Rockwell Medical, Inc. Provides Second Quarter 2021 Financial and Operational Update

August 16, 2021

-Entered into exclusive license agreement with Drogsan Pharmaceuticals for the rights to commercialize Triferic® in Turkey-

-Extended multi-year distribution agreement with Nipro Medical for dialysis concentrates in LATAM and the Caribbean-

-Q2 2021 conference call and webcast scheduled for today at 4:30 p.m. ET-

WIXOM, Mich., Aug. 16, 2021 (GLOBE NEWSWIRE) -- Rockwell Medical, Inc. (Nasdaq: RMTI) ("Rockwell Medical" or the "Company"), 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 June 30, 2021.

"We made significant progress in the second quarter on a number of fronts to develop and deliver innovative treatment to patients with iron deficiency anemia (IDA)," said Russell Ellison, M.D., M.Sc., President and Chief Executive Officer of Rockwell Medical. "Ferric pyrophosphate citrate (FPC) for the treatment of IDA in home infusion patients remains our top development priority. We have received a written response to our pre-IND submission and intend to engage with the FDA to clarify and refine study design elements for our planned Phase II study, the first potential study of its kind in this patient population. In the meantime, we continue to work on the logistics and preparatory aspects of the trial. Assuming positive FDA feedback, we expect a potential commencement date in 2H 2021."

"In the second quarter, we also extended our multi-year distribution with Nipro Medical for the distribution of dialysis concentrates in Latin America and the Caribbean, and we entered into an exclusive license agreement for the right to commercialize Triferic in Turkey, with new partner Drogsan Pharmaceuticals," concluded Dr. Ellison.

Second Quarter 2021 Operational Highlights

Dialysis Business

- Revenue from hemodialysis concentrates was approximately $14.9 million. The Company is in the process of analysis of its supply chain to identify efficiencies while actively exploring U.S. expansion of this business with our two largest customers.

- Revenue from Triferic was approximately $273,000. Rockwell Medical continues to generate data in clinics showing the benefits of Triferic in real world protocols.

- The Company announced in April that Triferic AVNU (ferric pyrophosphate citrate injection) received a Notice of Compliance (marketing approval) from Health Canada for the replacement of iron to maintain hemoglobin in adult patients with hemodialysis-dependent chronic kidney disease. Rockwell Medical expects Triferic AVNU to become commercially available in Canada during 2022.

- The Company announced in June an exclusive license agreement with Drogsan Pharmaceuticals, a leading pharmaceutical company in Turkey with an established presence in the nephrology space, for the rights to commercialize Triferic AVNU (ferric pyrophosphate citrate injection) in Turkey. With approximately 65,000 patients receiving hemodialysis annually, Turkey represents a potentially significant and expanding market opportunity.

- The Company also announced in June that it extended its distribution agreement with its long-term distribution partner, Nipro Medical Corporation (NMC), for a period of three years through May 2024. The agreement was originally initiated in 2008. With the extension of the agreement, NMC will continue to distribute dialysis concentrates manufactured by Rockwell Medical to numerous countries in Latin America and the Caribbean. NMC is a leading renal, medical, surgical, and interventional radiology products manufacturer and a major distributor of renal products in these regions.

Home Infusion Program

- The Company received a written response to its pre-IND submission and intends to work with FDA to clarify and refine study design elements for our planned Phase II study of FPC in patients with IDA receiving long-term home infusion therapy.

Pipeline Development

- Rockwell Medical continues to explore the use of its FPC platform for the treatment of hospitalized patients with acute

heart failure. Management currently believes that FPC may deliver rapidly bioavailable iron to the heart and improve cardiac energetics. This effect could help patients recover faster, resulting in shorter hospital stays and fewer 30-day re-admissions. The Company expects to have a meeting with the FDA in the second half of 2021 to discuss the pathway for a potential clinical development program.

Second Quarter 2021 Selected Financial Highlights

The following discussion and analysis should be read in conjunction with our condensed consolidated financial statements and related notes on Form 10-Q for the second quarter ended June 30, 2021.

Net sales were $15.1 million compared to net sales of $15.9 million during the same second quarter period last year and $15.5 million in the first quarter of this year. The decrease was primarily due to a decrease in sales of dialysis concentrates products related to the impact of COVID on the dialysis patient populations of our partners.

