



May 12, 2014

Rockwell Medical, Inc. Reports First Quarter 2014 Results

Triferic(TM) NDA Submission Highlights First Quarter

WIXOM, Mich., May 12, 2014 (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 first quarter ended March 31, 2014.

Q1 2014 Highlights

- Sales were \$13.0 million, a 5.1% increase over Q1 2013.
- Gross profit was \$1.7 million, a 31% increase over Q1 2013.
- R&D expense was \$4.6 million, a 64% decrease compared to \$12.8 million in Q1 2013.
- Cash and investments were \$14.7 million as of March 31, 2014.

Q1 2014 Drug Development Highlights

- Triferic New Drug Application submitted to FDA.
- Triferic formulation patent issued for Japan.
- Triferic long-term safety studies completed.
- KOL breakfast meeting held in New York to examine anemia management and potential iron delivery advancements for CKD-HD patients.
- Triferic clinical study abstracts and oral presentations accepted and presented at key nephrology conferences including the National Kidney Foundation Spring Clinical Meeting, Asia Pacific Congress on Nephrology and ISN Nexus Symposium.

For the quarter ended March 31, 2014, Rockwell reported a net loss of (\$7.8) million or (\$0.20) per share, which was a \$7.6 million or 49% improvement compared to a net loss of (\$15.4) million or (\$0.72) per share in the first quarter of 2013. R&D expense decreased by \$8.1 million compared to the first quarter of 2013.

"The submission of our Triferic NDA during the first quarter represents a major milestone for the Company," stated Mr. Robert L. Chioini, Founder, Chairman and CEO of Rockwell. "This NDA submission is the culmination of consistent, positive efficacy and safety results achieved across the entire Phase 3 Triferic clinical study program and it brings us much closer to the potential U.S. commercial launch of Triferic." Mr. Chioini continued, "R&D expense decreased significantly in the first quarter of 2014 as anticipated, and we expect a substantial decline each successive quarter during 2014."

Conference Call Information

Rockwell Medical will be hosting a conference call to review its first quarter 2014 results on Monday, May 12, 2014 at 4:30 pm ET. Investors are encouraged to call a few minutes in advance at (877) 383-7438, or for international callers (678) 894-3975, passcode # 43066158 or to listen to the call via webcast at the Rockwell Medical IR web page: <http://ir.rockwellmed.com/>

About Triferic

Triferic is a unique iron compound that is delivered to the hemodialysis patient via dialysate, replacing the 5-7 mg of iron that is lost during every dialysis treatment. Triferic is introduced into the sodium bicarbonate concentrate on-site at the dialysis clinic, which is subsequently mixed into dialysate. Once in the dialysate, Triferic crosses the dialyzer membrane and enters the blood where it immediately binds to apo-transferrin and is taken to the bone marrow to assist in new red blood cell formation, similar to how dietary iron is processed in the human body. In completed clinical trials to date, Triferic has demonstrated that it can safely and effectively deliver sufficient iron to the bone marrow, maintain hemoglobin and not increase iron stores (ferritin), while significantly reducing ESA dose.

About Rockwell Medical

Rockwell Medical 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 lead drug candidate Triferic is in late-stage clinical development for the treatment of iron replacement in dialysis patients. Triferic delivers iron to the bone marrow of dialysis patients in a non-invasive, physiologic manner during their regular dialysis treatment, using dialysate as the delivery mechanism. In completed clinical trials to date, Triferic has demonstrated that it can safely and effectively deliver sufficient iron to the bone marrow, maintain hemoglobin and not increase iron stores (ferritin), while significantly reducing ESA dose. Triferic has completed the efficacy trials of its Phase 3 clinical study program (CRUISE-1 and CRUISE-2). Triferic is expected to address an estimated \$600M U.S. market.

