



Rockwell Medical Reports Fourth Quarter and Year End 2017 Results

March 15, 2018

Conference call at 4:30 p.m. EDT today

WIXOM, Mich., March 15, 2018 (GLOBE NEWSWIRE) -- Rockwell Medical, Inc. (NASDAQ:RMTI), a fully-integrated biopharmaceutical company targeting end-stage renal disease (ESRD) and chronic kidney disease (CKD) with innovative products and services for the treatment of iron replacement, secondary hyperparathyroidism and hemodialysis, reported results for the fourth quarter and year ending December 31, 2017.

Q4 2017 Financial Highlights

- Sales were \$14.8 million, \$1.4 million or 10.8% higher than Q4 2016
- The company reported a negative gross profit of (\$1.2) million compared to \$2.0 million gross profit in Q4 2016 due to a \$3.3 million reserve incurred for expiring pharmaceutical inventory.
- SG&A expense was \$5.9 million compared to \$6.0 million in Q4 2016.
- R&D expense was \$2.1 million compared to \$1.2 million in Q4 2016.
- Net loss was (\$9.0) million or (\$0.18) per share compared to a (\$5.1) million net loss or (\$0.10) per share in Q4 2016.
- Cash and investments were \$33.1 million as of December 31, 2017.
- Net working capital was \$39.7 million as of December 31, 2017.

2017 Financial Highlights

- Sales were \$57.3 million compared to \$53.3 million in 2016, with the increase primarily due to higher concentrate unit volume.
- Gross profit was \$3.7 million compared to \$6.8 million in 2016. Gross profit was adversely impacted by increased drug product costs of \$1.9 million and lower gross profit of \$1.0 million on our concentrate business.
- SG&A expense was \$23.3 million compared to \$21.1 million in 2016.
- R&D expense was \$6.3 million compared to \$5.8 million in 2016.
- Net loss was (\$25.9) million or (\$0.51) per share versus (\$19.8) million or (\$0.39) per share in 2016.
- Cash used in operating activities in 2016 was \$21.1 million.

2017 Corporate Highlights

- Continued marketing and education of Triferic and in-center use to US dialysis providers.
- Data from clinics using Triferic via the drug sample program have shown improved patient outcomes and reduced costs.
- Proposal submitted to Centers for Medicare and Medicaid Innovation (CMS) for separate reimbursement for Triferic which is under review by CMS.
- Triferic ESA sparing patent covering composition and use issued in China.
- Signed exclusive license agreements for Triferic commercialization in Chile and Peru.

Mr. Robert L. Chioini, Chief Executive Officer of Rockwell stated, "We are pleased and excited with the substantial progress we have made working with policy makers in Washington D.C. to ensure hemodialysis patients across the U.S. will have access to our new, innovative anemia therapy Triferic. There is a timely emphasis on spurring innovation in the U.S. renal market to provide new therapies, like Triferic, that can improve patients' lives and lower healthcare costs. Based on our progress to date, we remain optimistic that Triferic will receive the proper reimbursement soon. Our marketing and education efforts for Triferic continue, and have been well received by the dialysis community. Data reported via our drug sample program has shown positive patient outcomes and cost-saving benefits, giving us further confidence that Triferic should be widely adopted if separate reimbursement is granted."

Conference Call Information

Rockwell Medical will be hosting a conference call to review its 2017 fourth quarter and year end results today, Thursday, March 15, 2018 at 4:30 p.m. EDT. Investors are encouraged to call a few minutes in advance at (866) 548-4713, or for international callers (323) 794-2093, Conference ID #8976030. To listen to the call via webcast, please go to the Rockwell Medical IR web page: <http://ir.rockwellmed.com/>

About Triferic

Triferic is the only FDA approved drug indicated to replace iron and maintain hemoglobin in hemodialysis patients suffering from anemia. Via dialysate during each dialysis treatment, Triferic replaces the 5-7 mg iron loss that occurs in all patients, effectively maintaining their iron balance. Unlike IV iron products, Triferic binds iron immediately and completely to transferrin (carrier of iron in the body) upon entering the blood and it is then transported directly to the bone marrow to be incorporated into hemoglobin, with no increase in ferritin (stored iron and inflammation) and no anaphylaxis, addressing a significant unmet 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, Inc.

