Rockwell Medical Provides First Quarter 2022 Financial and Operational Update

May 16, 2022

- First quarter net sales of $16.1 million, up 4.2% year-over-year -

- Submitted Supplemental Data to FDA for IND Application to enable Phase 2 FPC Home Infusion Trial -

- Amended and expanded supply agreement with DaVita, including $7.5M investment, strengthens Rockwell's financial position, laying groundwork for profitable concentrates business -

- Completion of patient enrollment ahead of schedule in pivotal Phase 3 trial of Triferic® in China -

- Conference call and webcast scheduled for today at 4:15 p.m. ET -

WIXOM, Mich., May 16, 2022 /PRNewswire/ -- Rockwell Medical, Inc. (Nasdaq: RMTI), a biopharmaceutical company dedicated to transforming the treatment of iron deficiency and anemia management and improving outcomes for patients around the world, today reported financial results and a business update for the three months ended March 31, 2022.

"As a result of our focused development plans for Ferric Pyrophosphate Citrate ("FPC"), we are setting Rockwell Medical on course to begin generating data in our Home Infusion program, where we believe FPC has the potential to be the future standard of care in the U.S. for patients receiving home infusion therapy and suffering from iron deficiency anemia. We look forward to beginning our proposed Phase 2 trial of FPC in the home infusion setting soon after the review and clearance of our recent submission by the FDA," said Russell Ellison, M.D., M.Sc., President and Chief Executive Officer of Rockwell Medical. "In our dialysis business, we are one of the two largest suppliers of life saving concentrates in the U.S., generating in excess of $60 million in revenues in 2021. We plan to restructure and grow this business to generate acceptable gross margins and cash flow. We believe we took a significant first step with our recently announced amended supply agreement and securities purchase agreement with DaVita, Inc."

First Quarter 2022 & Recent Highlights:

Home Infusion Program:

- On May 6, Rockwell provided the FDA with requested supplemental data related to its IND application submitted in December 2021 and must wait 30 calendar days from the date of submission before initiating any clinical trials, while the FDA has an opportunity to review the submission.

- Home health is an area of medicine experiencing significant growth – a trend that will likely continue over the next decade due to an aging US population, the need to control costs, the desire to improve patient outcomes, and the convenience of home healthcare. The global home healthcare market is expected to grow by nearly 8% annually to $545 billion by 2028, according to a new report by Grand View Research.

- Home infusion therapy represents a large and rapidly growing segment of home health. According to the National Home Infusion Association (NHIA), the number of US patients served by home infusion therapy has grown from approximately 800,000 in 2010 to over 3,000,000 in 2019. The home infusion setting is expected to continue to expand, which has been further accelerated by the COVID-19 pandemic and the desire to reduce or eliminate hospital and/or clinic exposure.

- Many patient groups requiring home infusion therapies suffer from diseases that are associated with an incidence of iron deficiency and anemia. For example, it is estimated that 40% to 55% of all home parenteral nutrition patients are iron deficient. We believe, based on the Company's data related to hemodialysis patients, that FPC as a home infusion therapy for iron deficiency anemia may have distinct advantages over currently available iron replacement therapy options.

Dialysis Business:

- In January 2022, Rockwell's partner in South Korea, Jeil Pharmaceutical Co., Ltd., received regulatory approval by the

Ministry of Food and Drug Safety of the Republic of Korea for Triferic Dialysate (ferric pyrophosphate citrate sodium sulfate co-precipitate hydrate) for maintaining hemoglobin in adult patients with HDD-CKD and regulatory approval for Triferic Injection, marketed in the United States as Triferic AVNU (ferric pyrophosphate citrate injection) for iron supplementation therapy and maintaining hemoglobin in adult patients with hemodialysis-dependent chronic kidney disease.

- In April 2022, Rockwell's partner in China, Wanbang Biopharmaceuticals, completed enrollment of its pivotal Phase 3 clinical trial for Triferic Dialysate (ferric pyrophosphate citrate sodium sulfate co-precipitate hydrate) ahead of schedule, to support a new drug application for regulatory approval in China, which is targeted for submission in the third quarter of 2023.

- First quarter revenue from hemodialysis concentrates was approximately $16.0 million, which is an increase of 4.7% year-over-year. The Company is in the process of analyzing its supply chain to identify efficiencies, while actively exploring U.S. and international expansion of this business with its customers.

- In April 2022, Rockwell announced an amended supply agreement with DaVita, Inc. ("DaVita") for the supply of our concentrate products that included price increases as well as the pass-through of certain costs. This amendment will provide Rockwell's concentrates business the potential to operate profitably in the future.

- In April 2022, Rockwell entered into a securities purchase agreement with DaVita for a $7.5 million investment in Rockwell's convertible preferred stock. An additional $7.5 million may be funded at a later date subject to certain conditions.

First Quarter 2022 Selected Financial Highlights

The following discussion and analysis should be read in conjunction with our unaudited condensed consolidated financial statements and related notes on Form 10-Q for the first quarter ended March 31, 2022.

