



Rockwell Medical, Inc. Reports Third Quarter 2018 Financial Results

November 9, 2018

WIXOM, Mich., Nov. 9, 2018 /PRNewswire/ -- Rockwell Medical, Inc. (NASDAQ: RMTI) (the "Company") today reported financial results for the third quarter ended September 30, 2018, and highlighted recent and upcoming corporate milestones.

Business Updates:

CMS Rule Clarifies U.S. Commercial Plans

IV Triferic Expected to be Eligible for TDAPA Pricing – Based on an analysis of CMS' November 1, 2018 final rule regarding the new Transitional Drug Add On Pricing Adjustment ("TDAPA") program, the Company believes that newly approved FDA therapies on or after January 1, 2020, are eligible for separate payment for a two year timeframe. Because the NDA filing for IV Triferic will be under a 505(b)1 pathway and therefore a new drug, the Company believes that, if approved by the FDA, this should allow for separate payment and a separate unique billing code. In accordance with the ruling, a separate TDAPA payment would last for two years following launch, after which IV Triferic would likely be priced inside the bundle. The Company is working with outside experts to optimize its NDA filing in 2019 and planning for a PDUFA action date and a U.S. launch of IV Triferic in the first half of 2020, subject to FDA approval.

Moving Ahead with U.S. Commercialization of Dialysate Triferic – Upon assessing the November 1, 2018 final payment rule from the Centers for Medicare & Medicaid Services ("CMS"), the Company has determined to move ahead with a commercial launch of its Dialysate formulation of Triferic, and is targeting a U.S. launch in the first half of 2019. Upon launch, the Company expects Dialysate Triferic to be bundled as part of the base rate to providers. Rockwell Medical is currently working to finalize its commercial plans and manufacturing scale-up, and is in the final stages of a market study to determine the optimal pricing and uptake of the 5 mL and powder packet versions of its Dialysate Triferic.

Closed Financing Transaction – On October 17, 2018, Rockwell Medical closed a financing transaction under which an affiliate of Richmond Brothers, Inc. invested a total of \$22 million for 5,541,562 units in a private placement, with each unit consisting of one share of common stock and a five year warrant to purchase 50% of a share of common stock at \$4.96 per share. With the proceeds from this offering, Rockwell Medical believes that it has sufficient capital to fund its business plan into 2020.

Assessing Commercial Potential for Calcitriol – Rockwell Medical is carefully examining Calcitriol's potential to drive acceptable gross profits, and intends to share an update regarding its commercialization plans for this product in the first quarter of 2019.

Working to Best Position Concentrates Products – The Company is currently in discussions with potential partners to improve upon the economics of this line of products, and intends to share an update regarding its plans to enhance profitability in the first quarter of 2019.

Senior Leadership Appointments – Since Mr. Paul joined Rockwell Medical as President and CEO in early September, the Company appointed Jim McCarthy to the newly-formed role of Senior Vice President, Corporate and Business Development, and named Anne Boardman as Vice President of Strategic Accounts. Additionally, the Company appointed Angus Smith as Chief Financial Officer, effective at the end of November 2018. The Company expects to complete the hiring of its senior management team, as well as other key launch professional resources, in the fourth quarter of 2018.

Mr. Paul said, "Since joining Rockwell Medical as President and CEO in early September, one of my priorities has been undertaking a top-to-bottom review of the Company. It has become increasingly clear to me that Dialysate Triferic and IV Triferic present a fundamental opportunity to positively impact patients in the dialysis community and global anemia market, while simultaneously creating value for all our stakeholders. The management team and I have been preparing for the U.S. commercialization of Dialysate Triferic, and are working toward a U.S. launch in the first half of 2019. Given the sizable market opportunity, we are also moving ahead with regulatory filings and the development of activities related to IV Triferic, which has significant potential to help patients both in the U.S. and abroad. If approved by the FDA, we are planning for a U.S. launch in the first half of 2020. In addition to Triferic-related activities, we are carefully studying the commercial opportunity for Calcitriol and are working to improve the overall economics in our Concentrates products given the profitability and strategic potential for this business line."

