



Rockwell Medical, Inc. Reports Fourth Quarter and Full Year 2019 Financial Results

March 12, 2020

- Company reports positive adoption trends for Dialysate Triferic® (ferric pyrophosphate citrate), highlighted by 77% increase in clinics under contract
- Signed contract with a Medium-Sized Dialysis Organization (MDO) for the purchase of Dialysate Triferic; provides access to up to 160 clinics --
- Entered into exclusive license and supply agreements with Sun Pharma for the rights to commercialize Triferic in India –

WIXOM, Mich., March 12, 2020 (GLOBE NEWSWIRE) -- Rockwell Medical, Inc. (NASDAQ:RMTI) ("Rockwell Medical" or the "Company"), a biopharmaceutical company dedicated to transforming anemia management and improving outcomes for patients around the world, today reported business highlights and financial results for the three months and full year ended December 31, 2019.

"We are pleased with the steady progress we are making to drive adoption of Dialysate Triferic as we strive to establish Triferic as the standard of care for hemodialysis patients in the United States. After two full quarters in market post-launch, our three-month Evaluation Program for Dialysate Triferic, with a consistent 75% conversion rate, continues to be a success and represents validation for the clinical benefits that dialysis centers see when they initiate Triferic therapy. In addition, with our first signed contract with an MDO, and continued execution of our sales, marketing and medical education initiatives, we expect adoption rates to accelerate through 2020. In support of the Triferic platform, we continue to invest in building our medical capabilities and our real-world data program in an effort to educate the clinical community about the unique properties of our highly innovative therapy," 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:
 - Entered into a contract with a Medium-Size Dialysis Organization (MDO) for the purchase of Dialysate Triferic. Provides access to up to 160 clinics for Dialysate Triferic, representing more than 10,000 patients. Successfully initiated Dialysate Triferic administration and purchasing in top five KOL-led clinics within system.
 - Signed contracts with 10 additional clinics during the fourth quarter of 2019, an increase of 77% compared to the number of clinics contracted at September 30, 2019.
 - Contracted patients on therapy increased to 1,650 as of December 31, 2019, representing an increase of 100,000 annualized treatments.
 - 75% of clinics that completed an Evaluation Program during the fourth quarter have converted to contracted customers and more than 80% of customers continue to order Dialysate Triferic on an ongoing basis.
- Strengthened medical capabilities with the appointments of Marc Hoffman, MD as Chief Medical Officer; Russell Ellison, MD, to the Board of Directors; and three world-renowned nephrologists to Medical Advisory Board: Stephen Fishbane, MD; Jay Wish, MD; and Anatole Besarab, MD.
- Entered into exclusive license and supply agreements with Sun Pharma for the rights to commercialize Triferic in India. Rockwell Medical will receive an upfront fee and will be eligible for milestone payments and royalties on net sales.
- The Company has a PDUFA date of March 28, 2020 for I.V. Triferic, which was developed pursuant to a Special Protocol Assessment (SPA) with the FDA. If approved, I.V. Triferic would allow dialysis centers to administer Triferic to patients regardless of the mode of bicarbonate delivery being used.
- Sales were \$15.5 million and \$61.3 million for the three and twelve months ended December 31, 2019, respectively, including sales of Triferic of approximately \$0.2 million and \$0.5 million, respectively.
- The Company completed the pricing of an underwritten public offering of the Company's common stock in February 2020 for gross proceeds of approximately \$8.1 million, before deducting underwriting discounts; and
- Cash flow used in operations for the three months ended December 31, 2019 was \$5.3 million. As of December 31, 2019, the Company had approximately \$26.0 million of cash, cash equivalents and investments available-for-sale. Additionally, the Company has approximately \$35 million remaining 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.

