



Rockwell Medical, Inc. Reports Third Quarter 2019 Financial Results

November 11, 2019

- Company reports first full quarter of results for Dialysate Triferic, highlighted by greater than 75% conversion rate from Triferic Evaluation Program –
- Signs leading East Coast academic medical center as first Center of Excellence –

WIXOM, Mich., Nov. 11, 2019 (GLOBE NEWSWIRE) -- Rockwell Medical, Inc. (NASDAQ:RMTI) ("Rockwell Medical" or the "Company"), a biopharmaceutical company dedicated to improving outcomes for patients with anemia, with an initial focus on end-stage renal disease (ESRD), today reported business highlights and financial results for the three- and nine-months ended September 30, 2019.

"Our mission is to transform anemia management in a wide variety of disease states across the globe while improving patients' lives. We believe Triferic is one of the most innovative advancements in patient iron management over the last two decades. Accordingly, we are building the foundation to become a leading medical and commercial organization in the field of dialysis, which we believe will enable Triferic to become, over time, the standard of care for ESRD patients. We are pleased with the early progress we are making with the commercialization of our Triferic portfolio," stated Stuart Paul, President and Chief Executive Officer of Rockwell Medical.

Recent Business and Financial Highlights:

- Key highlights for the Dialysate Triferic U.S. market introduction include:
 - 1,000+ patients on therapy at 13 contracted clinics as of September 30, 2019;
 - 1,300+ patients on therapy at 15 clinics enrolled in the Evaluation Program;
 - Since launch, experienced 75% conversion rate of clinics in Evaluation Program; and
 - The Company entered into its first contract with a Center of Excellence¹ ("COE") for the purchase of Dialysate Triferic.
- Appointed industry veteran John P. McLaughlin as Chairman of the Board of Directors, bringing over 30 years of executive and board experience in the biopharmaceutical industry;
- Continued to engage with the U.S. Food and Drug Administration ("FDA") on review activities regarding the I.V. Triferic New Drug Application ("NDA"), with a PDUFA date of March 28, 2020;
- Committed to enhancing the Company's medical capabilities to build a leading medical platform in the field of dialysis;
- Sales were \$15.4 million and \$45.8 million for the three and nine months ended September 30, 2019, respectively, including sales of Dialysate Triferic of approximately \$98,000 and \$112,000, respectively; and
- As of September 30, 2019, the Company had approximately \$29.0 million of cash and cash equivalents and investments available-for-sale.

"We recognize that transforming to a new therapy from a well-entrenched approach takes time. As we build the foundation to achieve our mission, both in the U.S. and internationally, we are off to a promising start, and will continue to dedicate our resources to ensuring that hemodialysis patients have access to this innovative therapeutic," concluded Paul.

¹ The Company defines Centers of Excellence as leading independent academic institutions that operate their own clinics or leading nephrology practices that are recognized as thought leaders in dialysis.

Third Quarter 2019 Financial Results

Net loss for the third quarter of 2019 was \$7.9 million, or \$0.12 per basic and diluted share, compared to a net loss of \$5.0 million, or \$0.10 per basic and diluted share, in the third quarter of 2018. The increase in net loss for the third quarter of 2019 compared to the third quarter of 2018 primarily reflects investments in the Company's medical and commercial platform in the field of dialysis to support the commercialization and continued development of Triferic as Rockwell Medical executes on its business plans.

Net sales for the third quarter of 2019 were \$15.4 million compared to sales of \$16.7 million during the three months ended September 30, 2018. Net sales of hemodialysis concentrates to dialysis providers and distributors in the U.S. and abroad were \$15.2 million for the three months ended September 30, 2019 compared to \$16.6 million for the three months ended September 30, 2018. The decrease of \$1.4 million was primarily due to lower sales to international customers, offset by an increase in sales pursuant to the Company's contract with DaVita Inc. Net sales of Triferic were \$166,000 for the three months ended September 30, 2019 compared to \$68,000 for the three months ended September 30, 2018. For each of the three months ended September 30, 2019 and September 30, 2018, Triferic net sales included approximately \$68,000 of deferred revenue recognized under the Company's license in the People's Republic of China with Wanbang Biopharmaceutical. Triferic net sales for the three months ended September 30, 2019 also included approximately \$98,000 of Triferic product sales to U.S. customers.