Mr. Paul added, "As part of my review to better understand our products and our operations, I've spent time over the last 70 days getting to know the fantastic Rockwell Medical team. Together with our newly appointed senior leaders, I am energized by the opportunities ahead as we work to realize the full potential of the Company's valuable assets, improve patient outcomes and create shareholder value."

Selected Financial Highlights for the Three and Nine Months ended September 30, 2018:

- Sales were \$16.7 million and \$46.5 million for the three and nine months ended September 30, 2018, an increase of 14% and 10% over the same periods last year. Sales are associated with the Company's Dialysate Concentrate products. Increases were primarily a result of international sales, up \$1.2 million and \$1.3 million respectively and an increase in billing to Baxter of \$0.4 million and \$1.4 million respectively for the three and nine months ended September 30, 2018.
- Gross profit was \$2.0 million and a loss of \$2.8 million for the three and nine months ended September 30, 2018, respectively, compared to a gross profit of \$1.0 million and \$5.0 million for the same periods in 2017, respectively. The increase for the three months ended September 30, 2018 was largely due to increases in international sales and billings to Baxter. Included in the three and nine months ended September 30, 2018 were Triferic inventory write-offs of \$0.1 million and \$7.1 million respectively.
- Net losses were (\$5.0) million, or (\$0.10) per share, and (\$22.7) million, or (\$0.44) per share, for the three and nine months ended September 30, 2018, compared to a net loss of (\$5.1) million or (\$0.10) per share, and (\$17) million or (\$0.33 per share), for the same periods in 2017, respectively. Contributing factors in the loss for the three and nine months ended September 30, 2018 are approximately \$1.3 million and \$3.7 million respectively for legal and professional fees and other expenses associated with changes in executive management (CEO and CFO) and composition of the Board of Directors, and related litigation expenses. Also included is \$0.1 million and \$7.1 million respectively for Triferic inventory write offs.

- Cash used in operating activities was \$4.9 million for the third quarter of 2018. As of September 30, 2018, the Company had cash and investments of \$17.7 million and working capital of \$19.4 million. Following the completion of the \$22 million investment by Richmond Brothers, Inc., the Company has \$39.7 million of cash and investments, pro- forma on October 1, 2018.

The Company encourages shareholders to also review its Form 10-Q for the quarter ended September 30, 2018, as filed by the Company with the Securities and Exchange Commission ("SEC").

Conference Call and Webcast

Rockwell Medical will host a conference call today at 8:30 AM Eastern Time to provide commentary on the business. Shareholders and interested participants may listen to a live broadcast of the conference call by dialing (866) 610-1072 ((973) 935-2840 for international callers) and referencing passcode 6451387 approximately 15 minutes prior to the call. The call will include a slide presentation, and participants are encouraged to listen to and view the presentation via webcast, which can be accessed at the Rockwell Medical Investor Relations web page at ir.rockwellmed.com. A replay of the conference call will be available through Friday, November 23, 2018 by dialing (800) 585-8367 and referencing passcode 6451387. An archived version of the replay will also be available at the Rockwell Medical Investor Relations web page at ir.rockwellmed.com.

About Rockwell Medical, Inc.

Rockwell Medical is a biopharmaceutical company targeting end-stage renal disease (ESRD) and chronic kidney disease (CKD). Rockwell Medical's renal drug therapies support disease management initiatives to improve the quality of life and care of dialysis patients and are intended to deliver safe and effective therapy, while decreasing drug administration costs and improving patient convenience. Rockwell Medical's anemia drug Triferic is the only FDA-approved product indicated for iron replacement and maintenance of hemoglobin in hemodialysis patients. Rockwell's FDA approved generic drug Calcitriol (active vitamin D) is for treating secondary hyperparathyroidism in patients undergoing chronic renal dialysis. Rockwell Medical is also an established manufacturer, supplier and leader in delivering high-quality hemodialysis concentrates/dialysates (used to maintain human life by removing toxins and replacing critical nutrients in the dialysis patient's bloodstream) 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. 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 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 and which are subject to inherent uncertainty. 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'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 timing and success of our planned NDA submission for IV Triferic; the potential market opportunity for IV Triferic and other Rockwell products; pricing and reimbursement status for IV Triferic, Dialysate Triferic and other Rockwell products, including eligibility for add-on reimbursement under TDAPA; liquidity and capital resources; expected duration of Rockwell's existing working capital; plans and timing relating to the planned commercialization of Triferic; and the timing and success of our efforts to renegotiate economic terms of our concentrates business. Rockwell 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.

