



## Rockwell Medical, Inc. Provides Business Update, Reports Second Quarter 2018 Financial Results and Restates First Quarter 2018 Financial Results

August 14, 2018

WIXOM, Mich., Aug. 14, 2018 /PRNewswire/ -- Rockwell Medical, Inc. (NASDAQ:RMTI) (the "Company") today provided a business update, financial results for the second quarter ended June 30, 2018 and announced the restatement of its financial results for the first quarter ended March 31, 2018.

### Recent Business Updates:

- **Appointment of Stuart Paul** – On August 8, 2018, the Company appointed Stuart Paul as Chief Executive Officer and a Class I Director of the Board of Directors with a term expiring at the 2019 annual meeting of shareholders. This appointment is effective September 4, 2018. Having previously served in senior leadership roles with Abbott Laboratories, Quest Diagnostics and Gambro AB, Mr. Paul brings extensive healthcare experience, including in the renal space, significant operating expertise and commercialization know-how across both domestic and international markets. Effective August 10, 2018, Benjamin Wolin, our Chairman of the Board, was appointed the Company's Interim Principal Executive Officer to serve until Mr. Paul joins the Company.
- **Litigation Settlement** – On August 7, 2018, the Company and certain of its directors entered into a confidential settlement agreement and mutual release agreement with its former CEO, CFO and two former board members.
- **Appointment of Marcum LLP** – As of July 26, 2018, the Audit Committee engaged Marcum LLP as its new independent registered public accounting firm.
- **Calcitriol Update** – On July 11, 2018, the Company received FDA approval of its Prior Approval Supplement for manufacturing Calcitriol, the Company's FDA approved active vitamin D injection for the management of hypocalcemia in patients undergoing chronic hemodialysis. This approval was necessary to market and commercialize Calcitriol in the U.S. The Company does not expect Calcitriol sales to have a material impact on its total revenue for 2018.
- **Commercialization of Triferic** – In June 2018, the Board determined that it was in the best interests of the Company's stakeholders to immediately move ahead with the commercial planning and launch of Triferic in the U.S. and has since recruited additional talent to support these efforts. In parallel, the Company continues to work closely with industry leaders and policy makers to pursue separate reimbursement for Triferic, as the Company believes separate reimbursement has the potential to expedite the process of delivering Triferic to an even broader group of dialysis patients and clinicians. The Company does not expect Triferic sales to have a material impact on its total revenue for 2018.

### Selected Financial Highlights for the Three and Six Months ended June 30, 2018:

- Sales were \$14.9 million and \$29.8 million for the three and six months ended June 30, 2018, an increase of 12% and 7% over the same periods last year, respectively. Sales were primarily a result of the Company's hemodialysis concentrates/dialysates to dialysis providers and distributors in the U.S. and abroad.
- Gross profits were a loss of (\$4.0) million and a loss of (\$4.7) million for the three and six months ended June 30, 2018, respectively, compared to a gross profit of \$1.5 million and \$3.9 million for the same periods in 2017, respectively. Included in the three and six months negative gross profit for 2018 is a charge of \$5.4 million and \$7.6 million, respectively, to write down Triferic inventory. The write downs are a non-cash charge and are associated with both Triferic Active Pharmaceutical Ingredients (API) and finished goods inventory expected to expire past their required shelf-life dating over the 30 months for Triferic API and the 12 months for Triferic finished goods.
- Net losses were (\$12.2) million, or (\$0.24) per share, and (\$17.8) million, or (\$0.34) per share, for the three and six months ended June 30, 2018, compared to a net loss of (\$7.1) million or (\$0.14) per share, and (\$11.8) million, or (\$0.23) per share, for the same periods in 2017, respectively. Included in the three and six months loss for 2018 is a write down of \$5.4 million and \$7.6 million, respectively, of Triferic inventory as stated above. Additionally, included in the net loss was a net charge of \$1.0 million, associated with the Company's settlement with its former CEO, CFO and two former board members.
- Cash used in operating activities was \$5.2 million for the second quarter of 2018. As of June 30, 2018, the Company had cash and investments of \$22.7 million and working capital of \$24.3 million.

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

"The Company has made headway on a number of fronts during the second quarter of 2018 to better position Rockwell Medical for the future," said Ben Wolin, Chairman of the Board and Interim Principal Executive Officer. "While there remains significant work ahead, we are pleased to enter the second half of the year having named a permanent CEO, engaged Marcum LLP as our new auditor and settled our dispute with former management. Further, we're excited to move forward with our commercial planning to launch Triferic, while continuing to pursue separate reimbursement with CMS and CMMI. With the addition of Stuart Paul as CEO, whose appointment becomes effective in the coming weeks, we expect to be able to accelerate our commercial progress to get Triferic in the hands of patients who need it the most."

Mr. Wolin added, "On behalf of our Board, I would like to express our gratitude to our shareholders for their patience and support over these last several months. I'd also like to thank our employees for their dedication to our Company and to the stakeholders we serve, and our customers for their support and shared vision of helping our patients live healthier lives. As we move forward, our focus remains on realizing the potential of our innovative renal drug therapies to enhance the lives of dialysis patients and drive value for our shareholders."

#### **Restated Financial Results for the Three Months Ended March 31, 2018:**

On August 14, 2018, the Company provided restated financial statements for the period ended March 31, 2018, as a result of its subsequent review of its reserve for Triferic inventory. As a result of this review, the Company restated its reserve for Triferic inventory for the period ended March 31, 2018, to include an additional write down of \$750,000. Additionally, management re-estimated its stock-based compensation expense and the bonus accrual and concluded the expenses were overstated by \$730,000 and \$1,000,000, respectively.

