

Rockwell Medical, Inc. Reports Fourth Quarter 2013 Results

Sales Increase; R&D Expense Decreases; Triferic NDA Submission on Track

WIXOM, Mich., Feb. 26, 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 fourth quarter and year ended December 31, 2013.

Q4 2013 Highlights

- Sales were \$14.0 million, a 7.4% increase over Q4 2012.
- Gross profit was \$2.1 million, a 21% increase over Q4 2012.
- R&D expense was \$5.8 million, a 51% decrease compared to \$11.8 million in Q4 2012
- Cash was \$23.9 million as of December 31, 2013.

2013 Highlights

- Sales were \$52.4 million, a 5.1% increase over 2012.
- Gross profit was \$6.7 million, about the same as 2012.
- R&D expense was \$39.4 million, an 18.4% decrease compared to \$48.3 million in 2012.

2013 Drug Development Highlights

- Three, large-scale, long-term clinical studies for investigational iron replacement drug Triferic[®] successfully met primary and key secondary endpoints.
- PRIME clinical marketing study results demonstrated significant 35% ESA reduction overall and 74.4% in hypo-responsive patients.
- CRUISE-1 and CRUISE-2 Phase 3 efficacy studies met primary and key secondary endpoints, achieved statistical significance, and delivered excellent safety results showing no acute safety signal or anaphylactic reaction in over 100,000 doses.
- Triferic[®] accepted as brand name for marketing upon FDA approval.
- Multiple Triferic[®] clinical study abstracts were presented at numerous kidney conferences, including the American Society of Nephrology (ASN) Annual Meeting, November 7-9, 2013.
- Calcitriol (active vitamin D injection) chemistry data submitted to FDA for manufacturing approval.

For the quarter ended December 31, 2013, Rockwell reported a loss of (\$8.3) million or (\$0.21) per share, a 39% reduction compared to (\$13.7) million or (\$0.66) per share in the fourth quarter of 2012.

For the year ended December 31, 2013, Rockwell reported a loss of (\$48.8) million or (\$1.48) per share, a 9.7% reduction compared to (\$54.0) million or (\$2.65) per share in 2012.

"We had a very productive and successful 2013," stated, Robert L. Chioini, Founder, Chairman and CEO of Rockwell. "We completed our Triferic[®] Phase 3 pivotal study program and achieved outstanding clinical efficacy and safety results. We presented our compelling clinical data to the nephrology community via the most prominent conferences, including the PRIME study results showing Triferic reduces ESA a notable 35% overall and 74% among hypo-responders. We achieved all of our clinical milestones in 2013, and we are on track to submit our New Drug Application for Triferic[®] to the FDA shortly. Based upon exceptional clinical results, we believe Triferic[®] has high likelihood of gaining FDA approval and becoming the standard-of-care for iron maintenance therapy for dialysis patients."

Mr. Chioini further stated, "Our sales continue to grow, led by our CitraPure[®] concentrate product line. We anticipate FDA manufacturing approval for Calcitriol will occur shortly and upon commercial launch we expect robust sales. Notably, R&D expense decreased significantly in the fourth quarter and we expect a similar decline quarterly through year-end 2014."

Conference Call Information

Rockwell Medical will be hosting a conference call to review its fourth quarter and 2013 year end results on Wednesday, February 26, 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 #84449204 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 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 twelve months ended December 31, 2013 and December 31, 2012

	Three Months Ended December 31, 2013	Three Months Ended December 31, 2012	Twelve Months Ended December 31, 2013	Twelve Months Ended December 31, 2012
Sales	\$13,964,624	\$12,999,846	\$52,379,543	\$49,842,392
Cost of Sales	11,904,730	11,297,621	45,720,323	43,148,965
Gross Profit	2,059,894	1,702,225	6,659,220	6,693,427
Selling, General and Administrative	3,795,325	3,635,386	14,336,449	12,683,860
Research and Product Development	5,793,579	11,751,256	39,382,037	48,271,649
Operating Income (Loss)	(7,529,010)	(13,684,417)	(47,059,266)	(54,262,082)
Interest and Investment Income, net	69,317	11,034	98,101	241,518
Interest Expense	872,412	105	1,822,147	951
Income (Loss) Before Income Taxes	(8,332,105)	(13,673,488)	(48,783,312)	(54,021,515)
Income Tax Expense	--	--	--	--
Net Income (Loss)	<u>\$(8,332,105)</u>	<u>\$(13,673,488)</u>	<u>\$(48,783,312)</u>	<u>\$(54,021,515)</u>
Basic Earnings (Loss) per Share	(\$.21)	(\$.66)	(\$ 1.48)	(\$ 2.65)
Diluted Earnings (Loss) per Share	(\$.21)	(\$.66)	(\$ 1.48)	(\$ 2.65)