Revenues were $16.1 million for the three months ended March 31, 2022, compared to $15.5 million for the three months ended March 31, 2021. The increase of $0.7 million was primarily due to an increase in sales of dialysis concentrates products from Baxter Healthcare Corporation and our international customers. We expect our concentrate sales to continue to grow due to the restructuring of our supply contract with DaVita.

Cost of sales was $16.9 million for the three months ended March 31, 2022, resulting in gross loss of $0.8 million, compared to $15.1 million for the three months ended March 31, 2021, resulting in gross profit of $0.4 million. Gross profit decreased by $1.2 million due to significant inflationary pressures related to national supply chain issues that impacted our concentrates business. Rockwell renegotiated certain terms of its supply contract with DaVita that included price increases as well as the pass-through of certain costs. As a result of these changes, Rockwell expects an improvement in margins for the remainder of 2022.

Net loss was $7.2 million, or $(0.84) split adjusted basic and diluted net loss per share for the three months ended March 31, 2022, compared to net loss of $7.8 million, or $(0.91) split adjusted basic and diluted net loss per share for the three months ended March 31, 2021.

As of March 31, 2022, cash and cash equivalents and working capital totaled $9.9 million and $5.2 million, respectively. In April 2022, Rockwell entered into a securities purchase agreement with DaVita, for a $7.5 million investment in Rockwell's convertible preferred stock. An additional $7.5 million may be funded at a later date subject to certain conditions.

First Quarter 2022 and Operating Results Conference Call and Webcast

Rockwell Medical's management team will host a conference call and audio webcast today at 4:15 p.m. ET to discuss Q1 2022 financial results and provide a business update.

To access the conference call, please dial (877) 383-7438 (local) or (678) 894-3975 (international) at least 10 minutes prior to the start time and refer to conference ID 2599375. A live webcast of the call will be available under "Events & Presentations" in the Investor section of the Company's website, https://ir.rockwellmed.com/. An archived webcast will be available on the Company's website approximately two hours after the event and will be available for 30 days.

About Rockwell Medical

Rockwell Medical is a commercial-stage biopharmaceutical company developing and commercializing its next-generation parenteral iron technology platform, Ferric Pyrophosphate Citrate which has the potential to lead transformative treatments for iron deficiency in multiple disease states, reduce healthcare costs and improve patients' lives. The Company has two FDA-approved therapies indicated for patients undergoing hemodialysis, which are the first two products developed from the FPC platform. Rockwell Medical is also advancing its FPC platform by developing FPC for the treatment of iron deficiency anemia in patients outside of dialysis, who are receiving intravenous medications in the home infusion setting. In addition, Rockwell Medical is one of two major suppliers of life-saving hemodialysis concentrate products to kidney dialysis clinics in the United States. For more information, visit www.RockwellMed.com.

About Triferic Dialysate and Triferic AVNU

Triferic Dialysate (ferric pyrophosphate citrate) and Triferic AVNU (ferric pyrophosphate citrate injection) are the only FDA-approved therapies in the U.S. indicated to replace iron and maintain hemoglobin in hemodialysis patients during each dialysis treatment. Triferic Dialysate and Triferic AVNU have a unique and differentiated mechanism of action, which has the potential to benefit patients and health care economics. Triferic Dialysate and Triferic AVNU represent a potential innovative medical advancement in hemodialysis patient iron management – with the potential to become the

future standard of care.

Triferic Dialysate and Triferic AVNU both deliver approximately 5-7 mg iron with every hemodialysis treatment to replace the ongoing losses to maintain hemoglobin without increasing iron stores. Both formulations donate iron immediately and completely to transferrin (carrier of iron in the body), which is then transported to the bone marrow to be incorporated into hemoglobin. Because of this unique mechanism of action, there is no increase in ferritin (a measure of stored iron). Triferic and Triferic AVNU address a significant medical need in treating functional iron deficiency in end-stage kidney disease patients.

The safety profile of Triferic is similar to placebo in controlled clinical trials in patients with end-stage kidney disease. Since approval, there have been no safety related changes to the product labeling.

IMPORTANT SAFETY INFORMATION FOR TRIFERIC AND TRIFERIC AVNU
INDICATION

TRIFERIC and TRIFERIC AVNU are indicated for the replacement of iron to maintain hemoglobin in adult patients with hemodialysis-dependent chronic kidney disease (HDD-CKD).

Limitations of Use

TRIFERIC AVNU is not intended for use in patients receiving peritoneal dialysis. TRIFERIC AVNU has not been studied in patients receiving home hemodialysis.

Warnings and Precautions

Serious hypersensitivity reactions, including anaphylactic-type reactions, some of which have been life-threatening and fatal, have been reported in patients receiving parenteral iron products. Patients may present with shock, clinically significant hypotension, loss of consciousness, and/or collapse. Monitor patients for signs and symptoms of hypersensitivity during and after hemodialysis until clinically stable. Personnel and therapies should be immediately available for the treatment of serious hypersensitivity reactions. Hypersensitivity reactions have been reported in 1 (0.3%) of 292 patients receiving TRIFERIC in two randomized clinical trials.