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ROCKWELL MEDICAL, INC. AND SUBSIDIARIES CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)

	<u>September 30, 2018</u>	<u>December 31, 2017</u>
ASSETS		
Cash and Cash Equivalents	\$ 4,292,328	\$ 8,406,917
Investments Available for Sale	13,410,151	24,648,459
Insurance Receivable	500,000	—
Accounts Receivable, net of a reserve of \$7,800 in 2018 and \$11,000 in 2017	7,581,699	6,355,566
Inventory	4,646,522	7,637,384
Prepaid and Other Current Assets	1,662,398	1,779,992
Total Current Assets	32,093,098	48,828,318
Property and Equipment, net	2,667,760	2,548,978
Inventory, Non-Current	1,865,834	5,986,752
Goodwill	920,745	920,745
Other Non-current Assets	536,605	494,847
Total Assets	\$ 38,084,042	\$ 58,779,640
LIABILITIES AND SHAREHOLDERS' EQUITY		
Accounts Payable	\$ 6,931,292	\$ 4,222,159
Accrued Liabilities	2,724,777	4,715,712
Settlement Payable	666,667	—
Current Portion of Deferred License Revenue	2,276,139	—
Customer Deposits	86,435	205,303
Total Current Liabilities	12,685,310	9,143,174
Deferred License Revenue	12,729,052	16,723,318
Total Liabilities	25,414,362	25,866,492

Commitments and Contingencies

Shareholders' Equity:

Common Shares, no par value, 51,769,294 shares issued and outstanding at September 30, 2018 and 51,768,424 shares issued and outstanding at December 31, 2017	275,634,848	273,210,907
Accumulated Deficit	(263,012,321)	(240,262,376)
Accumulated Other Comprehensive Income (Loss)	47,153	(35,383)
Total Shareholders' Equity	12,669,680	32,913,148
Total Liabilities And Shareholders' Equity	\$ 38,084,042	\$ 58,779,640

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

	Three Months Ended September 30, 2018	Three Months Ended September 30, 2017	Nine Months Ended September 30, 2018	Nine Months Ended September 30, 2017
Sales	\$ 16,672,416	\$ 14,626,904	\$ 46,534,358	\$ 42,462,265
Cost of Sales	<u>14,703,606</u>	<u>13,555,853</u>	<u>49,303,048</u>	<u>37,535,454</u>
Gross Profit (Loss)	1,968,810	1,071,051	(2,768,690)	4,926,811
Selling, General and Administrative	6,159,141	4,791,636	15,182,048	17,433,530
Settlement Expense, net of Reimbursement	—	—	1,030,000	—
Research and Product Development	<u>808,192</u>	<u>1,304,658</u>	<u>4,033,494</u>	<u>4,195,003</u>
Operating Loss	(4,998,523)	(5,025,243)	(23,014,232)	(16,701,722)
Interest and Investment Income (Loss)	<u>28,891</u>	<u>(31,751)</u>	<u>264,287</u>	<u>(180,279)</u>
Net Loss	\$ (4,969,632)	\$ (5,056,994)	\$ (22,749,945)	\$ (16,882,001)
Basic and Diluted Net Loss per Share	\$ (0.10)	\$ (0.10)	\$ (0.44)	\$ (0.33)
Basic and Diluted Weighted Average Shares Outstanding	51,288,537	51,260,975	51,288,462	50,995,079

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