



Rockwell Medical, Inc. Reports First Quarter 2019 Financial Results

May 9, 2019

Significant progress for portfolio of Triferic® therapeutics marked by launch of Dialysate Triferic

WIXOM, Mich., May 09, 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) and chronic kidney disease (CKD), today reported business updates and financial results for the three months ended March 31, 2019.

Recent Business and Financial Highlights:

- The Company announced the commencement of commercial sales of the first formulation in its Triferic portfolio, Dialysate Triferic, on May 6, 2019.
- The Company expects to submit a New Drug Application ("NDA") for I.V. Triferic in the U.S. during the second quarter of 2019.
- Received a preliminary recommendation from the Centers for Medicare and Medicaid Services ("CMS") on April 26, 2019 that, if finalized, would result in a unique J-code for the powder packet formulation of Dialysate Triferic.
- The Company presented positive data from two studies evaluating intravenous and peritoneal dialysate formulations of Triferic at the 39th Annual Dialysis Conference in March 2019.
- Sales for the first quarter of 2019 were \$15.6 million compared to \$14.9 million for the first quarter of 2018, an increase of 4%.
- As of March 31, 2019, the Company had cash, cash equivalents and investments available-for-sale of \$27.8 million. Cash used in operating activities for the first quarter of 2019 was \$5.4 million.

"The commercial launch of Dialysate Triferic marks an important milestone for Rockwell Medical. Triferic offers a much-needed alternative for healthcare providers who treat anemia in their hemodialysis patients. Our efforts during the first quarter of 2019 were primarily focused on completing our market and pricing research, enhancing our medical education platform, and building a strong commercial and medical infrastructure to execute on our launch plans," stated Stuart Paul, President and Chief Executive Officer of Rockwell Medical.

"We are also in the process of advancing I.V. Triferic, and we anticipate a large global opportunity for that formulation. We believe I.V. Triferic will potentially be eligible for separate reimbursement in the U.S., if approved by CMS, for a period of two years. It also allows for Triferic administration with dry bicarbonate bags/cartridges, which are commonly used in Europe, China and other countries around the globe. We are pleased with our progress and excited about the opportunities that lie ahead," continued Mr. Paul.

Selected First Quarter 2019 Financial Results

Net sales for the first quarter of 2019 were \$15.6 million, an increase of 4% compared to sales of \$14.9 million for the first quarter of 2018. The increase was primarily due to higher domestic dialysis concentrate sales to Baxter and an increase in international sales compared to the three months ended March 31, 2018. Revenue recognized from licensing fees was \$0.6 million for both the three months ended March 31, 2019 and 2018.

Cost of sales for the first quarter of 2019 was \$14.6 million, resulting in gross profit of \$1.0 million, compared to cost of sales of a \$15.7 million and a gross loss of \$0.7 million during the first quarter of 2018. Gross profit increased by \$1.7 million in the first quarter of 2019 compared to the first quarter of 2018, due primarily to an inventory reserve for Triferic of \$2.2 million for the first quarter of 2018, partially offset by a gross profit decrease of \$0.7 million in our dialysis concentrates products. The decrease in gross profit for our dialysis concentrates products was primarily attributable to increased labor, materials and overhead costs, partially offset by increased net sales.

Selling and marketing expenses were \$3.1 million for the first quarter of 2019 compared to \$0.2 million in the first quarter of 2018. The increase was due primarily to marketing costs incurred to prepare for the launch of Triferic and increased headcount.

General and administrative expenses were \$6.2 million for the first quarter of 2019 compared with \$3.1 million for the first quarter of 2018. The increase was primarily due to the reversal of certain compensation-related accruals in the first quarter of 2018 and an increase in annual reporting and consulting fees.

Research and product development expenses were \$0.5 million for the first quarter of 2019 compared to \$1.7 million for the first quarter of 2018. The decrease was due primarily to a reduction in clinical trial and other product development costs.

Net loss for the first quarter of 2019 was \$8.7 million, or \$0.15 per basic and diluted share, compared to a net loss of \$5.5 million, or \$0.11 per basic and diluted share, in the first quarter of 2018.

The Company encourages shareholders to also review its Form 10-Q for the quarter ended March 31, 2019, as filed by the Company with the Securities and Exchange Commission ("SEC").

