



November 5, 2013

## Rockwell Medical Reports Third Quarter 2013 Results

— *Successful Triferic™ Phase 3 Clinical Results Highlight Quarter* —

- *Conference Call 4:15pm Eastern Time* -

WIXOM, Mich., Nov. 5, 2013 (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 financial results for the third quarter of 2013.

### Q3 2013 Highlights

- Sales were \$13.1 million, a 3.2% increase over Q3 2012.
- Gross profit was \$1.6 million, equivalent to Q3 2012.
- R&D expense was \$10.6 million, a reduction of 35% compared to \$16.2 million in Q3 2012.
- Cash and investments of \$31.2 million as of September 30, 2013.

### Drug Development Highlights

- Phase 3 CRUISE-2 clinical study for investigational iron replacement drug Triferic™ met primary and key secondary endpoints, achieved statistical significance and delivered excellent safety results.
- Phase 3 CRUISE-1 and CRUISE-2 clinical studies achieved identical positive efficacy results, demonstrating effective iron delivery to the bone marrow while maintaining hemoglobin.
- Phase 3 CRUISE-1 and CRUISE-2 clinical studies demonstrated clean safety profile with over 100,000 accumulated administrations to date without a single acute safety signal or anaphylactic reaction.
- Triferic™ accepted as brand name for marketing upon FDA approval.
- (4) Triferic™ poster presentations and (1) oral presentation demonstrating clinical study results are accepted for presentation at the American Society of Nephrology (ASN) Annual Meeting, November 7-9, 2013.
- Triferic™ selected to be showcased at the ASN Kidney Week "Innovators Place" which highlights innovative investigational drugs and devices to the nephrology community.

For the quarter, Rockwell reported a loss of (\$13.2) million or (\$0.34) per share compared to (\$17.9) million or (\$0.86) per share in the third quarter of 2012. Non-cash charges for equity compensation were \$1.9 million.

For the nine months ending September 30, 2013, Rockwell's loss was (\$40.5) million or (\$1.32) per share compared to (\$40.3) million or (\$1.99) per share in the first nine months of 2012. Non-cash charges for equity compensation and warrant revaluation expense were \$5.9 million.

"During the third quarter we achieved several major clinical milestones that have the potential to transform Rockwell," stated, Rob Chioini, Founder, Chairman and CEO of Rockwell. "Top line data from our Phase 3 CRUISE-2 study was exceptional, confirming the prior CRUISE-1 results with an identical p-value and exhibiting an excellent safety profile. These exceptional Phase 3 results demonstrate that Triferic™, in place of IV iron, can effectively deliver iron and maintain hemoglobin levels in dialysis patients without increasing their iron stores. Coupled with the ESA sparing data from our PRIME study that showed a significant 35% ESA dose sparing effect, we have confidence that Triferic has tremendous potential to capture considerable market share quickly in the consolidated dialysis provider market upon FDA approval. Data from all three of our successful, large-scale clinical studies will be presented and showcased at the upcoming ASN Meeting, November 7-9, 2013 in Atlanta, GA."

Mr. Chioini further stated, "We look forward to receiving FDA manufacturing approval for Calcitriol, which will enable us to offer the lowest cost active vitamin D injection to dialysis clinics across the U.S., who are actively seeking low-cost drug alternatives. Our operating business is solid and our CitraPure® product line continues to grow rapidly amongst current and new customers, and we fully expect it will become the new standard of care in dialysate. Our five-year supply agreement with DaVita underscores the strength of our core business, providing innovative, cost-reducing products coupled with superior customer and delivery service."

## Conference Call Information

Rockwell Medical will be hosting a conference call to review its third quarter 2013 results on Tuesday, November 5, 2013 at 4:15 pm ET. Investors are encouraged to call a few minutes in advance at (877) 383-7438, or for international callers (678) 894-3975, passcode #93671915 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 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](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>.

The Rockwell Medical Technologies, Inc. logo is available at <http://www.globenewswire.com/newsroom/prs/?pkgid=6773>

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.

**ROCKWELL MEDICAL, INC. AND SUBSIDIARY**

**CONSOLIDATED INCOME STATEMENTS**

**For the three and nine months ended September 30, 2013 and September 30, 2012**

(Unaudited)

	Three Months Ended September 30, 2013	Three Months Ended September 30, 2012	Nine Months Ended September 30, 2013	Nine Months Ended September 30, 2012
<b>Sales</b>	<b>\$13,094,381</b>	<b>\$12,689,339</b>	<b>\$38,414,919</b>	<b>\$36,842,546</b>
Cost of Sales	11,461,100	11,043,412	33,815,593	31,851,344
<b>Gross Profit</b>	<b>1,633,281</b>	<b>1,645,927</b>	<b>4,599,326</b>	<b>4,991,202</b>
Selling, General and Administrative	3,386,367	3,325,411	10,541,124	9,048,474
Research and Product Development	10,611,219	16,238,450	33,588,458	36,520,393
<b>Operating Income (Loss)</b>	<b>(12,364,305)</b>	<b>(17,917,934)</b>	<b>(39,530,256)</b>	<b>(40,577,665)</b>
Interest and Investment Income, net	13,546	42,296	28,784	230,484
Interest Expense	857,505	137	949,735	846
Income (Loss) Before Income Taxes	(13,208,264)	(17,875,775)	(40,451,207)	(40,348,027)
Income Tax Expense	--	--	--	--
<b>Net Income (Loss)</b>	<b><u>\$(13,208,264)</u></b>	<b><u>\$(17,875,775)</u></b>	<b><u>\$(40,451,207)</u></b>	<b><u>\$(40,348,027)</u></b>
<b>Basic Earnings (Loss) per Share</b>	<b>(\$ .34)</b>	<b>(\$ .86)</b>	<b>(\$ 1.32)</b>	<b>(\$ 1.99)</b>
<b>Diluted Earnings (Loss) per Share</b>	<b>(\$ .34)</b>	<b>(\$ .86)</b>	<b>(\$ 1.32)</b>	<b>(\$ 1.99)</b>