Rockwell Medical, Inc. ("Rockwell") is a fully-integrated biopharmaceutical company targeting end-stage renal disease (ESRD) and chronic kidney disease (CKD) with innovative products and services for the treatment of iron replacement, secondary hyperparathyroidism and hemodialysis.

Rockwell's FDA approved drug Triferic is indicated for iron replacement and maintenance of hemoglobin in hemodialysis patients suffering from anemia. Triferic delivers iron to patients during their regular dialysis treatment, using dialysate as the delivery mechanism. Triferic has demonstrated that it safely and effectively delivers sufficient iron to the bone marrow and maintains hemoglobin, without increasing iron stores (ferritin). Rockwell intends to market Triferic to hemodialysis patients in the U.S. dialysis market and globally.

Rockwell's FDA approved generic drug Calcitriol is for treating secondary hyperparathyroidism in dialysis patients. Calcitriol (active vitamin D) injection is indicated in the management of hypocalcemia in patients undergoing chronic renal dialysis. It has been shown to significantly reduce elevated parathyroid hormone levels. Reduction of PTH has been shown to result in an improvement in renal osteodystrophy. Rockwell intends to market Calcitriol to hemodialysis patients in the U.S. dialysis market.

Rockwell is also an established manufacturer and leader in delivering high-quality hemodialysis concentrates/dialysates to dialysis providers and distributors in the U.S. and abroad. As one of the two major suppliers in the U.S., Rockwell's products are used to maintain human life by removing toxins and replacing critical nutrients in the dialysis patient's bloodstream. Rockwell has three U.S. manufacturing/distribution facilities.

Rockwell'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 is developing a pipeline of drug therapies, including extensions of Triferic for indications outside of hemodialysis. Please visit www.rockwellmed.com for more information.

Forward-Looking Statement Disclaimer

Certain statements in this press release constitute "forward-looking statements" within the meaning of the federal securities laws, including, but not limited to, Rockwell's prospects of obtaining the approval from CMS for separate reimbursement for Triferic and its intention to sell and market Calcitriol and Triferic. Words such as "may," "might," "will," "should," "believe," "expect," "anticipate," "estimate," "continue," "could," "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 Medical's SEC filings many of which are beyond our control, actual results could be materially different. Rockwell expressly disclaims any obligation to update or alter 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.

Investor Contact:

Michael Rice
LifeSci Advisors
(646) 597-6979
mrice@lifesciadvisors.com

Media Contact:

Matt Middleman
LifeSci Public Relations
(646) 627-8384
matt@lifescipublicrelations.com

Source: Rockwell Medical, Inc.

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED INCOME STATEMENTS

For the three and twelve months ended December 31, 2017 and December 31, 2016

	Three Months Ended December 31, 2017	Three Months Ended December 31, 2016	Year Ended December 31, 2017	Year Ended December 31, 2016
Sales	\$ 14,838,016	\$ 13,389,786	\$ 57,300,281	\$ 53,284,166
Cost of Sales	16,062,936	11,401,603	53,598,390	46,531,648
Gross Profit (Loss)	(1,224,920)	1,988,183	3,701,891	6,752,518
Selling, General and Administrative	5,869,879	6,049,663	23,303,409	21,120,901
Research and Product Development	2,126,397	1,200,729	6,321,400	5,840,346
Operating (Loss)	(9,221,196)	(5,262,209)	(25,922,918)	(20,208,729)
Interest and Investment Income	181,171	207,911	892	810,340
Foreign Currency Gain (Loss)	742	—	742	—
Income (Loss) Before Income Taxes	(9,039,283)	(5,054,298)	(25,921,284)	(19,398,389)
Income Tax Expense	—	—	—	(404,527)
Net (Loss)	\$ (9,039,283)	\$ (5,054,298)	\$ (25,921,284)	\$ (19,802,916)