"2019 was a pivotal year for Rockwell Medical. With the commercial launch of Dialysate Triferic, and the NDA submission for the I.V. formulation, we achieved important milestones and established a strong foundation for future growth and expansion. We are very pleased that we are gaining traction in bringing this much-needed therapeutic to hemodialysis patients both in the U.S. and around the world. Our experience thus far informs our belief that Triferic has the potential to improve the way anemia is managed in a variety of disease states, and we are actively focused on identifying and prioritizing other therapeutic indications for future development," concluded Mr. Paul.

Fourth Quarter 2019 Financial Results

Net loss for the fourth quarter of 2019 was \$7.3 million, or (\$0.11) per basic and diluted share, compared to a net loss of \$9.4 million, or (\$0.17) per basic and diluted share, in the fourth quarter of 2018. The decrease in net loss for the fourth quarter of 2019 compared to the fourth quarter of 2018 primarily reflects a reduction in general and administrative expenses and research and development expenses for licenses acquired, partially offset by an increase in research and development expenses to support the Company's investments in its medical platform.

Net sales for the fourth quarter of 2019 were \$15.5 million compared to sales of \$16.9 million for the fourth quarter of 2018. Net sales of hemodialysis

concentrates to dialysis providers and distributors in the U.S. and abroad were \$15.3 million for the three months ended December 31, 2019 compared to \$16.8 million for the three months ended December 31, 2018. The decrease in net sales was due to a decrease in international concentrates sales of \$1.1 million, a decrease of \$0.7 million in concentrates sales to Baxter related to true-ups for cost of sales and transportation cost pass-throughs, partially offset by increased sales to DaVita, Inc. of \$0.3 million and Triferic sales of \$0.2 million.

Cost of sales during the fourth quarter of 2019 was \$14.4 million compared to cost of sales of \$15.7 million during the fourth quarter of 2018. The decrease was due primarily to a decrease in distribution costs due to reduced rates for third party shipping and reduced costs for materials and overhead tied to the reduction in concentrates sales volume.

Gross profit for the fourth quarter of 2019 was approximately \$1.1 million compared to gross profit of \$1.2 million for the fourth quarter of 2018. The decrease in gross profit was primarily due to a reduction in concentrates sales compared to the fourth quarter of 2018, partially offset by an increase in Triferic sales.

Selling and marketing expenses were \$1.9 million during the three months ended December 31, 2019 compared with \$0.3 million during the three months ended December 31, 2018. The increase of \$1.6 million was due to investments the Company has made to develop a commercial platform to support the launch of Triferic.

General and administrative expenses were \$4.7 million during the three months ended December 31, 2019 compared with \$7.6 million during the three months ended December 31, 2018. The decrease of \$2.9 million was primarily driven by reductions in compensation, legal, consulting, and recruiting expenses, partially offset by an increase in insurance and facility-related expenses.

Research and product development expenses were \$2.0 million for the three months ended December 31, 2019 compared with \$1.6 million during the three months ended December 31, 2018. The increase was due primarily to an increase in clinical trial and consulting expenses, partially offset by a reduction due to the write off of Calcitriol inventory that occurred in the fourth quarter of 2018. 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, an increase in headcount to support medical education efforts for Triferic and potential investments in developing Triferic for new clinical indications.

Research and development for licenses acquired from a related party were nil for the three months ended December 31, 2019 compared to \$1.1 million for the three months ended December 31, 2018.

Other income for the three months ended December 31, 2019 was \$0.1 million, consisting primarily of interest income. Other income for the three months ended December 31, 2018 was approximately \$49,000, consisting primarily of interest income.

Full Year 2019

For the year ended December 31, 2019, net sales were \$61.3 million compared to \$63.4 million for the year ended December 31, 2018. The decrease was primarily due to lower international concentrates sales compared to the year ended December 31, 2018, partially offset by an increase in Triferic net sales and sales of concentrates pursuant to the Company's contract with DaVita Inc.

