

Rockwell Medical Reports Third Quarter 2015 Results

WIXOM, Mich., Nov. 9, 2015 (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 of 2015.

Q3 2015 Financial Highlights

- Sales were \$14.4 million, \$0.6 million or 4.6% higher than the third quarter of 2014.
- Gross profit was \$2.5 million, a 10.3% increase over Q3 2014.
- Gross profit margins increased to 17.4% compared to 16.5% in Q3 2014.
- SG&A expense was \$3.8 million, a decrease of \$0.3 million compared to Q3 2014.
- R&D expense was \$1.2 million compared to \$1.3 million in Q3 2014.
- Net loss was (\$2.4) million or (\$0.05) per share, compared to a net loss of (\$4.0) million or (\$0.10) per share in Q3 2014.
- Cash and investments were \$73.0 million as of September 30, 2015.

YTD 2015 Financial Highlights

- Sales in the first nine months of 2015 were \$41.2 million compared to \$39.7 million in the same period of 2014.
- Gross profit was \$6.9 million, a 15.3% increase over the first nine months of 2014.
- Gross profit margins increased to 16.7% compared to 15.0% in the first nine months of 2014.
- SG&A expense was \$13.0 million, an increase of \$0.6 million or 4.7% over the first nine months of 2014.
- R&D expense was \$2.9 million compared to \$6.1 million in the first nine months of 2014.
- Net loss was (\$8.7) million or (\$0.17) per share, compared to a net loss of (\$14.9) million or (\$0.37) per share in the first nine months of 2014.

2015 YTD Corporate Highlights

- Commenced U.S. commercial launch of Triferic[®] September 2015.
- Commenced marketing and advertising activity, including introduction of Triferic website (www.triferic.com) for commercial drug launch.
- Increased product inventory to support commercial launch.
- Successful PRIME ESA Sparing Clinical Study published in Kidney International.
- Successful CRUISE 1-2 Phase 3 Clinical Studies published in Nephrology Dialysis Transplantation.
- Triferic clinical data accepted and presented at multiple U.S. and international conferences.
 - National Kidney Foundation Spring Meeting
 - Annual Dialysis Conference
 - ERA-EDTA Congress in Europe
 - ASN Kidney Week Annual Meeting
- Received U.S. CMS Q-Code assignment for reimbursement of Triferic; effective July 1, 2015.
- Obtained U.S. FDA drug approval to market Triferic (ferric pyrophosphate citrate), the only iron replacement and hemoglobin maintenance product for hemodialysis patients.

"We had a very positive and productive third quarter," stated Robert L. Chioini, Chairman and CEO of Rockwell. "We experienced solid concentrate sales and results, and most importantly we commenced U.S. commercial launch of Triferic, our innovative iron replacement and hemoglobin maintenance drug to treat anemia in hemodialysis patients. The clinical community has responded favorably to Triferic and its unique mechanism of action, which enables iron to bind immediately to transferrin and bypass the current iron sequestration and RE block that occurs with IV iron products. The drug's ability to deliver iron at every patient treatment and maintain hemoglobin concentration without increasing iron stores has received strong interest across the spectrum of dialysis providers, from large-to-small. We anticipate broad clinical adoption over the next several months of this first-in-class iron maintenance therapy for ESRD patients."

Conference Call Information

Rockwell Medical will be hosting a conference call to review its third quarter 2015 results on Monday, November 9, 2015 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 # 57785567 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 replacement product that is delivered to hemodialysis patients via dialysate, replacing the ongoing iron loss that occurs during their dialysis treatment. Triferic is added to the bicarbonate concentrate on-site at the dialysis clinic. Once in dialysate, Triferic crosses the dialyzer membrane and enters the blood where it immediately binds to transferrin and is transported to the erythroid precursor cells to be incorporated into hemoglobin. In completed clinical trials, Triferic has demonstrated that it can effectively deliver sufficient iron to the bone marrow and maintain hemoglobin, without increasing iron stores (ferritin). Please visit www.triferic.com or call Rockwell Medical at 800-449-3353 for more information.

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 recent FDA approved drug Triferic is indicated for iron replacement and maintenance of hemoglobin in hemodialysis patients. Triferic delivers iron to patients during their regular dialysis treatment, using dialysate as the delivery mechanism. In completed clinical trials, Triferic has demonstrated that it safely and effectively delivers sufficient iron to the bone marrow and maintains hemoglobin, without increasing iron stores (ferritin). Rockwell intends to market Triferic to hemodialysis patients in the U.S. dialysis market.

Rockwell's FDA approved generic drug Calcitriol is for treating 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 for more information.

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 registered trademark of Rockwell Medical, Inc.

