminated. On November 13, 2024, in connection with the new registration statement, the Company filed a prospectus supplement covering the offer and sale of an aggregate offering price of up to $25.0 million of shares of the Company's common stock through the Agent under the Sales Agreement (as amended, the "ATM facility"). The offering and sale of such shares has been registered under the Securities Act of 1933, as amended.

During the year ended December 31, 2025, 4,964,636 shares were sold pursuant to the Sales Agreement for gross proceeds of $8.0 million, net of offering costs of $0.2 million, for net proceeds of $7.8 million. Approximately $13.1 million remains available for sale under the ATM facility.

During the year ended December 31, 2024, 4,718,923 shares were sold pursuant to the Sales Agreement for net proceeds of $10.2 million.

Warrant Issuance

In connection with the execution of the Third Amendment, as defined and described in Note 16, 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 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 Third Amendment. The warrant is equity-classified with a fair value of approximately $0.2 million at issuance, which was treated as a debt issuance cost and will be amortized through interest expense over the remaining contractual term of the Term Loan, as defined and described in Note 16.

On July 10, 2023, the Company entered into a letter agreement (the "Letter Agreement") with Armistice Capital Master Fund Ltd. ("Armistice"), in which 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 Reload Warrant may be exercised at all times prior to the 54 months' anniversary of its issuance date. The Reload Warrant provides that a holder (together with its affiliates) may not exercise any portion of 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.

Note 12. 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, 2025, 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 7,618,182. As of December 31, 2025, the 2018 LTIP had 1,944,938 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, 2025 and 2024 as follows (table in thousands):

	Year Ended December 31,	
	2025	2024
Service Based Awards:		
Restricted Stock Units	$ 968	$ 673
Stock Option Awards	848	619
Total	$ 1,816	$ 1,292

Performance Based Restricted Stock Awards

A summary of the Company's performance based restricted stock awards during the year ended December 31, 2025 is as follows:

Performance Based Restricted Stock Awards	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested at January 1, 2025	891	$ 62.70
Unvested at December 31, 2025	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, 2025, 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, 2025 is as follows:

Service Based Restricted Stock Units	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested at January 1, 2025	584,309	$ 1.72
Granted	1,025,000	$ 1.07
Forfeited	(417,649)	$ 1.85
Vested	(35,000)	$ 1.07
Unvested at December 31, 2025	1,156,660	$ 1.11

The fair value of service based restricted stock units are measured on the date of grant and amortized over the vesting period. The vesting periods range from one to three years. As of December 31, 2025, the unrecognized stock-based compensation expense was $0.7 million, which is expected to be recognized over the next 1.2 years.

Restricted Stock Units - Market Condition

During the year ended December 31, 2025, the Company granted 717,000 restricted stock units with a market condition ("RSU-MC") under its Amended and Restated 2018 Long Term Incentive Plan with a grant date fair value of $0.6 million. The RSU-MCs are subject to both service and market based vesting conditions.

The RSU-MCs will vest, subject to the recipient's continued employment through the vesting date, if the average closing price of the Company's common stock equals or exceeds $2.14 per share for any consecutive 60-day trading period occurring prior to the third anniversary of the grant date. Except in the event of a change in control or termination due to death or disability, no portion of the award will vest before the first anniversary of the grant date. The RSU-MCs qualify as equity instruments and are accounted for under ASC 718, *Compensation, Stock Compensation* ("ASU 718").

The unrecognized stock-based compensation expense in connection with the RSU-MCs was $0.5 million at December 31, 2025, which is expected to be recognized over the next 2.4 years.

The fair value of RSU-MCs was measured on the date of grant using the Monte Carlo Simulation valuation model based on the following assumptions:

Exercise price	$0.86
Expected stock price volatility	93.00%
Risk-free interest rate	3.95%
Term (years)	2.64

Service Based Stock Option Awards

The fair value of the service based stock option awards granted for the years ended December 31, 2025 and 2024 were based on the following assumptions:

	December 31,	
	2025	2024
Exercise Price	$0.87 - $1.26	$1.39 - $3.49
Expected Stock Price Volatility	90.4%	81.8% - 81.8%
Risk-free Interest Rate	3.74% - 4.14%	4.08% - 4.45%
Term (Years)	5.50 - 5.86	5.61 - 5.62

A summary of the Company's service based stock option activity for the year ended December 31, 2025 is as follows:

Service Based Stock Option Awards	Shares Underlying Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value *(in $1,000's)*
Outstanding at January 1, 2025	1,886,247	$ 3.98		$ —
Granted	1,595,000	$ 1.06		
Exercised	(10,313)	$ 1.48		
Forfeited	(139,146)	$ 1.30		
Expired	(55,224)	$ 6.38		
Outstanding at December 31, 2025	3,276,564	$ 2.64	8.0	$ —
Exercisable at December 31, 2025	1,170,397	$ 5.10	6.5	$ —

The aggregate intrinsic value is calculated as the difference between the closing price of the Company's common stock at the date indicated and the exercise price of the stock options that had strike prices below the closing price.

