



Rockwell Medical, Inc. Provides Second Quarter 2020 Financial and Operational Update

August 10, 2020

-Q2 2020 revenue of \$15.9 million-

-Increase in contracted clinics of 44 percent quarter-over-quarter-

-Reached contracted annualized treatment volume for Triferic Dialysate of over 400,000-

- \$40.0 million in cash, cash equivalents and investments available-for-sale as of June 30, 2020-

-Q2 2020 conference call and webcast scheduled for today at 4:30 p.m. ET-

- Management/KOL conference call and webcast scheduled for September 24, 2020, to review our prioritization programs for new potential FPC indications-

WIXOM, Mich., Aug. 10, 2020 (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, 2020.

"In the second quarter, we continued to make important progress in the commercialization of Triferic Dialysate, despite the challenges of the COVID-19 pandemic. We significantly increased the number of clinics contracted to administer the therapy, and we reached the highest number of contracted patients on therapy and contracted annualized treatment volume since our launch," said Russell Ellison, M.D., M.Sc., President and Chief Executive Officer of Rockwell Medical. "We continue to diligently prepare for a successful launch of Triferic AVNU in the United States later this year."

"Importantly, we value the scientific underpinning of our ferric pyrophosphate citrate technology and the potential this represents in the treatment of iron deficiency and anemia. Approximately 10 million people are iron deficient in the United States, including 5 million who have iron deficiency anemia. We are committed to prudent medical and scientific advancements, and look forward to reviewing our programs for two therapeutic indications that, we believe, represent new opportunities to extend the innovative potential of our platform."

Second Quarter 2020 Operational Highlights

Triferic Dialysate

- The Company signed contracts with 12 additional clinics during the second quarter of 2020, an increase of 44% in contracted clinics as compared to March 31, 2020. An additional eight clinics affiliated with a Medium-Sized Dialysis Organization (MDO) were trained and approved for adoption as of June 30, 2020. Substantially all clinics contracted within Q2 2020 signed and began purchasing in June 2020.
- There were nearly 2,800 contracted patients on therapy as of June 30, 2020, representing more than 400,000 annualized treatments. This compares to nearly 2,000 contracted patients and over 300,000 annualized treatments as of March 31, 2020.
- The Company, as of June 30, 2020, has active or committed Evaluation Programs with independent dialysis clinics and small and medium dialysis chains representing nearly 1,500 patients and 26 clinics.
- Triferic net sales were \$0.2 million in the second quarter of 2020.
- Additional clinics were enrolled in the Company's Real World Data program.
- The Company received regulatory approval for Triferic Dialysate in Chile in June 2020.
- China's National Medical Products Administration (NMPA) approved the protocol for a clinical trial of Triferic Dialysate, to be initiated by its licensee in China, Wanbang Biopharmaceutical, Co., Ltd.
- With respect to the COVID-19 pandemic, the Company continues to implement appropriate precautions to reduce the risk of possible exposure by restricting employee travel, adopting new preventative safety measures within its manufacturing facilities, instituting a work-from-home policy for substantially all employees, excluding its essential manufacturing and distribution employees, and leveraging virtual technology for the sales force to use in its communications with customers. The Company has experienced no material impact on its supply chain to date and has experienced an increase in demand for its dialysis concentrates products, believed to be attributed to customers building safety stock and international demand.

Additionally, we have experienced an impact in our sales and marketing efforts for Triferic Dialysate due to the restrictions put in place because of COVID-19. This caused us to change the way we interact with our current and potential customers. We intend to initiate a sample evaluation program for Triferic AVNU during the third quarter of 2020 in order to prepare for a commercial launch. We will monitor the evaluation program in relation to the COVID-19 pandemic through the balance of the year.

