



July 31, 2014

## Rockwell Medical, Inc. Reports Second Quarter 2014 Results

### Conference Call at 4:30 pm Eastern Time

WIXOM, Mich., July 31, 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 second quarter ended June 30, 2014.

### Q2 2014 Highlights

- Q2 sales were \$13.0 million, a 0.4% increase over Q2 2013.
- Q2 gross profit was \$2.0 million, a 19.8% increase over Q2 2013.
- Q2 gross profit margins improved by 2.5 percentage points to 15.5%, compared to 13.0% in Q2 2013.
- R&D expense was \$0.2 million, a 98% decrease compared to \$10.2 million in Q2 2013.
- Net loss decreased by \$8.7 million or 73% compared to Q2 2013.
- Cash and investments were \$11.9 million as of June 30, 2014.

### 1H 2014 Highlights

- Sales were \$26 million, up 2.7% over the first half of 2013.
- Gross profit was \$3.7 million, up 24.7% over the first half of 2013.
- Gross profit margins increased by 2.5 percentage points to 14.2%, compared to the first half of 2013.
- R&D spending decreased \$18.2 million or 79% compared to the first half of 2013.
- Net loss decreased \$16.3 million or 60% to \$11.0 million compared to the first half of 2013.
- Loss per share improved by \$0.76 per share with a year-to-date loss of (\$0.28) compared to a loss of (\$1.04) in the first half of 2013.

### Q2 2014 Drug Development Highlights

- Triferic New Drug Application (NDA) was accepted for review by the FDA.
- Triferic was given a Prescription Drug User Fee Act (PDUFA) action date of January 24, 2015 by the FDA.
- Triferic clinical study abstracts and oral presentations accepted and presented at key nephrology conferences including the National Kidney Foundation Spring Clinical Meeting in Dallas, the ERA-EDTA Congress in the Netherlands and at the Asian Pacific Congress of Nephrology in Japan.
- Rockwell won its Small Business Administration appeal for the PDUFA fee waiver, resulting in a \$2.2 million refund to the Company.
- Rockwell received FDA manufacturing approval for Calcitriol, the Company's low-cost, generic active vitamin D injection.

"We are pleased with our achievements and continued execution," stated Mr. Robert L. Chioini, Founder, Chairman and CEO of Rockwell Medical. "We achieved several important goals, including FDA acceptance of our Triferic NDA with a January 24, 2015 PDUFA date. We also received FDA manufacturing approval for Calcitriol, our generic, low-cost vitamin D injection. We are working in preparation of a successful Calcitriol commercial launch, while continuing to communicate with the FDA for their review for potential approval of Triferic, our novel iron delivery drug." Mr. Chioini further stated, "As anticipated, our R&D costs were reduced significantly. Our core business is solid and our gross margins are improving and consistent with our expectations. CitraPure continues to become the standard of care for dialysate in the renal market."

### Conference Call Information

Rockwell Medical will be hosting a conference call to review its second quarter 2014 results on Thursday, July 31, 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 # 74612608 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, similar to how dietary iron is processed in the human body. In completed clinical trials to date, Triferic has demonstrated that it may 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 investigational drug Triferic is currently under NDA review by the FDA for the treatment of iron replacement/maintenance 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 may 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 successfully completed the efficacy trials of its Phase 3 clinical study program (CRUISE-1 and CRUISE-2).

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 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 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 product 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](http://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<sup>™</sup> is a trademark of Rockwell Medical, Inc. / CitraPure<sup>®</sup> is a registered trademark of Rockwell Medical, Inc.

## ROCKWELL MEDICAL, INC. AND SUBSIDIARY

### CONSOLIDATED INCOME STATEMENTS

For the three and six months ended June 30, 2014 and June 30, 2013

(Unaudited)

Three Months Ended <u>June 30, 2014</u>	Three Months Ended <u>June 30, 2013</u>	Six Months Ended <u>June 30, 2014</u>	Six Months Ended <u>June 30, 2013</u>
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<b>Sales</b>	<b>\$ 13,033,361</b>	<b>\$ 12,984,164</b>	<b>\$ 25,997,013</b>	<b>\$ 25,320,538</b>
Cost of Sales	11,014,469	11,299,099	22,298,163	22,354,493
<b>Gross Profit</b>	<b>2,018,892</b>	<b>1,685,065</b>	<b>3,698,850</b>	<b>2,966,045</b>
Selling, General and Administrative	4,214,205	3,237,974	8,304,404	7,154,757
Research and Product Development	186,695	10,222,721	4,801,892	22,977,239
<b>Operating Income (Loss)</b>	<b>(2,382,008)</b>	<b>(11,775,630)</b>	<b>(9,407,446)</b>	<b>(27,165,951)</b>
Interest and Investment Income, net	69,633	4,566	143,848	15,238
Interest Expense	858,003	92,155	1,712,306	92,230
Income (Loss) Before Income Taxes	(3,170,378)	(11,863,219)	(10,975,904)	(27,242,943)
Income Tax Expense	--	--	--	--
<b>Net Income (Loss)</b>	<b>\$ (3,170,378)</b>	<b>\$ (11,863,219)</b>	<b>\$ (10,975,904)</b>	<b>\$ (27,242,943)</b>
<b>Basic Earnings (Loss) per Share</b>	<b>\$ (0.08)</b>	<b>\$ (0.38)</b>	<b>\$ (0.28)</b>	<b>\$ (1.04)</b>
<b>Diluted Earnings (Loss) per Share</b>	<b>\$ (0.08)</b>	<b>\$ (0.38)</b>	<b>\$ (0.28)</b>	<b>\$ (1.04)</b>