Iron status should be determined on pre-dialysis blood samples. Post-dialysis serum iron parameters may overestimate serum iron and transferrin saturation.

Adverse Reactions

Most common adverse reactions (incidence ≥3% and at least 1% greater than placebo) in controlled clinical studies include: headache, peripheral edema, asthenia, AV fistula thrombosis, urinary tract infection, AV fistula site hemorrhage, pyrexia, fatigue, procedural hypotension, muscle spasms, pain in extremity, back pain, and dyspnea.

Forward-Looking Statements

Certain statements in this press release may constitute "forward-looking statements" within the meaning of the federal securities laws. Words such as, "may," "might," "will," "should," "believe," "expect," "anticipate," "estimate," "continue," "could," "can," "would," "develop," "plan," "potential," "predict," "forecast," "project," "intend," "look forward to," "remain confident" or the negative of these terms, and similar expressions, or statements regarding intent, belief, or current expectations, are forward looking statements. There can be no assurance that Rockwell Medical will be able to maintain timing for planned clinical trials and regulatory filings, achieve planned cost savings to operate its concentrates business profitability, or that Rockwell Medical will be able to satisfy the funding conditions for the second tranche of the DaVita investment. While Rockwell Medical believes these forward-looking statements are reasonable, undue reliance should not be placed on any such forward-looking statements, which are based on information available to us on the date of this release. These forward-looking statements are based upon current estimates and assumptions and are subject to various risks and uncertainties (including, without limitation, those set forth in Rockwell Medical's SEC filings), many of which are beyond our control and subject to change. Actual results could be materially different. Risks and uncertainties include, but are not limited to those risks more fully discussed in the "Risk Factors" section of our Annual Report on Form 10-K for the year ended December 31, 2021, as such description may be amended or updated in any future reports we file with the SEC. Rockwell Medical expressly disclaims any obligation to update our forward-looking statements, except as may be required by law.

Financial Tables Follow

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets
(unaudited)

	March 31, 2022	December 31, 2021
	(Unaudited)	
ASSETS		
Cash and Cash Equivalents	$ 9,914	$ 13,280
Investments Available-for -Sale	—	9,158
Accounts Receivable, net of a reserve	7,121	5,913
Inventory	5,531	4,076
Prepaid and Other Current Assets	2,231	2,861
Total Current Assets	**24,797**	**35,288**
Property and Equipment, net	2,377	2,486

Inventory, Non-Current	1,523	1,523
Right of Use Assets, net	7,200	7,737
Goodwill	921	921
Other Non-current Assets	618	619
Total Assets	**$ 37,436**	**$ 48,574**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts Payable	$ 4,224	$ 3,739
Accrued Liabilities	4,373	5,090
Lease Liability - Current	1,983	2,004
Deferred License Revenue	2,163	2,171
Term Loan, Net of Issuance Costs	6,631	7,381
Insurance Financing Note Payable	—	437
Customer Deposits	221	144
Total Current Liabilities	**19,595**	**20,966**
Lease Liability - Long Term	5,400	5,887
Term Loan, Net of Issuance Costs	11,778	13,186
Deferred License Revenue	5,456	5,986
Long Term Liability - Other	14	14
Total Liabilities	**42,243**	**46,039**
Stockholders' Equity:		
Preferred Shares, $0.0001 par value, 2,000,000 shares authorized, no shares issued and outstanding at March 31, 2022 and December 31, 2021	—	—
Common Stock, $0.0001 par value,170,000,000 shares authorized, 8,544,225 and 8,544,225 shares issued and outstanding at March 31, 2022 and December 31,2021, respectively	1	1
Additional Paid-in Capital	372,383	372,562
Accumulated Deficit	(377,242)	(370,080)
Accumulated Other Comprehensive Income	51	52
Total Stockholders' Equity	**(4,807)**	2535
Total Liabilities And Stockholders' Equity	**$ 37,436**	**$ 48,574**

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Operations
(unaudited)
(In Thousands, Except Shares and Per Share Amounts)

	Three Months Ended March 31, 2022	Three Months Ended March 31, 2021
Net Sales	$ 16,124	$ 15,473
Cost of Sales	16,910	15,072
Gross (Loss) Profit	(786)	401
Research and Product Development	1,567	1,809
Selling and Marketing	455	1,851
General and Administrative	3,818	3,923
Operating Loss	(6,626)	(7,182)
Other (Expense) Income		
Realized Gain on Investments	4	—
Interest Expense	(540)	(581)
Interest Income	—	11
Total Other Expense	(536)	(570)
Net Loss	$ (7,162)	$ (7,752)
Basic and Diluted Net Loss per Share	$ (0.84)	$ (0.91)
Basic and Diluted Weighted Average Shares Outstanding	8,544,225	8,508,278

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