Cost of sales for the year ended December 31, 2019 was \$58.5 million, resulting in a gross profit of \$2.8 million in 2019, compared to cost of sales of \$65.0 million and a gross loss of \$1.6 million in 2018. Gross profit increased in 2019 compared to 2018, due primarily to non-cash charges taken for inventory reserves for Triferic during the year ended December 31, 2018, partially offset by a gross profit decrease in dialysis concentrates products during 2019.

Selling and marketing expenses were \$9.1 million during the year ended December 31, 2019 compared with \$1.0 million during the year ended December 31, 2018. The increase of \$8.1 million was due to investments the Company is making in developing a commercial platform to support the launch of Triferic.

General and administrative expenses were \$21.0 million for the year ended December 31, 2019 compared to \$22.1 million for the year ended December 31, 2018. The decrease was primarily driven by a reduction 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 an increase in insurance, stock-based compensation and facility-related expenses.

Settlement expenses were \$0.4 million for the year ended December 31, 2019 compared to \$1.0 million for the year ended December 31, 2018.

Research and product development expenses were \$6.9 million for the year ended December 31, 2019 compared to \$5.6 million for the year ended December 31, 2018. The increase was due to the Company's commitment to investing in and building its medical capabilities, including generating data from studies and real-world use of Triferic to support medical education and development efforts for Triferic, as well as the expansion of the Company's internal medical affairs staff.

Research and development for licenses acquired from a related party were nil for the year ended December 31, 2019 compared to \$1.1 million for the year ended December 31, 2018.

Net loss for the year ended December 31, 2019 was \$34.1 million, or (\$0.56) per basic and diluted share, compared to a net loss of \$32.1 million, or (\$0.61) per basic and diluted share, in 2018.

The Company encourages shareholders to also review its Form 10-K for the year ended December 31, 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 fourth quarter 2019 conference call as follows:

Date: Thursday, March 12, 2020
Time: 4:30 PM ET

Telephone U.S: (877) 383-7438
International: (678) 894-3975
Webcast (live and archive): <https://edge.media-server.com/mmc/p/jmkqdrca>

About Rockwell Medical

Rockwell Medical is a biopharmaceutical company dedicated to transforming 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 renal disease (ESRD). Rockwell Medical's exclusive renal drug therapy, Triferic (ferric pyrophosphate citrate), is the only FDA-approved therapeutic indicated for iron replacement and maintenance of hemoglobin in hemodialysis 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. 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

Triferic is the only FDA-approved therapy in the U.S. indicated to replace iron and maintain hemoglobin in hemodialysis patients via dialysate during each dialysis treatment. Triferic has a unique and differentiated mechanism of action which has the potential to benefit patients and health care economics. Triferic represents a potential innovative medical advancement in hemodialysis patient iron management— with the potential to become the future standard of care.

Triferic delivers approximately 5-7 mg iron with every hemodialysis treatment to the bone marrow and maintains hemoglobin without increasing iron stores (ferritin). 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.

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, Rockwell Medical's expectations regarding the consummation of the offering, the terms of the offering, and the satisfaction of customary closing conditions with respect to the offering and the anticipated use of the net proceeds of the offering. Words such as "may," "might," "will," "should," "believe," "expect," "anticipate," "estimate," "continue," "could," "plan," "potential," "predict," "forecast," "project," "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; the potential market opportunity and commercialization of Dialysate Triferic in China upon regulatory approval; the timing and regulatory approval process for our NDA filing for I.V. Triferic as filed with the FDA; the potential market opportunity for I.V. Triferic, as well as other Rockwell Medical products; CMS' announced final rule relating to the eligibility criteria for TDAPA; liquidity and capital resources; expected duration of Rockwell Medical's existing working capital; the success of our commercialization of Dialysate Triferic, which commenced in May 2019; and the timing and success of our efforts to maintain, grow and improve the profit margin of the Company's concentrate business; and the impact of general economic, health, industrial or political conditions in the United States or internationally, as well as those risks more fully discussed in Rockwell Medical's SEC filings. Accordingly, you should not place undue reliance on these forward-looking statements. 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.