A Form 10-Q/A for the quarter ended March 31, 2018 was filed by the Company with the SEC to reflect its restated financial statements for the quarter ended March 31, 2018.

#### **Conference Call and Webcast**

Rockwell Medical will host a conference call today at 5:00 pm 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 3884015 approximately 15 minutes prior to the call. A webcast of the call can be accessed at the Rockwell Medical Investor Relations web page at [ir.rockwellmed.com](http://ir.rockwellmed.com). A replay of the conference call will be available through Tuesday, August 28, 2018 by dialing (800) 585-8367 and referencing passcode 3884015. An archived version of the replay will also be available at the Rockwell Medical Investor Relations web page at [ir.rockwellmed.com](http://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 exclusive 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](http://www.rockwellmed.com) for more information.

#### **Forward-Looking Statement**

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's intention to bring to market Triferic and Calcitriol. 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 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'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 our liquidity and capital resources; our ability to maintain compliance with SEC and NASDAQ rules and requirements; plans relating to the commercialization of Triferic and Calcitriol; the timing and ability of the Company to obtain add-on reimbursement for Triferic; the Company's ability to obtain FDA and EMA approval of the intravenous formulation of Triferic; and whether the Company can successfully execute on its new business strategy. 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.

#### **Contacts**

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### **ROCKWELL MEDICAL, INC. AND SUBSIDIARIES CONDENSED CONSOLIDATED BALANCE SHEETS**

(Unaudited)

**June 30,  
2018**

**December 31,  
2017**

**ASSETS**

Cash and Cash Equivalents	\$ 1,748,135	\$ 8,406,917
Investments Available for Sale	20,936,973	24,648,459
Insurance Receivable	500,000	—
Accounts Receivable, net of a reserve of \$3,400 in 2018 and \$11,000 in 2017	5,354,406	6,355,566
Inventory	4,519,807	7,637,384
Prepaid and Other Current Assets	2,471,740	1,779,992
<b>Total Current Assets</b>	<b>35,531,061</b>	<b>48,828,318</b>
Property and Equipment, net	2,606,145	2,548,978
Inventory, Non-Current	1,865,834	5,986,752
Goodwill	920,745	920,745
Other Non-current Assets	494,238	494,847
<b>Total Assets</b>	<b>\$ 41,418,023</b>	<b>\$ 58,779,640</b>

**LIABILITIES AND SHAREHOLDERS' EQUITY**

Accounts Payable	\$ 3,206,620	\$ 4,222,159
Accrued Liabilities	4,040,868	4,715,712
Settlement Payable	1,530,000	—
Current Portion of Deferred License Revenue	2,281,034	—
Customer Deposits	173,396	205,303
<b>Total Current Liabilities</b>	<b>11,231,918</b>	<b>9,143,174</b>
Deferred License Revenue	13,296,866	16,723,318
<b>Total Liabilities</b>	<b>24,528,784</b>	<b>25,866,492</b>
<b>Commitments and Contingencies</b>	—	—
<b>Shareholders' Equity:</b>		
Common Shares, no par value, 51,768,424 shares issued and outstanding at June 30, 2018 and December 31, 2017	275,022,242	273,210,907
Accumulated Deficit	(258,042,689)	(240,262,376)
Accumulated Other Comprehensive Loss	(90,314)	(35,383)
<b>Total Shareholders' Equity</b>	<b>16,889,239</b>	<b>32,913,148</b>
<b>Total Liabilities And Shareholders' Equity</b>	<b>\$ 41,418,023</b>	<b>\$ 58,779,640</b>

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

(Unaudited)

	<b>Three Months Ended June 30, 2018</b>	<b>Three Months Ended June 30, 2017</b>	<b>Six Months Ended June 30, 2018</b>	<b>Six Months Ended June 30, 2017</b>
<b>Sales</b>	\$ 14,913,363	\$ 13,243,107	\$ 29,861,943	\$ 27,835,361
Cost of Sales	18,930,371	11,744,819	34,599,442	23,979,601
Gross Profit (Loss)	(4,017,008)	1,498,288	(4,737,499)	3,855,760
Selling, General and Administrative	5,690,949	6,541,179	9,022,906	12,641,894
Settlement Expense, net of Reimbursement	1,030,000	—	1,030,000	—
Research and Product Development	1,558,946	1,675,494	3,225,302	2,890,345

Operating Loss	(12,296,903)	(6,718,385)	(18,015,707)	(11,676,479)
Interest and Investment Income (Loss)	<u>66,111</u>	<u>(364,599)</u>	<u>235,394</u>	<u>(148,528)</u>
<b>Net Loss</b>	<b><u>\$ (12,230,792)</u></b>	<b><u>\$ (7,082,984)</u></b>	<b><u>\$ (17,780,313)</u></b>	<b><u>\$ (11,825,007)</u></b>
<b>Basic and Diluted Net Loss per Share</b>	<b><u>\$ (0.24)</u></b>	<b><u>\$ (0.14)</u></b>	<b><u>\$ (0.35)</u></b>	<b><u>\$ (0.23)</u></b>
<b>Basic and Diluted Weighted Average Shares Outstanding</b>	<b><u>51,288,424</u></b>	<b><u>51,031,899</u></b>	<b><u>51,288,424</u></b>	<b><u>50,859,927</u></b>

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