Net sales of hemodialysis concentrates were approximately $14.9 million in the second quarter of 2021, which was about $800,000 lower compared to the second quarter of 2020, and about $320,000 lower than in first quarter 2021. Total sales of Triferic were approximately $273,000, roughly an 15% increase versus the sales of Triferic in the second quarter of 2020, but essentially flat versus the first quarter 2021.

Cost of sales for the second quarter of 2021 was $15.4 million, resulting in gross loss of $0.3 million, compared to cost of sales of $15.0 million and a gross profit of $0.9 million during the second quarter of 2020. Gross profit decreased by $1.2 million mainly due to a decrease in concentrate sales and an increase in costs related to protocols implemented because of the ongoing COVID-19 pandemic, shipping, fuel and labor. Gross profits are primarily related to our Dialysis concentrates products at this time. The Company anticipates that potential future sales of Triferic will impact the mix on our future gross profits.

Research and product development expenses were $2.4 million for the second quarter of 2021 compared to $1.6 million for the second quarter of 2020. The increase of $0.8 million was primarily due to the Company continuing to invest in its medical and scientific programs to support the continued advancement of our FPC technology platform.

Selling and marketing expenses were $1.5 million for the second quarter of 2021 compared to $2.0 million for the second quarter of 2020. The decrease of $0.5 million is primarily due to a decrease in marketing costs related to Triferic (dialysate) partially offset by a slight increase in costs associated with the launch of Triferic AVNU.

General and administrative expenses were $3.7 million for the second quarter of 2021 compared to $2.9 million for the second quarter of 2020. The increase of $0.8 million was primarily due to an increase in stock compensation of $1.9 million, which was a decrease in incentive compensation in second quarter 2020 of $1.5 million from forfeited equity awards of the former President and Chief Executive Officer, partially offset by a decrease of $0.8 million for the reduction of severance costs related to our former President and Chief Executive Officer.

Net loss for the second quarter of 2021 was $8.4 million, or $0.09 per basic and diluted share, compared to a net loss of $6.9 million during the second quarter of 2020, or $0.10 per basic and diluted share.

Cash, cash equivalents and investments totaled approximately $41 million at the end of the second quarter 2021, which we believe keeps the Company in a strong position to drive our strategic initiatives. Net cash used in operating activities was $4.9 million for the three months ended June 30, 2021, compared to net cash used in operating activities of $9.6 million for the three months ended June 30, 2020. Net cash used in operating activities was $17.4 million for the six months ended June 30, 2021, compared to net cash used in operating activities of $16.2 million for the six months ended June 30, 2020. The increase in cash used from operating activities during the first half of 2021 was primarily due to changes in current balance sheet accounts in the ordinary course of business of approximately $3.0 million, including an increase in net accounts receivable of $1.2 million and a reduction in accounts payable and accrued expense of approximately $0.4 million. Overall, our cash burn for the six months ended June 30, 2021 was in line with our expectations, and we continue to expect, in aggregate, 2021 cash burn to be lower than 2020 cash burn.

As of June 30, 2021, there were 93,811,381 shares of common stock outstanding versus 93,599,519 shares outstanding as of March 31, 2021.

Second Quarter 2021 and Business Update Conference Call and Webcast

Rockwell Medical's management team will host a conference call and audio webcast today at 4:30 p.m. ET to discuss Q2 2021 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 1254179. 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 (FPC), 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. The Company is developing FPC for the treatment of iron deficiency in patients outside of dialysis, who are receiving intravenous medications in the home infusion setting, a large and rapidly growing segment of healthcare, and where these patients suffer from chronic diseases associated with high incidence of iron deficiency and anemia. 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 and Triferic AVNU 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 and TRIFERIC AVNU are not intended for use in patients receiving peritoneal dialysis. TRIFERIC and TRIFERIC AVNU have 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, including, but not limited to, the development plans and timing for Rockwell Medical’s FPC pipeline candidates, the timing and outcome of meetings with the FDA, including meetings to clarify and refine requirements for our planned Phase II study of FPC in patients with IDA, the timing and outcome of foreign clinical trials and regulatory approval, the timing for the commencement of our clinical trial of FPC for treatment of IDA in adult patients in the home infusion setting, the benefits of Triferic and the timing for a commercial launch of Triferic AVNU in Canada. Words such as, “may,” “might,” “will,” “should,” “believe,” “expect,” “anticipate,” “estimate,” “continue,” “could,” “can,” “would,” “develop,” “plan,” “potential,” “predict,” “forecast,” “project,” “intend” and similar expressions, or statements regarding intent, belief, or current expectations, are forward looking statements. 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: the continuance of the COVID-19 pandemic (including, applicable federal state or local orders) on business, labor availability and operating results, including our supply chain, dialysis concentrates business and the Company’s commercialization of both pharmaceutical and medical device products; the challenges inherent in new product development, other new indications and therapeutics areas for our products; the success of our commercialization of Triferic (dialysate) and Triferic AVNU; the success and timing of international clinical trials for Triferic Dialysate; the success and timing of international regulatory and reimbursement approval for Triferic (dialysate) and Triferic AVNU; the success of our commercial launch of Triferic AVNU in the United States; the success and timing of the development of our FPC pipeline candidates, the risk that topline clinical data and real world data results may not demonstrate efficacy or may not be predictive of future results; expected financial performance, including cash flows, revenues, growth, margins, funding, liquidity and capital resources; and those risks more fully discussed in the “Risk Factors” section of our Annual Report on Form 10-K for the year ended December 31, 2020, 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)