ROCKWELL MEDICAL, INC. AND SUBSIDIARY

CONSOLIDATED INCOME STATEMENTS

For the three and nine months ended September 30, 2015 and June 30, 2014

(Unaudited)

Three Months Ended	Three Months Ended	Nine Months Ended	Nine Months Ended
<u>September 30, 2015</u>	<u>September 30, 2014</u>	<u>September 30, 2015</u>	<u>September 30, 2014</u>

Sales	\$14,378,528	\$13,743,778	\$41,218,065	\$39,740,791
Cost of Sales	11,875,122	11,473,961	34,336,359	33,772,125
Gross Profit	2,503,406	2,269,817	6,881,706	5,968,666
Selling, General and Administrative	3,827,904	4,098,835	12,989,261	12,403,240
Research and Product Development	1,246,727	1,301,824	2,931,577	6,103,716
Operating Income (Loss)	(2,571,225)	(3,130,842)	(9,039,132)	(12,538,290)
Interest and Investment Income, net	156,672	55,263	388,638	199,113
Interest Expense	--	892,027	--	2,604,333
Income (Loss) Before Income Taxes	(2,414,553)	(3,967,606)	(8,650,494)	(14,943,510)
Income Tax Expense	--	--	--	--
Net Income (Loss)	\$(2,414,553)	\$(3,967,606)	\$(8,650,494)	\$(14,943,510)
Basic Earnings (Loss) per Share	(\$0.05)	(\$0.10)	(\$0.17)	(\$0.37)

ROCKWELL MEDICAL, INC. AND SUBSIDIARY

CONSOLIDATED BALANCE SHEETS

As of September 30, 2015 and December 31, 2014

(Unaudited)

	September 30, December 31,	
	2015	2014
ASSETS		
Cash and Cash Equivalents	\$33,172,740	\$65,800,451
Investments Available for Sale	39,818,118	19,927,310
Accounts Receivable, net of a reserve of \$88,000 in 2015 and \$52,000 in 2014	5,896,487	4,472,002
Inventory	7,415,281	3,920,185
Other Current Assets	1,601,211	587,201
Total Current Assets	87,903,837	94,707,149
Property and Equipment, net	1,341,795	1,496,912
Intangible Assets	207,415	332,686
Goodwill	920,745	920,745
Other Non-current Assets	542,223	542,224
Total Assets	\$90,916,015	\$97,999,716
LIABILITIES AND SHAREHOLDERS' EQUITY		
Accounts Payable	\$5,223,394	\$5,294,515
Accrued Liabilities	2,937,245	4,325,997
Customer Deposits	313,082	183,890
Total Current Liabilities	8,473,721	9,804,402
Deferred License Revenue	18,012,839	19,492,520
Shareholders' Equity:		
Common Shares, no par value, 50,227,877 and 50,284,007 shares issued and outstanding	253,777,785	249,018,189
Accumulated Deficit	(188,768,220)	(180,117,726)

Accumulated Other Comprehensive Income (Loss)	<u>(580,110)</u>	<u>(197,669)</u>
Total Shareholders' Equity	<u>64,429,455</u>	<u>68,702,794</u>
Total Liabilities And Shareholders' Equity	<u>\$90,916,015</u>	<u>\$97,999,716</u>

ROCKWELL MEDICAL, INC. AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CASH FLOWS

For the nine months ended September 30, 2015 and September 30, 2014

(Unaudited)

	<u>2015</u>	<u>2014</u>
Cash Flows From Operating Activities:		
Net (Loss)	\$(8,650,494)	\$(14,943,510)
Adjustments To Reconcile Net Loss To Net Cash Used In Operating Activities:		
Depreciation and Amortization	608,152	767,386
Share Based Compensation- Employees	6,097,122	6,293,250
Restricted Stock Tendered in Satisfaction of Tax Liabilities	(2,912,859)	--
Amortization of Debt Issuance Costs	--	357,140
Non-Cash Interest Expense	--	353,994
Loss on Disposal of Assets	4,292	4,827
Loss on Sale of Investments, net	58,095	1,223
Changes in Assets and Liabilities:		
(Increase) Decrease in Accounts Receivable	(1,424,485)	388,653
(Increase) in Inventory	(3,495,096)	(181,858)
(Increase) in Other Assets	(1,014,009)	(317,194)
(Decrease) in Accounts Payable	(71,121)	(3,514,762)
(Decrease) in Other Liabilities	(1,259,560)	(2,506,918)
Deferred License Revenue	<u>(1,479,681)</u>	<u>--</u>
Changes in Assets and Liabilities	<u>(8,743,952)</u>	<u>(6,132,079)</u>
Cash Used In Operating Activities	(13,539,644)	(13,297,769)
Cash Flows From Investing Activities:		
Purchase of Investments Available for Sale	(21,800,000)	(2,000,000)
Sale of Investments Available for Sale	1,468,656	4,976,000
Purchase of Equipment	(336,856)	(613,311)
Proceeds from Sale of Assets	<u>4,800</u>	<u>--</u>
Cash Provided By (Used In) Investing Activities	(20,663,400)	2,362,689
Cash Flows From Financing Activities:		
Payments on Notes Payable and Capital Lease Obligations	--	(564,410)
Proceeds from the Issuance of Common Shares and Purchase Warrants	<u>1,575,333</u>	<u>2,634,876</u>
Cash Provided By Financing Activities	1,575,333	2,070,466

Increase (Decrease) In Cash	(32,627,711)	(8,864,614)
Cash At Beginning Of Period	<u>65,800,451</u>	<u>11,881,451</u>
Cash At End Of Period	<u>\$33,172,740</u>	<u>\$3,016,837</u>

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Source: Rockwell Medical, Inc.

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