Key Objectives for 2019

- Increase awareness of Triferic in the dialysis community, build and enhance relationships with key opinion leaders, and support medical education of nephrologists and other clinicians, while generating real-world evidence to support the use of Triferic in adult hemodialysis patients.
- File an NDA with the U.S. Food and Drug Administration (FDA) for I.V. Triferic during the second quarter of 2019.
- Advance international opportunities for the Triferic portfolio through strategic partnerships and licensing agreements.
- Expand and improve operating margin for the Company's concentrates business.

Conference Call

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

Date		Thursday, May 9, 2019
Time		4:30 PM EDT
Telephone	U.S:	(877) 383-7438
	International:	(678) 894-3975
Webcast (live and archive)		https://edge.media-server.com/m6/p/7ci5to7r

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 675,000 patient administrations, addressing a significant medical need in overcoming Functional Iron Deficiency (FID) in ESRD patients. Please visit www.triferic.com to view the Triferic mode-of-action (MOA) video and for more information.

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) and chronic kidney disease (CKD). 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, 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.

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 success of our planned NDA submission for I.V. Triferic; the potential market opportunity for I.V. Triferic and other Rockwell products; pricing and reimbursement status for I.V. Triferic, Triferic and other Rockwell products, including eligibility for add-on reimbursement under TDAPA; liquidity and capital resources; expected duration of Rockwell Medical's existing working capital; success of our recently announced commercialization plans for Dialysate Triferic; and timing and success of our efforts to renegotiate economic terms of our 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: wilson@insitecony.com

Source: Rockwell Medical, Inc.

Financial Tables Follow

	March 31, 2019 (Unaudited)	December 31, 2018
ASSETS		
Cash and Cash Equivalents	\$ 20,919,518	\$ 22,713,980
Investments Available-for -Sale	6,876,221	10,818,059
Accounts Receivable, net of a reserve of \$2,240 in 2019 and \$2,104 in 2018	6,711,410	6,979,514
Insurance Receivable	—	371,217
Inventory	4,001,570	4,038,778
Prepaid and Other Current Assets	1,680,818	1,903,682
Total Current Assets	40,189,537	46,825,230
Property and Equipment, net	2,572,680	2,638,293
Inventory, Non-Current	1,501,000	1,637,000
Right of Use Assets, net	3,005,792	—
Goodwill	920,745	920,745
Other Non-current Assets	555,310	536,516
Total Assets	\$ 48,745,064	\$ 52,557,784
LIABILITIES AND SHAREHOLDERS' EQUITY		
Accounts Payable	\$ 4,522,225	\$ 4,492,071
Accrued Liabilities	6,272,040	5,129,761
Settlement Payable	166,669	416,668
Lease Liability - Current	1,680,475	—
Deferred License Revenue - Current	2,248,062	2,252,868
Customer Deposits	240,239	63,143
Other Current Liability - Related Party	600,000	850,000
Total Current Liabilities	15,729,710	13,204,511
Lease Liability - Long-Term	1,336,319	—
Deferred License Revenue - Long-Term	11,517,988	12,076,399
Total Liabilities	28,584,017	25,280,910
Shareholders' Equity:		
Preferred Shares, no par value, no shares issued and outstanding at March 31, 2019 and December 31, 2018	—	—
Common Shares, no par value, 57,128,327 and 57,034,154 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively	301,171,733	299,601,960
Accumulated Deficit	(281,066,581)	(272,388,234)
Accumulated Other Comprehensive Income	55,895	63,148
Total Shareholders' Equity	20,161,047	27,276,874
Total Liabilities And Shareholders' Equity	\$ 48,745,064	\$ 52,557,784

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

	Three Months Ended March 31, 2019	Three Months Ended March 31, 2018
Net Sales	\$ 15,559,439	\$ 14,948,579
Cost of Sales	14,549,047	15,669,072
Gross Profit (Loss)	1,010,392	(720,493)
Selling and Marketing	3,102,378	215,083
General and Administrative	6,220,499	3,116,872
Research and Product Development	497,276	1,666,356
Operating Loss	(8,809,761)	(5,718,804)
Other Income (Expense)		
Realized Gain (Loss) on Investments	13,888	(2,892)
Interest Income	117,526	175,307

Other Income	—	(3,132)
Total Other Income (Expense)	131,414	169,283	
Net Loss	\$ (8,678,347)	\$ (5,549,521
)
Basic and Diluted Net Loss per Share	\$ (0.15)	\$ (0.11
)
Basic and Diluted Weighted Average Shares Outstanding	57,098,947	51,288,424	



Source: Rockwell Medical, Inc.