	June 30, 2021	December 31, 2020
	(Unaudited)	
ASSETS		
Cash and Cash Equivalents	$ 32,378	$ 48,682
Investments Available-for -Sale	8,574	9,997
Accounts Receivable, net of a reserve	5,357	4,171
Inventory	4,677	3,913
Prepaid and Other Current Assets	1,413	2,706
Total Current Assets	**52,399**	**69,469**
Property and Equipment, net	2,529	2,642
Inventory, Non-Current	1,122	1,176
Right of Use Assets, net	6,085	2,911
Goodwill	921	921
Other Non-current Assets	628	629
Total Assets	$ **63,684**	$ **77,748**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts Payable	$ 4,932	$ 4,155
Accrued Liabilities	3,993	5,013
Lease Liability - Current	1,674	1,167
Deferred License Revenue	2,166	2,175
Term Loan, Net of Issuance Costs	21,133	—
Customer Deposits	140	152
Other Current Liability - Related Party	—	131
Total Current Liabilities	**34,038**	**12,793**
Lease Liability - Long Term	4,506	1,821
Term Loan, Net of Issuance Costs	—	20,949
Deferred License Revenue	6,937	8,015
Total Liabilities	**45,481**	**43,578**
Stockholders' Equity:		
Preferred Shares, $0.0001 par value, 2,000,000 shares authorized, no shares issued and outstanding at June 30, 2021 and December 31, 2020	—	—
Common Stock, $0.0001 par value,170,000,000 shares authorized, 93,811,381 and 93,573,165 shares issued and outstanding at June 30, 2021 and December 31,2020, respectively	9	9
Additional Paid-in Capital	371,700	371,510
Accumulated Deficit	(353,558)	(337,406)
Accumulated Other Comprehensive Income	52	57
Total Stockholders' Equity	**18,203**	**34,170**
Total Liabilities And Stockholders' Equity	$ **63,684**	$ **77,748**

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Operations
(unaudited)

	Three Months Ended June 30, 2021	Three Months Ended June 30, 2020	Six Months Ended June 30, 2021	Six Months Ended June 30, 2020
Net Sales	$ 15,137	$ 15,896	$ 30,611	$ 31,753
Cost of Sales	15,399	15,015	30,471	29,759
Gross Profit	(262)	881	140	1,994
Research and Product Development	2,416	1,616	4,224	3,438
Selling and Marketing	1,468	1,997	3,319	4,069
General and Administrative	3,677	2,871	7,602	8,145
Operating Loss	(7,823)	(5,603)	(15,005)	(13,658)
Other (Expense) Income				

Realized Gain on Investments	(1)	2	(1)	4
Warrant Modification Expense	—	(837)	—	(837)
Interest Expense	(583)	(521)	(1,164)	(623)
Interest Income	7	67	18	238
Total Other Expense	(577)	(1,289)	(1,147)	(1,218)
Net Loss	$ (8,400)	$ (6,892)	$ (16,152)	$ (14,876)
Basic and Diluted Net Loss per Share	$ (0.09)	$ (0.10)	$ (0.17)	$ (0.22)
Basic and Diluted Weighted Average Shares Outstanding	93,703,492	69,428,574	93,647,583	68,473,407

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