Cost of sales during the three months ended September 30, 2019 was \$15.4 million compared to cost of sales of \$14.7 million during the three months ended September 30, 2018. Cost of sales for the three months ended September 30, 2019 included \$14.3 million of manufacturing and distribution costs associated with the Company's concentrates products, and \$1.1 million of inventory reserve expenses and product costs for Triferic,

compared to \$14.6 million and \$0.1 million, respectively, for the three months ended September 30, 2018. Gross loss for the three months ended September 30, 2019 was approximately \$16,000 compared to gross profit of \$2.0 million for the three months ended September 30, 2018. Gross profit (loss) for the three months ended September 30, 2019 consisted of a gross loss from Triferic of \$0.9 million, partially offset by gross profit of \$0.9 million for the Company's concentrates products, compared to a gross loss of \$0.1 million and gross profit of \$2.0 million, respectively, for the three months ended September 30, 2018.

Selling and marketing expenses were \$1.8 million during the three months ended September 30, 2019 compared with \$0.1 million during the three months ended September 30, 2018. The increase of \$1.7 million was due to investments the Company is making in developing a commercial platform to support the commercial launch of Triferic.

General and administrative expenses were \$4.6 million during the three months ended September 30, 2019 compared with \$6.0 million during the three months ended September 30, 2018. The decrease of \$1.4 million is primarily due to a decrease in legal and related costs associated with various matters, including litigation activities, related to the departure of certain executives and directors during 2018, partially offset by increases in insurance premiums.

Research and product development expenses were \$1.5 million for the three months ended September 30, 2019 compared with \$0.8 million during the three months ended September 30, 2018. The increase was due to the Company's commitment to investing in and building the medical capabilities mentioned above, including generating data from studies and real-world use of Triferic to support medical education and development efforts, as well as the expansion of the Company's internal medical affairs staff. The Company expects its research and product development expenses to increase in the future due to additional clinical development of Dialysate and I.V. Triferic, including the pediatric clinical trial for Triferic, expenses associated with real-world data collection and analysis for Triferic, and an increase in headcount to support medical education efforts for Triferic.

Other income for the three months ended September 30, 2019 was \$0.1 million, consisting primarily of interest income. Other income for the three months ended September 30, 2018 was approximately \$29,000, consisting of \$0.13 million of interest income, offset by \$0.1 million of realized gains on investments.

The Company encourages shareholders to also review its Form 10-Q for the quarter ended September 30, 2019, as filed by the Company with the United States Securities and Exchange Commission ("SEC").

Conference Call

As previously announced, Rockwell Medical management will host its third quarter 2019 conference call as follows:

Date	Monday, November 11, 2019
Time	4:30 PM EST
Telephone	U.S: (877) 383-7438 International: (678) 894-3975
Webcast (live and archive)	https://edge.media-server.com/mmc/p/kxajr6w6

About Rockwell Medical

Rockwell Medical is a biopharmaceutical company dedicated to improving outcomes for patients with anemia, with an initial focus on end-stage renal disease (ESRD). Rockwell Medical's exclusive renal drug therapy, Triferic, supports disease management initiatives to improve the quality of life and care of dialysis patients and is intended to deliver safe and effective therapy, while decreasing drug administration costs and improving patient convenience. The Company has developed multiple formulations of Triferic: (1) Dialysate Triferic; and (2) I.V. Triferic. Dialysate Triferic is the only FDA-approved therapeutic indicated for iron replacement and maintenance of hemoglobin in hemodialysis patients. The Company's strategy is to bring its therapeutics to market in the United States and to utilize partners to develop and commercialize such therapeutics in international markets. 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. Please visit www.rockwellmed.com for more information.

About Triferic

Triferic is the only FDA-approved therapy indicated to replace iron and maintain hemoglobin in hemodialysis patients via dialysate during each dialysis treatment. Triferic delivers approximately 5-7 mg iron with every hemodialysis treatment to the bone marrow and maintains hemoglobin without increasing iron stores (ferritin). Unlike traditional IV iron products, Triferic donates iron immediately and completely to transferrin (carrier of iron in the body) upon entry into the blood and 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 ESRD patients. The Company has developed multiple formulations of Triferic: (1) FDA-approved Dialysate Triferic; and (2) I.V. Triferic, for which the Company filed a New Drug Application in May 2019 with a PDUFA date of March 28, 2020. Please visit www.triferic.com to view the Triferic mode-of-action (MOA) video and for more information.

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%).

For more information, including full prescribing information, visit: <http://www.triferic.com>.