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

	December 31,	December 31,
	2019	2018
ASSETS		
Cash and Cash Equivalents	\$ 11,794,526	\$ 22,713,980
Investments Available-for -Sale	14,250,176	10,818,059
Accounts Receivable, net of a reserve of \$8,932 in 2019 and \$2,104 in 2018	4,202,725	6,979,514
Insurance Receivable	—	371,217
Inventory	3,646,906	4,038,778
Prepaid and Other Current Assets	2,979,504	1,903,682
Total Current Assets	36,873,837	46,825,230
Property and Equipment, net	2,433,405	2,638,293
Inventory, Non-Current	441,000	1,637,000
Right of Use Assets, net	3,212,530	
Goodwill	920,745	920,745
Other Non-current Assets	434,935	536,516
Total Assets	\$ 44,316,452	\$ 52,557,784
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts Payable	\$ 3,018,424	\$ 4,492,071
Accrued Liabilities	4,517,732	5,129,761
Settlement Payable	104,000	416,668
Lease Liability - Current	1,493,394	—
Deferred License Revenue	2,233,640	2,252,868
Insurance Financing Note Payable	763,422	—
Customer Deposits	55,100	63,143
Other Current Liability - Related Party	187,849	850,000
Total Current Liabilities	12,373,561	13,204,511
Lease Liability - Long Term	1,780,626	
Deferred License Revenue	9,842,762	12,076,399
Total Liabilities	23,996,949	25,280,910
Stockholders' Equity:		
Preferred Shares, \$0.0001 par value, 2,000,000 shares authorized, no shares issued and outstanding at December 31, 2019 and 2018	—	—
Common Stock, \$0.0001 par value, 65,378,890 and 57,034,154 shares issued and outstanding at December 31, 2019 and 2018, respectively	6,538	5,703
Additional Paid-in Capital	326,777,250	299,596,257
Accumulated Deficit	(306,516,265)	(272,388,234)
Accumulated Other Comprehensive Income	51,980	63,148
Total Stockholders' Equity	20,319,503	27,276,874
Total Liabilities And Stockholders' Equity	\$ 44,316,452	\$ 52,557,784

(unaudited)

	Three Months Ended December 31, 2019	Three Months Ended December 31, 2018	Year Ended December 31, 2019	Year Ended December 31, 2018
Net Sales	\$ 15,490,325	\$ 16,854,259	\$ 61,302,801	\$ 63,388,617
Cost of Sales	14,378,560	15,670,109	58,463,859	64,973,157
Gross Profit (Loss)	1,111,765	1,184,150	2,838,942	(1,584,540)
Selling and Marketing	1,901,185	288,170	9,050,033	1,004,584
General and Administrative	4,657,277	7,612,086	20,997,948	22,077,720
Settlement Expense, net of Reimbursement	—	—	430,000	1,030,000
Research and Product Development	1,955,964	1,608,823	6,886,251	5,642,317
Research and Development - Licenses Acquired (Related Party)	—	1,100,000	—	1,100,000
Operating Loss	(7,402,661)	(9,424,929)	(34,525,290)	(32,439,161)
Other Income (Expense)				
Realized Gain (Loss) on Investments	5,890	(325)	30,182	(222,338)
Interest Income	94,341	48,932	367,077	535,328
Other Expense	—	410	—	313
Foreign Currency Gain	—	—	—	—
Total Other Income	100,231	49,017	397,259	313,303
Net Loss	\$ (7,302,430)	\$ (9,375,912)	\$ (34,128,031)	\$ (32,125,858)
Basic and Diluted Net Loss per Share	\$ (0.11)	\$ (0.17)	\$ (0.56)	\$ (0.61)
Basic and Diluted Weighted Average Shares Outstanding	64,450,030	56,041,350	60,918,544	52,824,486



Source: Rockwell Medical, Inc.