ROCKWELL MEDICAL, INC. AND SUBSIDIARY

CONSOLIDATED BALANCE SHEETS

As of December 31, 2013 and 2012

	December 31, 2013	December 31, 2012
ASSETS		
Cash and Cash Equivalents	\$11,881,451	\$4,711,730
Investments Available for Sale	12,034,622	--
Accounts Receivable, net of a reserve of \$37,000 in 2013 and \$26,000 in 2012	4,578,319	4,431,932
Inventory	2,799,648	2,649,639
Other Current Assets	623,734	1,356,131
Total Current Assets	<u>31,917,774</u>	<u>13,149,432</u>
Property and Equipment, net	1,648,949	1,858,442
Intangible Assets	499,715	666,744
Goodwill	920,745	920,745
Other Non-current Assets	1,374,941	429,723
Total Assets	<u><u>\$36,362,124</u></u>	<u><u>\$17,025,086</u></u>

LIABILITIES AND SHAREHOLDERS' EQUITY

Note Payable Capitalized Lease Obligations	\$2,308,145	\$ --
Capitalized Lease Obligations Capitalized Lease Obligations	--	2,280
Accounts Payable	8,686,153	14,833,565
Accrued Liabilities	6,647,828	12,015,978
Customer Deposits	<u>207,545</u>	<u>135,133</u>
Total Current Liabilities	17,849,671	26,986,956
Long Term Debt	17,916,914	--
Shareholders' Equity:		
Common Shares, no par value, 40,110,661 and 21,494,696 shares issued and outstanding	154,457,878	92,866,458
Common Share Purchase Warrants, 983,071 and 2,233,240 warrants issued and outstanding	4,895,811	7,178,929
Accumulated Deficit	(158,790,569)	(110,007,257)
Accumulated Other Comprehensive Income	<u>32,419</u>	<u>--</u>
Total Shareholders' Equity (Deficit)	<u>595,539</u>	<u>(9,961,870)</u>
Total Liabilities And Shareholders' Equity	<u>\$36,362,124</u>	<u>\$17,025,086</u>

ROCKWELL MEDICAL, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CASH FLOWS

For the years ended December 31, 2013 and 2012

	<u>2013</u>	<u>2012</u>
Cash Flows From Operating Activities:		
Net (Loss)	\$(48,783,312)	\$(54,021,515)
Adjustments To Reconcile Net Loss To Net Cash Used In		
Operating Activities:		
Depreciation and Amortization	1,007,411	1,087,397
Share Based Compensation - Non-employee	1,862,874	2,322,417
Share Based Compensation- Employees	5,849,196	4,979,724
Loss (Gain) on Disposal of Assets	16,410	17,876
Loss on Sale of Investments Available for Sale	--	67,303
Amortization of Debt Issuance Costs	227,059	--
Non-Cash Interest Expense	225,059	--
Changes in Assets and Liabilities:		
(Increase) Decrease in Accounts Receivable	(146,387)	(209,116)
(Increase) Decrease in Inventory	(150,009)	(145,512)
(Increase) Decrease in Other Assets	669,896	1,855,787
Increase (Decrease) in Accounts Payable	(6,147,412)	9,469,028
Increase (Decrease) in Other Liabilities	<u>(5,295,738)</u>	<u>3,829,767</u>
Changes in Assets and Liabilities	<u>(11,069,650)</u>	<u>14,799,954</u>
Cash (Used In) Operating Activities	(50,664,953)	(30,746,844)

Cash Flows From Investing Activities:

Purchase of Investments Available for Sale	(12,002,203)	(2,012,671)
Sale of Investments Available for Sale	--	14,037,255
Purchase of Equipment	(654,197)	(507,788)
Proceeds on Sale of Assets	6,898	1,578
Purchase of Intangible Assets	<u>--</u>	<u>--</u>
Cash Provided By (Used In) Investing Activities	(12,649,502)	11,518,374

Cash Flows From Financing Activities:

Proceeds from Issuance of Common Shares and Purchase Warrants	51,596,232	18,231,424
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>(2,280)</u>	<u>(6,470)</u>
Cash Provided By Financing Activities	70,484,176	18,224,954

Increase (Decrease) In Cash	7,169,721	(1,003,516)
Cash At Beginning Of Period	<u>4,711,730</u>	<u>5,715,246</u>
Cash At End Of Period	<u>\$11,881,451</u>	<u>\$4,711,730</u>

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Investor Relations

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Source: Rockwell Medical, Inc.

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