Rockwell is preparing to launch its FDA approved generic drug Calcitriol, to treat 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 launch Calcitriol once it receives FDA manufacturing approval, addressing an estimated \$350M U.S. 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 manufacturing/distribution facilities located in the U.S. and its operating infrastructure is a ready-made sales and distribution channel that is able to provide seamless integration into the commercial market for its drug products, Calcitriol and Triferic upon FDA market approval.

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. For a demonstration of the Triferic unique mechanism of action in delivering iron via dialysate, please view the animation video at <http://www.rockwellmed.com/collateral/documents/english-us/mode-of-action.html>.

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 intention to launch Calcitriol and Triferic[®] following FDA approval. Words such as "may," "might," "will," "should," "believe," "expect," "anticipate," "estimate," "continue," "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. Thus, actual results could be materially different. Rockwell Medical 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 trademark of Rockwell Medical, Inc.

ROCKWELL MEDICAL, INC. AND SUBSIDIARY

CONSOLIDATED INCOME STATEMENTS

For the three months ended March 31, 2014 and March 31, 2013

(Unaudited)

	Three Months Ended March 31, 2014	Three Months Ended March 31, 2013
Sales	\$ 12,963,652	\$ 12,336,374
Cost of Sales	11,283,694	11,055,394
Gross Profit	1,679,958	1,280,980
Selling, General and Administrative	4,090,199	3,916,783

Common Share Purchase Warrants, 838,071 and 983,071 warrants issued and outstanding	4,225,669	4,895,811
Accumulated Deficit	(166,596,095)	(158,790,569)
Accumulated Other Comprehensive Income	66,279	32,419
Total Shareholders' Equity (Deficit)	<u>(3,527,190)</u>	<u>595,539</u>
Total Liabilities And Shareholders' Equity	<u>\$ 26,793,552</u>	<u>\$ 36,362,124</u>

ROCKWELL MEDICAL, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CASH FLOWS

For the three months ended March 31, 2014 and March 31, 2013

(Unaudited)

	<u>2014</u>	<u>2013</u>
Cash Flows From Operating Activities:		
Net (Loss)	\$ (7,805,526)	\$ (15,379,724)
Adjustments To Reconcile Net Loss To Net Cash Used In Operating Activities:		
Depreciation and Amortization	257,761	250,530
Share Based Compensation - Non-employee	--	966,227
Share Based Compensation- Employees	2,174,212	1,350,959
Amortization of Debt Issuance Costs	113,529	--
Non-Cash Interest Expense	112,529	--
Loss on Disposal of Assets	1,662	5,109
Changes in Assets and Liabilities:		
Decrease (Increase) in Accounts Receivable	477,866	(30,367)
Increase in Inventory	(110,180)	(215,871)
Decrease (Increase) in Other Assets	(243,936)	257,464
Increase (Decrease) in Accounts Payable	(3,552,886)	1,266,909
Increase (Decrease) in Other Liabilities	<u>(1,790,208)</u>	<u>220,809</u>
Changes in Assets and Liabilities	<u>(5,219,344)</u>	<u>1,498,944</u>
Cash Used In Operating Activities	(10,365,177)	(11,307,955)
Cash Flows From Investing Activities:		
Purchase of Investments Available for Sale	(2,000,000)	--
Purchase of Equipment	(329,882)	(153,380)
Proceeds on Sale of Assets	--	5,998
Cash Used In Investing Activities	(2,329,882)	(147,382)
Cash Flows From Financing Activities:		
Proceeds from the Issuance of Common Shares and Purchase Warrants	1,474,725	12,518,733
Payments on Notes Payable and Capital Lease Obligations	--	(829)
Cash Provided By Financing Activities	1,474,725	12,517,904

Increase (Decrease) In Cash	(11,220,334)	1,062,567
Cash At Beginning Of Period	<u>11,881,451</u>	<u>4,711,730</u>
Cash At End Of Period	<u>\$ 661,117</u>	<u>\$ 5,774,297</u>

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Source: Rockwell Medical, Inc.

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