Triferic AVNU (I.V. Formulation)

- The Company filed a New Drug Submission (“NDS”) for Triferic AVNU in Canada in May 2020. Health Canada accepted the NDS in June 2020. The Company currently expects regulatory approval in mid-2021.
- The Company continues to execute its commercial strategy to leverage the experience gained from the 2019 launch of Triferic Dialysate and lay the groundwork for the commercial introduction of Triferic AVNU. The Company currently expects to launch evaluation programs during the third quarter of 2020 to allow clinics to gain direct experience with Triferic AVNU, and expects Triferic AVNU to be available commercially during the fourth quarter of 2020, following the completion of the initial evaluation programs.

New Indications for FPC

- In the second quarter of 2020, and based upon analysis of development considerations, economics, pricing, and regimen ergonomics, the Company identified two new potential indications for its Ferric Pyrophosphate Citrate (“FPC”) platform:
 - FPC for the treatment of iron deficiency in patients requiring home infusion therapy, which the Company considers its first priority new indication to pursue; and
 - FPC to improve cardiac function in hospitalized acute congestive heart failure patients, which is under consideration by the Company.
- The Company plans to host a Management and KOL update conference call and webcast on Thursday, September 24, 2020, to discuss further details of its plans to pursue new FPC indications. The Company will provide additional details on accessing the conference call and webcast in the near future.

Second Quarter 2020 Corporate Updates

- In June 2020, the Board of Directors appointed industry leader and renowned authority on kidney disease, Allen R. Nissenson, M.D., F.A.C.P., to serve as a director. Dr. Nissenson serves as an Emeritus Professor of Medicine at the David Geffen School of Medicine at University California Los Angeles, Emeritus Chief Medical Officer of DaVita Kidney Care, and a member of the board of directors of Angion Biomedica Corp.

Second Quarter 2020 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, 2020.

Net sales for the second quarter of 2020 were \$15.9 million, an increase of 7.1% compared to net sales of \$14.8 million for the second quarter of 2019. The increase was primarily due to an increased demand for our dialysis concentrates products. Triferic net sales for the three months ended June 30, 2020 was approximately \$0.2 million. Triferic was launched in Q2 2019 via the sample evaluation program and there were nominal revenues for the same period in 2019.

Cost of sales for the second quarter of 2020 was \$15.0 million, resulting in gross profit of \$0.9 million, compared to cost of sales of \$14.1 million and a gross profit of \$0.7 million during the second quarter of 2019. 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.

Selling and marketing expenses were \$2.0 million for the second quarter of 2020 compared to \$2.2 million for the second quarter of 2019. The Company has invested in a specialty commercial team and marketing programs to support the launch of Triferic in Q2 of 2019 and the commercial introduction to Triferic AVNU.

General and administrative expenses were \$2.9 million for the second quarter of 2020 compared to \$5.5 million for the second quarter of 2019. The decrease of \$2.6 million was primarily due to a decrease in incentive compensation from forfeited equity awards associated with the departure of our former President and Chief Executive Officer in April 2020, a decrease in legal expense relating to previous litigation that has since been resolved; partially offset by severance pay relating to the same former President and Chief Executive Officer.

Research and product development expenses were \$1.6 million for the second quarter of 2020 compared to \$3.0 million for the second quarter of 2019. The decrease of \$1.4 million was due primarily to the payment for the Triferic AVNU NDA application fee of \$1.3 million in Q2 2019. The Company is continuing to invest in its medical and scientific programs to support the global launch of Triferic and the advancement of our ferric pyrophosphate citrate technology platform.

Net loss for the second quarter of 2020 was \$6.9 million, or \$0.10 per basic and diluted share, compared to a net loss for first quarter of 2019 of \$10.3

million, or \$0.18 per basic and diluted share.

