

ROCKWELL MEDICAL, INC.

FORM 8-K (Current report filing)

Filed 11/07/16 for the Period Ending 11/07/16

Address	30142 S WIXOM RD WIXOM, MI 48393
Telephone	2489609009
CIK	0001041024
Symbol	RMTI
SIC Code	3845 - Electromedical and Electrotherapeutic Apparatus
Industry	Pharmaceuticals
Sector	Healthcare
Fiscal Year	12/31

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event Reported): November 7, 2016

Rockwell Medical, Inc.

(Exact Name of Registrant as Specified in Charter)

MICHIGAN
(State or Other Jurisdiction of
Incorporation)

000-23661
(Commission File Number)

38-3317208
(I.R.S. Employer Identification Number)

30142 Wixom Road, Wixom, Michigan 48393
(Address of Principal Executive Offices) (Zip Code)

(248) 960-9009
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
-
-

Item 2.02. Results of Operations and Financial Condition.

On November 7, 2016, the Company issued the press release attached hereto as Exhibit 99.1, announcing its financial results for the quarter and nine months ended September 30, 2016.

Item 9.01. Financial Statements and Exhibits.

The following exhibit is furnished with this Form 8-K:

<u>Exhibit</u>	<u>Description</u>
99.1	Press Release dated November 7, 2016.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Rockwell Medical, Inc.

Date: November 7, 2016

By: /s/ Thomas E. Klema
Thomas E. Klema
Its: Chief Financial Officer

EXHIBIT INDEX

<u>Exhibit</u>	<u>Description</u>
99.1	Press Release dated November 7, 2016

Rockwell Medical Reports Third Quarter Results

WIXOM, Mich., Nov. 07, 2016 (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 2016.

Q3 2016 Financial Highlights

- Sales were \$12.8 million, or \$1.6 million lower than Q3 2015, primarily due to lower contract manufacturing sales.
- Gross profit was \$1.6 million compared to \$2.5 million in Q3 2015, due to lower contract manufacturing revenue and due to an increase in manufacturing and costs related to our drug products.
- SG&A expense was \$5.1 million compared \$3.8 million in Q3 2015.
- R&D expense was \$1.3 million and at the same level as in Q3 2015.
- Net loss was \$4.5 million or (\$0.09) per share compared to a \$2.4 million loss or (\$0.05) per share in Q3 2015.
- Net loss in Q3 was lower sequentially by \$0.8 million compared to Q2 2016 due to lower R&D expenses.
- Cash and investments were \$57.7 million as of September 30, 2016.
- Net working capital was \$72.5 million as of September 30, 2016.

YTD 2016 Financial Highlights

- Sales were \$39.9 million, compared to \$41.2 million in the first nine months of 2015.
- Gross profit was \$4.8 million compared to \$6.9 million in the first nine months of 2015.
- Gross profit was impacted by higher drug manufacturing costs, a value add tax paid on the \$4.0 million payment received from Wanbang Biopharma and lower third party contract manufacturing revenue.
- SG&A expense was \$15.1 million compared \$13.0 million in the first nine months of 2015.
- R&D expense was \$4.6 million compared to \$2.9 million in the first nine months of 2015.
- Net loss was \$14.7 million or (\$0.29) per share versus \$8.7 million or (\$0.17) per share in 2015.

YTD Corporate Highlights

- Triferic Phase-1 Healthy Volunteer Intravenous (IV) Pharmacokinetic Study published in the September 2016 edition of the Journal of Clinical Pharmacology.
- Entered into license agreement with ARAM Medical to market Triferic in Saudi Arabia and other middle eastern countries.
- Received FDA approval to market Triferic powder packet.
- Partnered with Wanbang Biopharma to commercialize Triferic and Calcitriol in the People's Republic of China, receiving up to \$39 million in milestone payments and ongoing profit on commercial product sales in China.

Mr. Robert L. Chioini, Chairman and Chief Executive Officer of Rockwell stated, "We continue to make solid progress in our efforts to obtain transitional add-on reimbursement for Triferic. We believe we are moving closer to our goal of securing it. Multiple stakeholders have aided us and support add-on reimbursement for Triferic. Concurrently, we have been educating our customers and patients about Triferic and its unique benefits. We also have advanced Triferic clinical development work for the renal application outside the U.S. as well as additional therapeutic indications. Overall, we are pleased with our progress, which includes ensuring we have redundancy in our manufacturing and supply capability."

Conference Call Information

Rockwell Medical will be hosting a conference call to review its second quarter 2016 results on Monday, November 7, 2016 at 4:30 pm ET. Investors are encouraged to call a few minutes in advance at (877)-857-6150, or for international callers (719)325-4825, passcode # 8926063 or to listen to the call via webcast at the Rockwell Medical IR web page: <http://ir.rockwellmed.com/>

About Triferic

Triferic is the only FDA approved drug indicated to replace iron and maintain hemoglobin in hemodialysis patients suffering from anemia. Via dialysate during each dialysis treatment, Triferic replaces the 5-7 mg iron loss that occurs in all patients, effectively maintaining their iron balance. Unlike IV iron products, Triferic binds iron immediately and completely to transferrin (carrier of iron in the body) upon entering the blood and it is then transported directly to the bone marrow to be incorporated into hemoglobin, with no increase in ferritin (stored iron and inflammation) and no anaphylaxis, addressing a significant unmet need in overcoming Functional Iron Deficiency (FID) in ESRD patients. Please visit www.triferic.com to view the Triferic mode-of-action (MOA) video and 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. 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 and globally.

