

ROCKWELL MEDICAL, INC.

FORM 8-K (Current report filing)

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Address	30142 S WIXOM RD WIXOM, MI 48393
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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): March 15, 2017

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))
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Item 2.02. Results of Operations and Financial Condition.

On March 15, 2017, the Company issued the press release attached hereto as Exhibit 99.1, announcing its financial results for the quarter and year ended December 31, 2016.

Item 9.01. Financial Statements and Exhibits.

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

Exhibit **Description**

99.1 Press Release dated March 15, 2017.

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: March 15, 2017

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

EXHIBIT INDEX

Exhibit **Description**

[99.1](#) Press Release dated March 15, 2017.

Rockwell Medical Reports Fourth Quarter Results

WIXOM, Mich., March 15, 2017 (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 quarter and year ending December 31, 2016.

Q4 2016 Financial Highlights

- Sales were \$13.4 million, or \$0.7 million lower than Q4 2015, primarily due to lower domestic and lower contract manufacturing concentrate sales.
- Gross profit was \$2.0 million compared to \$2.1 million in Q4 2015.
- SG&A expense was \$6.0 million compared \$6.1 million in Q4 2015.
- R&D expense was \$1.2 million compared to \$2.0 million in Q4 2015.
- Net loss was \$5.1 million or (\$0.10) per share compared to a \$5.8 million loss or (\$0.12) per share in Q4 2015. Net loss was \$0.7 million less year over year primarily due to lower R&D expense of \$0.8 million.
- Cash and investments were \$57.9 million as of December 31, 2016.
- Net working capital was \$68.4 million as of December 31, 2016.

2016 Financial Highlights

- Sales were \$53.3 million compared to \$55.4 million in 2015, primarily due to lower contract manufacturing sales and lower international concentrate sales.
- Gross profit was \$6.8 million compared to \$8.9 million in 2015. Gross profit was impacted by increased drug product costs of \$1.5 million, lower third party contract manufacturing revenue and a \$0.2 million value add tax paid on the \$4.0 million received from Wanbang Biopharma.
- SG&A expense was \$21.1 million compared \$19.1 million in 2015.
- R&D expense was \$5.8 million compared to \$5.0 million in 2015.
- Net loss was \$19.8 million or (\$0.39) per share versus \$14.4 million or (\$0.29) per share in 2015.
- Cash used in operating activities in 2016 was \$12.5 million of which R&D related expense was \$5.8 million and investment in Triferic inventory was \$6.1 million.

2016 Corporate Highlights

- Made significant progress to secure transitional add-on reimbursement for Triferic.
- Formed wholly owned subsidiary in India to initiate commercialization activities of Triferic in India.
- Secured partnership in Canada for distribution of Triferic.
- Advanced clinical development with several new indications for Triferic, including peritoneal dialysis, total parenteral nutrition and orphan indication IRIDA.
- Triferic Phase-1 Healthy Volunteer Intravenous (IV) Pharmacokinetic Study published in the September 2016 edition of the Journal of Clinical Pharmacology.
- Received FDA approval to market Triferic powder packet.
- Built redundancy into Triferic product supply chain to manage anticipated customer demand.
- Entered into license agreement with ARAM Medical to market Triferic in Saudi Arabia, Egypt and Middle Eastern countries.
- 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 are pleased and excited with our progress to obtain transitional add-on reimbursement for Triferic. Our effort and movement on the add-on reimbursement front has been very strong and we feel we are closer to our goal of securing it. We continue to garner support from key stakeholders for add-on reimbursement for Triferic. We are also very pleased with the response, and the positive clinical findings being reported from dialysis providers using Triferic through our drug sample program. Our marketing and education efforts on Triferic have been well received and continue to be very effective.” Mr. Chioini also stated, “We have advanced our clinical development work for Triferic in both the China and India markets, while implementing the necessary clinical steps to advance the use of Triferic in the Peritoneal dialysis, Total Parenteral Nutrition and Cancer markets.”