**ROCKWELL MEDICAL, INC. AND SUBSIDIARY**

**CONSOLIDATED BALANCE SHEETS**

**As of September 30, 2013 and December 31, 2012**

	September 30, 2013 (Unaudited)	December 31, 2012
<b>ASSETS</b>		
Cash and Cash Equivalents	\$21,212,826	\$4,711,730
Investments Available for Sale	10,004,943	--
Accounts Receivable, net of a reserve of \$32,800 in 2013 and \$26,000 in 2012	4,222,411	4,431,932
Inventory	2,814,165	2,649,639
Other Current Assets	687,367	1,356,131
<b>Total Current Assets</b>	<b>38,941,712</b>	<b>13,149,432</b>
Property and Equipment, net	1,705,258	1,858,442
Intangible Assets	541,472	666,744
Goodwill	920,745	920,745
Other Non-current Assets	1,492,214	429,723
<b>Total Assets</b>	<b><u>\$43,601,401</u></b>	<b><u>\$17,025,086</u></b>

## LIABILITIES AND SHAREHOLDERS' EQUITY

Loan Payable	\$571,355	\$ --
Capitalized Lease Obligations	--	2,280
Accounts Payable	7,111,561	14,833,565
Accrued Liabilities	10,124,949	12,015,978
Customer Deposits	<u>263,825</u>	<u>135,133</u>
Total Current Liabilities	18,071,690	26,986,956
Long Term Debt	19,428,645	--
Shareholders' Equity:		
Common Shares, no par value, 39,997,961 and 21,494,696 shares issued and outstanding	151,396,640	92,866,458
Common Share Purchase Warrants, 1,063,071 and 2,233,240 warrants issued and outstanding	5,158,558	7,178,929
Accumulated Deficit	(150,458,464)	(110,007,257)
Accumulated Other Comprehensive Income	<u>4,332</u>	<u>--</u>
Total Shareholders' Equity (Deficit)	<u>6,101,066</u>	<u>(9,961,870)</u>
Total Liabilities And Shareholders' Equity	<u>\$43,601,401</u>	<u>\$17,025,086</u>

## ROCKWELL MEDICAL, INC. AND SUBSIDIARY CONSOLIDATED STATEMENTS OF CASH FLOWS

For the nine months ended September 30, 2013 and September 30, 2012

(Unaudited)

	<u>2013</u>	<u>2012</u>
Cash Flows From Operating Activities:		
<b>Net (Loss)</b>	<b>\$(40,451,207)</b>	<b>\$(40,348,027)</b>
Adjustments To Reconcile Net Loss To Net Cash Used In Operating Activities:		
Depreciation and Amortization	752,360	828,676
Share Based Compensation — Non-employee	1,435,344	1,309,502
Share Based Compensation- Employees	4,449,110	3,727,224
Non-cash Interest Expense	426,938	--
Loss (Gain) on Disposal of Assets	15,500	26,340
Changes in Assets and Liabilities:		
(Increase) Decrease in Accounts Receivable	209,521	(95,917)
(Increase) in Inventory	(164,526)	(167,940)
Decrease in Other Assets	606,263	1,233,592
Increase (Decrease) in Accounts Payable	(7,722,004)	2,726,145
Increase (Decrease) in Other Liabilities	<u>(2,079,489)</u>	<u>7,184,330</u>
Changes in Assets and Liabilities	<u>(9,150,235)</u>	<u>10,880,210</u>
<b>Cash Provided By (Used In) Operating Activities</b>	<b>(42,522,190)</b>	<b>(23,576,075)</b>
Cash Flows From Investing Activities:		
Purchase of Equipment	(496,302)	(381,400)
Proceeds on Sale of Assets	6,898	1,578
Purchase of Intangible Assets	--	(550,000)

Sale of Investments Available for Sale	--	3,986,750
(Purchase) of Investments Available for Sale	<u>(10,000,611)</u>	<u>(2,000,000)</u>
<b>Cash (Used In) Investing Activities</b>	<b>(10,490,015)</b>	<b>1,056,928</b>
Cash Flows From Financing Activities:		
Proceeds from the Issuance of Common Shares and Purchase Warrants	50,625,357	17,983,844
Proceeds from the Issuance of Notes Payable	20,000,000	--
Debt Issuance Costs	(1,109,776)	--
Payments on Capital Lease Obligations	<u>(2,280)</u>	<u>(5,672)</u>
<b>Cash Provided By Financing Activities</b>	<b>69,513,301</b>	<b>17,978,172</b>
<b>Increase (Decrease) In Cash</b>	<b>16,501,096</b>	<b>(4,540,975)</b>
Cash At Beginning Of Period	<u>4,711,730</u>	<u>5,715,246</u>
<b>Cash At End Of Period</b>	<b><u>\$21,212,826</u></b>	<b><u>\$1,174,271</u></b>

CONTACT: Michael Rice, Investor Relations; 646-597-6979



Source: Rockwell Medical, Inc.

News Provided by Acquire Media