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 U.S. manufacturing/distribution facilities.

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 sell and market Calcitriol and Triferic. 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 SUBSIDIARIES
CONSOLIDATED INCOME STATEMENTS

For the three and nine months ended September 30, 2016 and September 30, 2015
(Unaudited)

	Three Months Ended September 30, 2016	Three Months Ended September 30, 2015	Nine Months Ended September 30, 2016	Nine Months Ended September 30, 2015
Sales	\$ 12,814,815	\$ 14,378,528	\$ 39,894,380	\$ 41,218,065
Rebates	—	—	—	—
Cost of Sales	11,234,934	11,875,122	35,130,045	34,336,359
Gross Profit	1,579,881	2,503,406	4,764,335	6,881,706
Selling, General and Administrative	5,070,127	3,827,904	15,071,238	12,989,261
Research and Product Development	1,261,863	1,246,727	4,639,617	2,931,577
Operating Income (Loss)	(4,752,109)	(2,571,225)	(14,946,520)	(9,039,132)
Interest and Investment Income	188,847	156,672	602,429	388,638
Interest (Expense)	—	—	—	—
Income (Loss) Before Income Taxes	(4,563,262)	(2,414,553)	(14,344,091)	(8,650,494)
Income Tax Expense	—	—	(404,527)	—
Net Income (Loss)	<u>\$ (4,563,262)</u>	<u>\$ (2,414,553)</u>	<u>\$ (14,748,618)</u>	<u>\$ (8,650,494)</u>
Basic Earnings (Loss) per Share	\$ (0.09)	\$ (0.05)	\$ (0.29)	\$ (0.17)
Diluted Earnings (Loss) per Share	\$ (0.09)	\$ (0.05)	\$ (0.29)	\$ (0.17)

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

As of September 30, 2016 and December 31, 2015
(Unaudited)

	September 30, 2016	December 31, 2015
ASSETS		
Cash and Cash Equivalents	\$ 19,293,454	\$ 31,198,182
Investments Available for Sale	38,434,312	39,482,732
Accounts Receivable, net of a reserve of \$39,000 in 2016 and \$75,000 in 2015	8,031,196	5,046,733
Inventory	11,760,269	7,871,780

Other Current Assets	2,264,583	1,026,889
Total Current Assets	79,783,814	84,626,316
Property and Equipment, net	1,506,155	1,646,568
Intangible Assets	42,555	165,657
Goodwill	920,745	920,745
Other Non-current Assets	601,187	462,839
Total Assets	<u>\$ 82,854,456</u>	<u>\$ 87,822,125</u>
LIABILITIES AND SHAREHOLDERS' EQUITY		
Accounts Payable	\$ 3,396,789	\$ 3,995,216
Accrued Liabilities	3,825,374	3,831,356
Customer Deposits	91,005	264,879
Total Current Liabilities	7,313,168	8,091,451
Deferred License Revenue	19,783,978	17,410,852
Shareholders' Equity:		
Common Shares, no par value, 51,527,711 and 51,501,877 shares issued and outstanding	265,648,345	257,773,494
Accumulated Deficit	(209,286,794)	(194,538,176)
Accumulated Other Comprehensive Income	(604,241)	(915,496)
Total Shareholders' Equity	55,757,310	62,319,822
Total Liabilities And Shareholders' Equity	<u>\$ 82,854,456</u>	<u>\$ 87,822,125</u>

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
For the nine months ended September 30, 2016 and September 30, 2015
(Unaudited)

	<u>2016</u>	<u>2015</u>
Cash Flows From Operating Activities:		
Net (Loss)	\$ (14,748,618)	\$ (8,650,494)
Adjustments To Reconcile Net Loss To Net Cash Used In Operating Activities:		
Depreciation and Amortization	583,501	608,152
Share Based Compensation—Employees	7,794,690	6,097,122
Restricted Stock Retained in Satisfaction of Tax Liabilities	—	(2,912,859)
Loss on Disposal of Assets	7,340	4,292
Loss on Sale of Investments Available for Sale	26,820	58,095
Changes in Assets and Liabilities:		
(Increase) in Accounts Receivable	(2,984,463)	(1,424,485)
(Increase) in Inventory	(3,888,489)	(3,495,096)
(Increase) in Other Assets	(1,376,042)	(1,014,009)
(Decrease) in Accounts Payable	(598,427)	(71,121)
(Decrease) in Other Liabilities	(179,856)	(1,259,560)
Increase (decrease) in Deferred License Revenue	2,373,126	(1,479,681)
Changes in Assets and Liabilities	(6,654,151)	(8,743,952)
Cash (Used) In Provided By Operating Activities	(12,990,418)	(13,539,644)
Cash Flows From Investing Activities:		
Purchase of Investments Available for Sale	(23,158,809)	(21,800,000)
Sale of Investments Available for Sale	24,491,678	1,468,656
Purchase of Equipment	(328,322)	(336,856)
Proceeds on Sale of Assets	1,000	4,800
Cash (Used In) Investing Activities	1,005,547	(20,663,400)
Cash Flows From Financing Activities:		
Proceeds from Issuance of Common Shares and Purchase Warrants	80,161	1,575,333

Cash Provided By Financing Activities	80,161	1,575,333
Effects of exchange rate changes	(18)	—
(Decrease) Increase In Cash	(11,904,728)	(32,627,711)
Cash At Beginning Of Period	31,198,182	65,800,451
Cash At End Of Period	<u>\$ 19,293,454</u>	<u>\$ 33,172,740</u>

Michael Rice,
Investor Relations;
646-597-6979