



November 10, 2014

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

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

WIXOM, Mich., Nov. 10, 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 third quarter ended September 30, 2014.

### 2014 Q3 Highlights

- Q3 sales were \$13.7 million, a 5.0% increase over Q3 2013.
- Q2 gross profit was \$2.3 million, a 39.0% increase over Q3 2013.
- Q2 gross profit margins improved by 4.0 percentage points to 16.5%, compared to 12.5% in Q3 2013.
- R&D expense was \$1.3 million, an 87.7% decrease compared to \$10.6 million in Q3 2013
- Net loss decreased by \$9.2 million or 70% compared to Q3 2013.
- Cash and investments were \$12.0 million as of September 30, 2014.

### 2014 Nine Months Highlights

- Sales were \$39.7 million, up 3.5% over the first nine months of 2013.
- Gross profit was \$6.0 million, up \$1.4 million 29.8% over the first nine months of 2013.
- Gross profit margins increased by 3.0 percentage points to 15.0%, compared to the first nine months of 2013.
- R&D spending decreased \$27.5 million or 82% compared to the first nine months of 2013.
- Net loss decreased \$25.5 million or 63% to \$14.9 million compared to the first nine months of 2013.
- Loss per share improved by \$0.98 per share with a year-to-date loss of (\$0.34) compared to a loss of (\$1.32) in the first nine months of 2013.

### Q3 and Recent 2014 Drug Development Highlights

- Received PDUFA fee refund of \$2.2 million per successful appeal to the Small Business Administration.
- Received majority vote from FDA Advisory Committee for approval of Triferic as a therapy to treat iron loss and maintain hemoglobin in hemodialysis patients.

### Recent Business Development Highlights

- Strengthened balance sheet in early October with \$43 million in cash, comprised of
  - \$20 million for granting Baxter exclusive rights commercialize Rockwell's dialysis concentrate products in the U.S. and select foreign markets.
  - \$15 million equity investment in RMTI Common Shares from Baxter at \$11.39 per share.
  - \$8 million from the exercise of Common Share Purchase Warrants.

"We achieved a strong 3<sup>rd</sup> quarter and then two significant accomplishments; our successful confirmatory vote on Triferic from the FDA Advisory Committee and our commercialization agreement with Baxter," stated Mr. Robert L. Chioini, Founder, Chairman and CEO of Rockwell Medical. "The Advisory Committee's majority vote recommending Triferic as a therapy to treat iron loss and maintain hemoglobin in hemodialysis patients adds to our conviction that this drug can make a positive difference for ESRD patients in addressing this unmet need. We remain committed to working with the FDA on completing its review for marketing approval of Triferic. Our exclusive distribution agreement with Baxter, a global leader in selling dialysis products, enabled us to monetize a valuable asset and strengthen our balance sheet while also providing dialysis patients and service providers expanded access to our market leading products in new territories. These two recent milestone events, in addition to our strong sales and margin improvements in the third quarter, give us great momentum moving forward."

### Conference Call Information

Rockwell Medical will be hosting a conference call to review its third quarter 2014 results on Monday, November 10, 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 # 28319994 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 hemodialysis patients via dialysate, replacing approximately 5-7 mg of iron during their dialysis treatment. Triferic is introduced into 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 transferrin and is taken to the bone marrow, similar to how dietary iron binds in the 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 and hemoglobin maintenance in dialysis patients, with a PDUFA date of January 24, 2015. Triferic delivers iron to dialysis patients 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.

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 nine months ended September 30, 2014 and September 30, 2013**

(Unaudited)

	Three Months Ended	Three Months Ended	Nine months Ended	Nine Months Ended
	<u>September 30,</u>	<u>September 30,</u>	<u>September 30,</u>	<u>September 30,</u>
	<u>2014</u>	<u>2013</u>	<u>2014</u>	<u>2013</u>
<b>Sales</b>	<b>\$ 13,743,778</b>	<b>\$ 13,094,381</b>	<b>\$ 39,740,791</b>	<b>\$ 38,414,919</b>
Cost of Sales	11,473,961	11,461,100	33,772,125	33,815,593
<b>Gross Profit</b>	<b>2,269,817</b>	<b>1,633,281</b>	<b>5,968,666</b>	<b>4,599,326</b>
Selling, General and Administrative	4,098,835	3,386,367	12,403,240	10,541,124
Research and Product Development	1,301,824	10,611,219	6,103,716	33,588,458
<b>Operating Income (Loss)</b>	<b>(3,130,842)</b>	<b>(12,364,305)</b>	<b>(12,538,290)</b>	<b>(39,530,256)</b>
Interest and Investment Income, net	55,263	13,546	199,113	28,784
Interest Expense	892,027	857,505	2,604,333	949,735
Income (Loss) Before Income Taxes	(3,967,606)	(13,208,264)	(14,943,510)	(40,451,207)
Income Tax Expense	--	--	--	--
<b>Net Income (Loss)</b>	<b><u>\$ (3,967,606)</u></b>	<b><u>\$ (13,208,264)</u></b>	<b><u>\$ (14,943,510)</u></b>	<b><u>\$ (40,451,207)</u></b>
<b>Basic Earnings (Loss) per Share</b>	<b>(\$ 0.10)</b>	<b>(\$ 0.34)</b>	<b>(\$ 0.37)</b>	<b>(\$ 1.32)</b>
<b>Diluted Earnings (Loss) per Share</b>	<b>(\$ 0.10)</b>	<b>(\$ 0.34)</b>	<b>(\$ 0.37)</b>	<b>(\$ 1.32)</b>