Cash, cash equivalents, and investments available-for-sale totaled \$40.0 million as of June 30, 2020, compared to \$48.9 million on March 31, 2020. Working capital was \$40.0 million as of June 30, 2020 compared to \$46.1 million as of March 31, 2020. Additionally, the Company has a debt facility of \$35.0 million of which the first tranche of \$22.5 million was funded in March 2020 and is classified as long-term debt on the balance sheet. The Company will be eligible to draw on a second and third tranche of \$5.0 million and \$7.5 million, respectively, upon achievement of certain milestones. Lastly, the Company has an at-the-market equity offering facility of \$40.0 million of which approximately \$32.6 million remains available for issuance under its at-the-market equity offering facility, pursuant to which the Company may sell, at such times and amounts as it deems appropriate, shares of common stock to support its business plan, subject to certain restrictions on use.

As of June 30, 2020, there were 70,156,922 shares of common stock outstanding versus 69,049,102 shares outstanding as of March 31, 2020.

Second Quarter 2020 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 2020 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 7990808. 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 biopharmaceutical company dedicated to transforming iron deficiency and anemia management in a wide variety of therapeutic areas and across the globe, improving the lives of very sick patients. The Company's initial focus is the treatment of anemia in end-stage kidney disease (ESKD). Rockwell Medical's exclusive renal drug therapies, Triferic (ferric pyrophosphate citrate) Dialysate and Triferic AVNU, are the only FDA-approved therapeutics indicated for iron replacement and maintenance of hemoglobin in hemodialysis patients. Rockwell Medical is also an established manufacturer, supplier and leader in delivering high-quality hemodialysis concentrates/dialysates to dialysis providers and distributors in the U.S. and abroad.

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 the bone marrow and maintain hemoglobin without increasing iron stores (ferritin). Both formulations donate iron immediately and completely to transferrin (carrier of iron in the body) upon entry into the blood which is then transported directly to the bone marrow to be incorporated into hemoglobin, with no increase in ferritin (stored iron and inflammation) and no reports of anaphylaxis in over 1,000,000 patient administrations, addressing a significant medical need in overcoming Functional Iron Deficiency (FID) in ESKD patients.

Important Safety Information

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.

The most common adverse reactions ($\geq 3\%$ and at least 1% greater than placebo) in controlled clinical studies include: procedural hypotension (21.6%), muscle spasms (9.6%), headache (9.2%), pain in extremity (6.8%), peripheral edema (6.8%), dyspnea (5.8%), back pain (4.5%), pyrexia (4.5%), urinary tract infection (4.5%), asthenia (4.1%), fatigue (3.8%), arteriovenous (AV) fistula thrombosis (3.4%), and AV fistula site hemorrhage (3.4%).

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 impact of COVID-19 on Rockwell Medical's business and operations, the commercialization of Triferic Dialysate, the launch of Triferic AVNU, the selection of and plans for Rockwell Medical's FPC pipeline candidates, the initiation of a clinical trial in China, the timeline for receipt of a target action date in Canada and the Company's expected research and development expenses. Words such as, "may," "might," "will," "should," "believe," "expect," "anticipate," "estimate," "continue," "could," "can," "would," "develop," "plan," "potential," "predict," "forecast," "project," "intend" or the negative of these terms, 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 impact of the COVID-19 pandemic (including, applicable federal state or local orders) on business and operating results, including our supply chain, dialysis concentrates business and the commercial launch of Triferic AVNU; the challenges inherent in new product development and other indications and therapeutics areas for our products; the success of our commercialization strategy; the success and timing of our commercialization of Triferic Dialysate; the success and timing of international clinical trials for Triferic Dialysate; the success and timing of our

evaluation program for Triferic AVNU and our commercial launch of Triferic AVNU in the United States; the success and timing of the development of our FPB pipeline candidates, the risk that topline clinical data and real world results may not be predictive of future results; the anticipated number of future clinics with which we may contract for use of Triferic Dialysate; the expected number of annualized treatments for Triferic Dialysate; anticipated research and development expenses, 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 Quarterly Report on Form 10-Q for the period ended June 30, 2020 and of our Annual Report on Form 10-K for the year ended December 31, 2019, 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.