Basic Earnings (Loss) per Share	\$ (0.18)	\$ (0.10)	\$ (0.51)	\$ (0.39)
Diluted Earnings (Loss) per Share	\$ (0.18)	\$ (0.10)	\$ (0.51)	\$ (0.39)

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

As of December 31, 2017 and 2016

	December 31, 2017	December 31, 2016
ASSETS		
Cash and Cash Equivalents	\$ 8,406,917	\$ 17,180,594
Investments Available for Sale	24,648,459	40,759,703
Accounts Receivable, net of a reserve of \$11,000 in 2017 and \$5,000 in 2016	6,355,566	6,393,228
Inventory	7,637,384	12,141,072
Other Current Assets	1,779,992	2,034,598
Total Current Assets	48,828,318	78,509,195
Property and Equipment, net	2,548,978	1,391,575
Inventory, Non-Current	5,986,752	1,826,554
Intangible Assets	4,028	4,382
Goodwill	920,745	920,745
Other Non-current Assets	490,819	501,187
Total Assets	\$ 58,779,640	\$ 83,153,638
LIABILITIES AND SHAREHOLDERS' EQUITY		
Accounts Payable	\$ 4,222,159	\$ 5,858,234
Accrued Liabilities	4,715,712	4,210,151
Customer Deposits	205,303	77,217
Total Current Liabilities	9,143,174	10,145,602
Deferred License Revenue	16,723,318	20,051,737
Shareholders' Equity:		
Common Shares, no par value, 51,768,424 and 51,527,711 shares issued and outstanding	273,210,907	268,199,939
Accumulated Deficit	(240,262,376)	(214,341,092)
Accumulated Other Comprehensive Income	(35,383)	(902,548)
Total Shareholders' Equity	32,913,148	52,956,299
Total Liabilities And Shareholders' Equity	\$ 58,779,640	\$ 83,153,638

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

For the years ended December 31, 2017 and 2016

	2017	2016
Cash Flows From Operating Activities:		
Net (Loss)	\$ (25,921,284) \$ (19,802,916
Adjustments To Reconcile Net Loss To Net Cash Used In Operating Activities:		
Depreciation and Amortization	514,362	762,368
Share Based Compensation—Non-employee	228,847	—
Share Based Compensation—Employees	6,945,749	10,346,284

Loss on Disposal of Assets	10,777		8,168	
Loss on Sale of Investments Available for Sale	792,207		26,820	
Changes in Assets and Liabilities:				
(Increase) in Accounts Receivable	(962,338)	(1,162,469)
(Increase) in Inventory	343,490		(6,095,846)
(Increase) in Other Assets	264,975		(1,230,084)
(Decrease) Increase in Accounts Payable	(1,636,840)	1,863,018	
(Decrease) Increase in Other Liabilities	634,238		191,134	
(Decrease) in Deferred License Revenue	(2,099,028)	(2,065,785)
(Decrease) Increase in Deferred Drug License Revenue	(229,390)	4,706,670	
Changes in Assets and Liabilities	(3,684,893)	(3,793,362)
Cash (Used In) Operating Activities	(21,114,235)	(12,452,638)
Cash Flows From Investing Activities:				
Purchase of Investments Available for Sale	(35,733,677)	(25,781,853)
Sale of Investments Available for Sale	51,918,745		24,491,677	
Purchase of Equipment	(1,682,913)	(355,264)
Proceeds on Sale of Assets	725		1,000	
Cash Provided by (Used In) Investing Activities	14,502,880		(1,644,440)
Cash Flows From Financing Activities:				
Proceeds from Issuance of Common Shares	123,603		80,161	
Restricted Stock Retained in Satisfaction of Tax Liabilities	(2,287,231)	—	
Cash (Used In) Provided By Financing Activities	(2,163,628)	80,161	
Effects of exchange rate changes	1,306		(671)
(Decrease) In Cash	(8,773,677)	(14,017,588)
Cash At Beginning Of Period	17,180,594		31,198,182	
Cash At End Of Period	\$ 8,406,917		\$ 17,180,594	

 [Primary Logo](#)

Source: Rockwell Medical, Inc.