The weighted average per share grant date fair value for service based stock option awards during the years ended December 31, 2025 and 2024 was $0.86 and $1.03, respectively.

As of December 31, 2025, total stock-based compensation expense related to unvested options not yet recognized totaled approximately $0.9 million which is expected to be recognized over the next 2.3 years.

Note 13. 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 its 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 an employment agreement.

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 can 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 considered probable, and no milestone payments have been accrued as of December 31, 2025 and 2024.

Note 14. 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 acquires insurance policies to protect against potential losses or to partially insure against certain risks. For the Company's subsidiary, Rockwell Transportation, Inc., Rockwell previously maintained a partially self-insured workers' compensation policy. Under the policy, its self-insurance retention was $350,000 per occurrence and $618,000 in aggregate coverage for the policy year ending June 1, 2024. There were no claims paid or accrued as of December 31, 2025 for the policy year ended June 1, 2024. Estimated loss and additional future claims of approximately $84,000 have been reserved and accrued for as of December 31, 2025.

As of December 31, 2025, approximately $0.4 million was held in cash collateral and escrow by the insurance carrier for workers' compensation insurance. At December 31, 2025, 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 15. 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 six 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 2027. During March 2024, the lease for the Wixom facilities was extended by three years to August 2027, which was accounted for as a modification.

Rockwell also occupies a 51,000 square foot facility in Grapevine, Texas, under a lease expiring in February 2031. The lease, which previously expired in December 2025, was extended by 62 months to February 2031.

The Company previously operated in a 57,000 square foot facility in Greer, South Carolina, but the Company concluded manufacturing at that facility in the third quarter of 2025 as part of its ongoing efforts to streamline operations and improve efficiency. The lease expired in February 2026. The Company recognized a gain of $24,000 related to the early termination of this lease during the year ended December 31, 2025, resulting from the derecognition of the related right-of-use asset and lease liability.

During the year ended December 31, 2025, Rockwell entered into a lease for a 16,800-square foot storage facility in Allentown, Pennsylvania, that expires in April 2030, resulting in the recognition of a right-of-use asset and corresponding lease liability of approximately $1.0 million on the consolidated balance sheets.

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

	For the year ended December 31,	
	2025	2024
Operating Leases		
Operating Lease Cost	$ 1,868	$ 1,608
Variable Lease Cost	555	508
Operating Lease Expense	2,423	2,116
Finance Leases		
Amortization of Right-of-use Assets	488	559
Interest on Lease Obligations	73	114
Finance Lease Expense	561	673
Short-term Lease Rent Expense	21	21
Total Lease Expense	$ 3,005	$ 2,810
Other Information		
Operating Cash Flows from Operating Leases	$ 1,872	$ 1,753
Operating Cash Flows from Finance Leases	$ 103	$ 114
Financing Cash Flows from Finance Leases	$ 529	$ 558

	December 31,	
	2025	2024
Other Information		
Weighted-average Remaining Lease Term – Operating Leases	2.7	2.4
Weighted-average Remaining Lease Term – Finance Leases	1.7	2.5
Weighted-average Discount Rate – Operating Leases	9.6 %	6.3 %
Weighted-average Discount Rate – Finance Leases	6.8 %	6.4 %

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

	Operating	Finance
Year Ending December 31, 2026	$ 1,316	$ 504
Year Ending December 31, 2027	912	311
Year Ending December 31, 2028	328	—
Year Ending December 31, 2029	283	—
Year Ending December 31, 2030	96	—
Total	2,935	815
Less Present Value Discount	(326)	(42)
Operating and Finance Lease Liabilities	$ 2,609	$ 773

Note 16. Loan and Security Agreement

On March 16, 2020, the Company and Rockwell Transportation, Inc., as Borrowers, entered into a Loan and Security Agreement (the "Loan Agreement") with 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. The Company is no longer eligible to draw on additional tranches. 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 issued to Innovatus a warrant (each a “Warrant”, and together 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 Loans 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 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 Loans were scheduled to mature on March 16, 2025, and bore 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. 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.

On January 2, 2024, the Company entered into the Third Amendment to and Restatement of the Loan and Security Agreement (the "Third Amendment") with Innovatus, dated January 1, 2024 (the "Effective Date"). The Third Amendment provides for the continuation of term loans initially borrowed under the Loan Agreement amounting to $8.0 million as of January 1, 2024. The Company will make interest-only payments on the Term Loans for 36 months as certain conditions in the Third Amendment were met. The Company will make equal monthly payments of principal, together with applicable interest, in arrears, starting February 1, 2027. The Term Loans will mature on January 1, 2029. Effective on January 1, 2024, the Term Loans bear interest equal to the sum of (i) the greater of (a) Prime Rate (as defined in the Third Amendment) and (b) 7.50% plus (ii) 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) 1.0% of the principal amount of the Term Loans prepaid if the payment is made after January 1, 2026 but on or before January 1, 2027, or (ii) 0% of the principal amount of the Term Loans prepaid if the payment is made after January 1, 2027 through maturity; and (y) the 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 Third Amendment was treated as a modification for accounting purposes.