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, Rockwell Medical's intention to bring to market Triferic, and I.V. Triferic. Words such as "may," "might," "will," "should," "believe," "expect," "anticipate," "estimate," "continue," "could," "plan," "potential," "predict," "forecast," "project," "plan", "intend" or 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: statements about the issuance of a unique J code for our Triferic Powder Packet; timing and regulatory approval process for Dialysate Triferic in China; timing and regulatory approval process of our NDA filing for I.V. Triferic as filed with the FDA; the potential market opportunity and commercialization of Dialysate Triferic in China; potential market opportunity for I.V. Triferic, as well as other Rockwell Medical products; pricing and reimbursement status for I.V. Triferic and other Rockwell Medical products, CMS' recently announced final rule regarding eligibility for TDAPA; liquidity and capital resources; expected duration of Rockwell Medical's existing working capital; the progress and success with regard to our recently announced commercialization of Dialysate Triferic; and timing and success of our efforts to maintain, grow and improve the profit margin of the Company's concentrate business. Rockwell Medical expressly disclaims any obligation to update or alter any statements whether as a result of new information, future events or otherwise, except as required by law.

Triferic® is a registered trademark of Rockwell Medical, Inc.

Contact

Investor Relations:

Lisa M. Wilson, In-Site Communications, Inc.

T: 212-452-2793

E: lwilson@insitecony.com

Source: Rockwell Medical, Inc.

Financial Tables Follow

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2019	December 31, 2018
	(Unaudited)	
ASSETS		
Cash and Cash Equivalents	\$ 14,421,394	\$ 22,713,980
Investments Available-for -Sale	14,575,589	10,818,059
Accounts Receivable, net	5,122,453	6,979,514
Insurance Receivable	—	371,217
Inventory	3,583,452	4,038,778
Prepaid and Other Current Assets	2,861,708	1,903,682
Total Current Assets	40,564,596	46,825,230
Property and Equipment, net	2,506,093	2,638,293
Inventory, Non-Current	528,000	1,637,000
Right of Use Assets, net	3,011,805	—
Goodwill	920,745	920,745
Other Non-current Assets	555,933	536,516
Total Assets	\$ 48,087,172	\$ 52,557,784
LIABILITIES AND SHAREHOLDERS' EQUITY		
Accounts Payable	\$ 3,194,039	\$ 4,492,071
Accrued Liabilities	3,916,069	5,129,761
Settlement Payable	270,000	416,668
Lease Liability - Current	1,482,441	—
Deferred License Revenue - Current	2,238,450	2,252,868
Insurance Financing Note Payable	1,145,133	—
Customer Deposits	48,163	63,143
Other Current Liability - Related Party	100,000	850,000
Total Current Liabilities	12,394,295	13,204,511
Lease Liability - Long-Term	1,589,098	—
Deferred License Revenue - Long-Term	10,401,166	12,076,399
Total Liabilities	24,384,559	25,280,910

Shareholders' Equity:

Preferred Shares, \$.0001 par value, no shares issued and outstanding at September 30, 2019 and December 31, 2018	—	—
Common Shares, \$.0001 par value; 170,000,000 shares authorized; 63,887,384 and 57,034,154 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	6,389	5,703
Additional paid-in capital	322,837,353	299,596,257
Accumulated Deficit	(299,213,836)	(272,388,234)
Accumulated Other Comprehensive Income	72,707	63,148
Total Shareholders' Equity	23,702,613	27,276,874
Total Liabilities And Shareholders' Equity	\$ 48,087,172	\$ 52,557,784

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

(Unaudited)

	Three Months Ended September 30, 2019	Three Months Ended September 30, 2018	Nine Months Ended September 30, 2019	Nine Months Ended September 30, 2018
Net Sales	\$ 15,407,248	\$ 16,672,416	\$ 45,812,475	\$ 46,534,358
Cost of Sales	15,423,612	14,703,606	44,085,298	49,303,048
Gross Profit (Loss)	(16,364)	1,968,810	1,727,177	(2,768,690)
Selling and Marketing	1,827,473	121,874	7,148,848	716,414
General and Administrative	4,623,503	6,037,267	16,340,672	14,465,634
Settlement Expense	—	—	430,000	1,030,000
Research and Product Development	1,474,735	808,192	4,930,287	4,033,494
Operating Loss	(7,942,075)	(4,998,523)	(27,122,630)	(23,014,232)
Other Income				
Realized Gain (Loss) on Investments	6,268	(97,027)	24,292	(222,014)
Interest Income, net	80,735	125,918	272,736	486,301
Total Other Income	87,003	28,891	297,028	264,287
Net Loss	\$ (7,855,072)	\$ (4,969,632)	\$ (26,825,602)	\$ (22,749,945)
Basic and Diluted Net Loss per Share	\$ (0.12)	\$ (0.10)	\$ (0.45)	\$ (0.44)
Basic and Diluted Weighted Average Shares Outstanding	63,796,723	51,288,537	59,728,446	51,288,462



Source: Rockwell Medical, Inc.