**ROCKWELL MEDICAL, INC. AND SUBSIDIARY**

**CONSOLIDATED BALANCE SHEETS**

**As of June 30, 2014 and December 31, 2013**

(Unaudited)

<b>ASSETS</b>	<b>June 30, 2014</b>	<b>December 31, 2013</b>
Cash and Cash Equivalents	\$ 2,858,724	\$ 11,881,451
Investments Available for Sale	9,076,243	12,034,622
Accounts Receivable, net of a reserve of \$45,000 in 2014 and \$37,000 in 2013	4,218,917	4,578,319
Other Receivable	2,169,883	--
Inventory	2,784,142	2,799,648
Other Current Assets	589,074	623,734
Total Current Assets	21,696,983	31,917,774
Property and Equipment, net	1,650,003	1,648,949
Intangible Assets	416,200	499,715
Goodwill	920,745	920,745
Other Non-current Assets	1,197,882	1,374,941
Total Assets	<u>\$ 25,881,813</u>	<u>\$ 36,362,124</u>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Note Payable	\$ 5,969,511	\$ 2,308,145
Accounts Payable	6,276,561	8,686,153
Accrued Liabilities	2,784,711	6,647,828
Customer Deposits	284,105	207,545
Total Current Liabilities	15,314,888	17,849,671
Long Term Debt	14,480,606	17,916,914

Shareholders' Equity:		
Common Shares, no par value, 40,895,726 and 40,110,661 shares issued and outstanding	161,575,859	154,457,878
Common Share Purchase Warrants, 838,071 and 983,071 warrants issued and outstanding	4,225,669	4,895,811
Accumulated Deficit	(169,766,473)	(158,790,569)
Accumulated Other Comprehensive Income	51,264	32,419
Total Shareholders' Equity (Deficit)	<u>(3,913,681)</u>	<u>595,539</u>
Total Liabilities And Shareholders' Equity	<u>\$ 25,881,813</u>	<u>\$ 36,362,124</u>

**ROCKWELL MEDICAL, INC. AND SUBSIDIARY**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

**For the six months ended June 30, 2014 and June 30, 2013**

(Unaudited)

	<u>2014</u>	<u>2013</u>
Cash Flows From Operating Activities:		
<b>Net (Loss)</b>	<b>\$ (10,975,904)</b>	<b>\$ (27,242,943)</b>
Adjustments To Reconcile Net Loss To Net Cash Used In		
Operating Activities:		
Depreciation and Amortization	506,465	502,178
Share Based Compensation - Non-employee	--	1,200,785
Share Based Compensation- Employees	4,406,012	2,779,121
Amortization of Debt Issuance Costs	227,058	--
Non-Cash Interest Expense	225,058	--
Loss on Disposal of Assets	4,827	5,516
Loss on Sale of Investments, net	1,223	--
Changes in Assets and Liabilities:		
Decrease (Increase) in Accounts Receivable	359,402	(144,560)
Decrease (Increase) in Inventory	15,506	(266,960)
Decrease (Increase) in Other Assets	(2,393,555)	528,866
(Decrease) in Accounts Payable	(2,409,592)	(6,529,600)
(Decrease) in Other Liabilities	<u>(3,578,224)</u>	<u>(3,666,596)</u>
Changes in Assets and Liabilities	<u>(8,006,463)</u>	<u>(10,078,850)</u>
<b>Cash Used In Operating Activities</b>	<b>(13,611,724)</b>	<b>(32,834,193)</b>
Cash Flows From Investing Activities:		
Purchase of Investments Available for Sale	(2,000,000)	--
Sale of Investments Available for Sale	4,976,000	--
Purchase of Equipment	(428,831)	(313,014)
Proceeds on Sale of Assets	<u>--</u>	<u>6,898</u>
<b>Cash Provided By (Used) In Investing Activities</b>	<b>2,547,169</b>	<b>(306,116)</b>

Cash Flows From Financing Activities:

Proceeds from the Issuance of Common Shares and Purchase Warrants	2,041,828	50,463,613
Proceeds from the Issuance of Notes Payable	--	20,000,000
Debt Issuance Costs	--	(1,081,279)
Payments on Notes Payable and Capital Lease Obligations	<u>--</u>	<u>(1,688)</u>
<b>Cash Provided By Financing Activities</b>	<b>2,041,828</b>	<b>69,380,646</b>
<b>Increase (Decrease) In Cash</b>	<b>(9,022,727)</b>	<b>36,240,337</b>
Cash At Beginning Of Period	<u>11,881,451</u>	<u>4,711,730</u>
<b>Cash At End Of Period</b>	<b><u>\$ 2,858,724</u></b>	<b><u>\$ 40,952,067</u></b>

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Source: Rockwell Medical, Inc.

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