The Third Amendment contains various financial covenants and customary representations and warranties and affirmative and negative covenants, subject to exceptions as described in the Third Amendment. The Company's ability to comply with the covenants under the Third Amendment may be adversely affected by events beyond its control. If the Company is unable to comply with the covenants under the Third Amendment, 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. As of December 31, 2025, the Company was in compliance with all covenants under the Third Amendment.

In connection with the execution of the Third Amendment, on January 2, 2024, the Company issued a warrant to purchase shares of the Company's common stock. The warrant is equity-classified with a fair value of $0.2 million at issuance, which was treated as a debt issuance cost and in being amortized through interest expense over the remaining contractual term of the Term Loans. For additional information, see Note 11.

The effective interest rate used to amortize the debt issuance cost relating to these warrants is 11.0% as of December 31, 2025. As of December 31, 2025, the outstanding balance of the Term Loans was $8.8 million, net of aggregate unamortized issuance costs, discounts, and premium of $1.3 million. For both of the years ended December 31, 2025 and 2024, interest expense, including paid-in-kind interest, amounted to $1.1 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.

The following table reflects the schedule of principal payments on the Term Loans as of December 31, 2025 (in thousands):

Year	Principal Payments
2026	$ —
2027	3,852
2028	4,202
2029 (Inclusive of Final Fee)	1,335
Total Debt Maturities	9,389
Unamortized Issuance Costs and Discount	(563)
Term Loans, net	$ 8,826

Note 17. Income Taxes

The U.S. and foreign components of pretax loss are as follows:

	Year Ended December 31,	
	2025	2024
Pretax Loss		
U.S.	$ (5,314)	$ (480)
Foreign	—	—
Total Pretax Loss	$ (5,314)	$ (480)

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

	Year Ended December 31,			
	2025		2024	
Tax Expense Computed at Federal Statutory Rate	$ (1,116)	21.0 %	$ (101)	21.0 %
State and Local Income Tax, net of Federal Income Tax Effect	(69)	1.3 %	(6)	1.3 %
Effect of Change in Valuation Allowance	1,185	(22.3)%	107	(22.3)%
Total Income Tax Expense	$ —	— %	$ —	— %

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

	December 31,	
	2025	2024
Deferred tax assets:		
Net Operating Loss Carryforward	$ 72,886	$ 71,423
Stock Based Compensation	3,230	4,584
General Business Credit	6,872	6,872
Research & Experimental Expenses	219	338
Inventories	27	474
Deferred Interest	2,150	1,909
Accrued Expenses	68	84
Deferred License Revenue	—	106
Other Deferred Tax Assets	244	65
Total Deferred Tax Assets	85,696	85,855
Deferred Tax Liabilities:		
Goodwill & Intangible Assets	363	327
Prepaid Expenses	208	205
Book over Tax Depreciation	7	60
Total Deferred Tax Liabilities	578	592
Net Deferred Tax Asset Before Valuation Allowance	85,118	85,263
Valuation Allowance	(85,118)	(85,263)
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 $326.4 million of which approximately $192.1 million began expiring in 2025 and will continue to expire through 2040.

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, 2025 and 2024 as a result of a full valuation allowance against the net deferred tax assets as of December 31, 2025 and 2024. The valuation allowance decreased by $0.1 million during the year ended December 31, 2025. Considered together with the Company's limited history of operating income and its net losses in 2025 and 2024, management has placed a full valuation allowance against the net deferred tax assets as of December 31, 2025 and 2024.

The Company 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, 2025 and 2024. The Company has not been under tax examination in any jurisdiction for the years ended December 31, 2025 and 2024. The Company completed an audit by the Internal Revenue Services for the 2021 tax year resulting in no adjustments. Tax examination years of 2022 through 2024 remain open. A recent IRC Section 382 study has not been performed, which could limit the value of the Company's net operating losses. No income taxes have been paid or refunded during the tax year.

Note 18. Subsequent Events

Subsequent to December 31, 2025 and prior to the issuance of these financial statements, the Company renewed operating lease for its 51,000 square foot manufacturing facility in Grapevine, Texas. The related lease expired in December 2025. The renewed lease has a term from January 1, 2026 to February 28, 2031 and provides for aggregate minimum lease payments of approximately $3.3 million. The Company will recognize the related right-of-use asset and lease liability upon lease commencement in 2026.

ROCKWELL MEDICAL, INC.

Corporate Information

Annual Meeting

The Annual Meeting of the Stockholders will be held:

Friday, June 12, 2026
At 10:00 am EDT
Virtual Stockholder Meeting
www.virtualshareholdermeeting.com/RMTI2026

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, 2025 is available upon written request to:

Investor Relations
Rockwell Medical, Inc.
30142 Wixom Road
Wixom, MI 48393
IR@rockwellmed.com

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, www.sec.gov/search-filings

Transfer Agent and Registrar

Equiniti Trust Company LLC
28 Liberty Street, 53rd Floor
New York, NY 10005
Shareholder Services (800) 937-5449

Stockholder Information

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

2025 ANNUAL REPORT

www.rockwellmed.com