Triferic® is a registered trademark of Rockwell Medical, Inc. Triferic AVNU is pending with the U.S. Patent and Trademark Office. All other product names, logos, and brands are property of their respective owners in the United States and/or other countries. All company, product and service names used on this website are for identification purposes only. Use of these names, logos, and brands does not imply endorsement.

Financial Tables Follow

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

	June 30, 2020	December 31, 2019
	(Unaudited)	
ASSETS		
Cash and Cash Equivalents	\$ 26,697,063	\$ 11,794,526
Investments Available-for-Sale	13,258,197	14,250,176
Accounts Receivable, net	3,565,292	4,202,725
Inventory, net	4,557,177	3,646,906
Prepaid and Other Current Assets	3,458,104	2,979,504
Total Current Assets	51,535,833	36,873,837
Property and Equipment, net	2,306,462	2,433,405
Inventory, Non-Current	821,000	441,000
Right of Use Assets, net	2,440,115	3,212,530
Goodwill	920,745	920,745
Other Non-Current Assets	560,588	434,935
Total Assets	\$ 58,584,743	\$ 44,316,452
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts Payable	\$ 3,313,240	\$ 3,018,424
Accrued Liabilities	4,437,080	4,517,732
Settlement Payable	-	104,000
Lease Liability - Current	1,342,228	1,493,394
Deferred License Revenue - Current	2,174,626	2,233,640
Insurance Financing Note Payable	-	763,422
Customer Deposits	38,273	55,100
Other Current Liability - Related Party	189,600	187,849
Total Current Liabilities	11,495,047	12,373,561
Lease Liability - Long-Term	1,204,210	1,780,626
Term Loan, Net of Issuance Costs	20,764,213	-
Deferred License Revenue - Long-Term	8,909,703	9,842,762
Total Liabilities	42,373,173	23,996,949
Stockholders' Equity:		
Preferred Stock, \$0.0001 par value, 2,000,000 shares authorized; no shares issued and outstanding at June 30, 2020 and December 31, 2019	-	-

Common Stock, \$0.0001 par value; 170,000,000 shares authorized; 70,156,922 and 65,378,890 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	7,017	6,538
Additional Paid-in Capital	337,551,385	326,777,250
Accumulated Deficit	(321,392,548)	(306,516,265)
Accumulated Other Comprehensive Income	45,716	51,980
Total Stockholders' Equity	16,211,570	20,319,503
Total Liabilities and Stockholders' Equity	\$ 58,584,743	\$ 44,316,452

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended June 30, 2020	Three Months Ended June 30, 2019	Six Months Ended June 30, 2020	Six Months Ended June 30, 2019
Net Sales	\$ 15,895,971	\$ 14,845,788	\$ 31,752,510	\$ 30,405,227
Cost of Sales	15,015,404	14,112,639	29,759,017	28,661,686
Gross Profit	880,567	733,149	1,993,493	1,743,541
Selling and Marketing	1,996,595	2,218,997	4,069,393	5,321,375
General and Administrative	2,871,013	5,496,670	8,144,445	11,717,169
Settlement Expense	-	430,000	-	430,000
Research and Product Development	1,616,393	2,958,276	3,437,881	3,455,552
Operating Loss	(5,603,434)	(10,370,794)	(13,658,226)	(19,180,555)
Other Income (Expense)				
Realized Gain on Investments	2,065	4,135	3,994	18,023
Warrant Modification Expense	(837,322)	-	(837,322)	-
Interest Expense	(520,604)	-	(622,556)	-
Interest Income	66,750	74,476	237,827	192,002
Total Other Income	(1,289,111)	78,611	(1,218,057)	210,025
Net Loss	\$ (6,892,545)	\$ (10,292,183)	\$ (14,876,283)	\$ (18,970,530)
Basic and Diluted Net Loss per Share	\$ (0.10)	\$ (0.18)	\$ (0.22)	\$ (0.33)
Basic and Diluted Weighted Average Shares Outstanding	69,428,574	58,216,066	68,473,407	57,660,947

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Source: Rockwell Medical, Inc.