**ROCKWELL MEDICAL, INC. AND SUBSIDIARY**

**CONSOLIDATED BALANCE SHEETS**

As of September 30, 2014 and December 31, 2013

(Unaudited)

<b>ASSETS</b>	<b>September 30,</b>	<b>December 31,</b>
	<b>2014</b>	<b>2013</b>
Cash and Cash Equivalents	\$ 3,016,837	\$ 11,881,451
Investments Available for Sale	9,017,395	12,034,622
Accounts Receivable, net of a reserve of \$52,000 in 2014 and \$37,000 in 2013	4,189,666	4,578,319
Inventory	2,981,506	2,799,648
Other Current Assets	688,475	623,734
Total Current Assets	19,893,879	31,917,774
Property and Equipment, net	1,615,320	1,648,949
Intangible Assets	374,443	499,715
Goodwill	920,745	920,745
Other Non-current Assets	1,067,800	1,374,941
Total Assets	<u>\$ 23,872,187</u>	<u>\$ 36,362,124</u>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Note Payable Capitalized Lease Obligations	\$ 7,962,819	\$ 2,308,145
Accounts Payable	5,171,391	8,686,153
Accrued Liabilities	3,816,884	6,647,828
Customer Deposits	329,117	207,545
Total Current Liabilities	17,280,211	17,849,671

Long Term Debt	12,051,824	17,916,914
Shareholders' Equity:		
Common Shares, no par value, 41,015,392 and 40,110,661 shares issued and outstanding	164,056,146	154,457,878
Common Share Purchase Warrants, 838,071 and 983,071 warrants issued and outstanding	4,225,669	4,895,811
Accumulated Deficit	(173,734,079)	(158,790,569)
Accumulated Other Comprehensive Income	(7,584)	32,419
Total Shareholders' Equity (Deficit)	(5,459,848)	595,539
Total Liabilities And Shareholders' Equity	<u>\$ 23,872,187</u>	<u>\$ 36,362,124</u>

**ROCKWELL MEDICAL, INC. AND SUBSIDIARY**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

**For the nine months ended September 30, 2014 and September 30, 2013**

(Unaudited)

	<u>2014</u>	<u>2013</u>
Cash Flows From Operating Activities:		
<b>Net (Loss)</b>	<b>\$ (14,943,510)</b>	<b>\$ (40,451,207)</b>
Adjustments To Reconcile Net Loss To Net Cash Used In Operating Activities:		
Depreciation and Amortization	767,386	752,360
Share Based Compensation - Non-employee	--	1,435,344
Share Based Compensation - Employees	6,293,250	4,449,110
Amortization of Debt Issuance Costs	357,140	--
Non-Cash Interest Expense	353,994	426,938
Loss on Disposal of Assets	4,827	15,500
Loss on Sale of Investments, net	1,223	--
Changes in Assets and Liabilities:		
Decrease in Accounts Receivable	388,653	209,521
(Increase) in Inventory	(181,858)	(164,526)
Decrease (Increase) in Other Assets	(317,194)	606,263
(Decrease) in Accounts Payable	(3,514,762)	(7,722,004)
(Decrease) in Other Liabilities	(2,506,918)	(2,079,489)
Changes in Assets and Liabilities	<u>(6,132,079)</u>	<u>(9,150,235)</u>
<b>Cash Used In Operating Activities</b>	<b>(13,297,769)</b>	<b>(42,522,190)</b>
Cash Flows From Investing Activities:		
Purchase of Investments Available for Sale	(2,000,000)	(10,000,611)
Sale of Investments Available for Sale	4,976,000	--
Purchase of Equipment	(613,311)	(496,302)
Proceeds on Sale of Assets	--	6,898
<b>Cash Provided By (Used) In Investing Activities</b>	<b>2,362,689</b>	<b>(10,490,015)</b>
Cash Flows From Financing Activities:		

Cash Flows From Financing Activities:

Proceeds from the Issuance of Common Shares and Purchase Warrants	2,634,876	50,625,357
Proceeds from the Issuance of Notes Payable	--	20,000,000
Debt Issuance Costs	--	(1,109,776)
Payments on Notes Payable and Capital Lease Obligations	<u>(564,410)</u>	<u>(2,280)</u>
<b>Cash Provided By Financing Activities</b>	<b>2,070,466</b>	<b>69,513,301</b>
<b>Increase (Decrease) In Cash</b>	<b>(8,864,614)</b>	<b>16,501,096</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>\$ 3,016,837</u></b>	<b><u>\$ 21,212,826</u></b>

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Source: Rockwell Medical, Inc.

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