Conference Call Information

Rockwell Medical will be hosting a conference call to review its fourth quarter and year end 2016 results on Wednesday, March 15, 2017 at 4:30 pm ET. Investors are encouraged to call a few minutes in advance at (888) 438-5453, or for international callers (719) 457-2637, passcode # 8360933 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 twelve months ended December 31, 2016 and December 30, 2015

	Three Months Ended December 31, 2016	Three Months Ended December 31, 2015	2016	2015
Sales	\$ 13,389,786	\$ 14,132,637	\$ 53,284,166	\$ 55,350,702
Cost of Sales	11,401,603	12,076,489	46,531,648	46,412,848
Gross Profit	1,988,183	2,056,148	6,752,518	8,937,854
Selling, General and Administrative	6,049,663	6,089,606	21,120,901	19,078,867
Research and Product Development	1,200,729	2,029,736	5,840,346	4,961,313
Operating Income (Loss)	(5,262,209)	(6,063,194)	(20,208,729)	(15,102,326)
Interest and Investment Income	207,911	293,238	810,340	681,876
Interest (Expense)	—	—	—	—
Income (Loss) Before Income Taxes	(5,054,298)	(5,769,956)	(19,398,389)	(14,420,450)
Income Tax Expense	—	—	(404,527)	—
Net Income (Loss)	<u>\$ (5,054,298)</u>	<u>\$ (5,769,956)</u>	<u>\$ (19,802,916)</u>	<u>\$ (14,420,450)</u>
Basic Earnings (Loss) per Share	\$ (0.10)	\$ (0.12)	\$ (0.39)	\$ (0.29)
Diluted Earnings (Loss) per Share	\$ (0.10)	\$ (0.12)	\$ (0.39)	\$ (0.29)

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

As of December 31, 2016 and December 31, 2015

	December 31, 2016	December 31, 2015
ASSETS		

Cash and Cash Equivalents	\$ 17,180,594	\$ 31,198,182
Investments Available for Sale	40,759,703	39,482,732
Accounts Receivable, net of a reserve of \$5,000 in 2016 and \$75,000 in 2015	6,393,228	5,046,733
Inventory	12,141,072	7,871,780
Other Current Assets	2,034,598	1,026,889
Total Current Assets	78,509,195	84,626,316
Property and Equipment, net	1,391,575	1,646,568
Inventory, Non-Current	1,826,554	—
Intangible Assets	4,382	165,657
Goodwill	920,745	920,745
Other Non-current Assets	501,187	462,839
Total Assets	<u>\$ 83,153,638</u>	<u>\$ 87,822,125</u>
LIABILITIES AND SHAREHOLDERS' EQUITY		
Accounts Payable	\$ 5,858,234	\$ 3,995,216
Accrued Liabilities	4,210,151	3,831,356
Customer Deposits	77,217	264,879
Total Current Liabilities	10,145,602	8,091,451
Deferred License Revenue	20,051,737	17,410,852
Shareholders' Equity:		
Common Shares, no par value, 51,527,711 and 51,501,877 shares issued and outstanding	268,199,939	257,773,494
Accumulated Deficit	(214,341,092)	(194,538,176)
Accumulated Other Comprehensive Income	(902,548)	(915,496)
Total Shareholders' Equity	52,956,299	62,319,822
Total Liabilities And Shareholders' Equity	<u>\$ 83,153,638</u>	<u>\$ 87,822,125</u>

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

For the years ended December 31, 2016 and December 31, 2015

	<u>2016</u>	<u>2015</u>
Cash Flows From Operating Activities:		
Net (Loss)	\$ (19,802,916)	\$ (14,420,450)
Adjustments To Reconcile Net Loss To Net Cash Used In Operating Activities:		
Depreciation and Amortization	762,368	822,294
Share Based Compensation—Employees	10,346,284	8,887,977
Restricted Stock Retained in Satisfaction of Tax Liabilities	—	(2,912,859)
Loss on Disposal of Assets	8,168	5,281
Loss on Sale of Investments Available for Sale	26,820	58,095
Changes in Assets and Liabilities:		
(Increase) in Accounts Receivable	(1,162,469)	(574,731)
(Increase) in Inventory	(6,095,846)	(3,951,595)
(Increase) in Other Assets	(1,230,084)	(360,303)
(Decrease) in Accounts Payable	1,863,018	(1,299,299)
(Decrease) in Other Liabilities	191,134	(413,652)
Increase (decrease) in Deferred License Revenue	(2,065,785)	(2,081,668)
Increase (decrease) in Deferred Drug License Revenue	4,706,670	—
Changes in Assets and Liabilities	<u>(3,793,362)</u>	<u>(8,681,248)</u>
Cash (Used) In Provided By Operating Activities	(12,452,638)	(16,240,910)
Cash Flows From Investing Activities:		

Purchase of Investments Available for Sale	(25,781,853)	(21,800,000)
Sale of Investments Available for Sale	24,491,677	1,468,656
Purchase of Equipment	(355,264)	(815,002)
Proceeds on Sale of Assets	1,000	4,800
Cash (Used In) Investing Activities	(1,644,440)	(21,141,546)
Cash Flows From Financing Activities:		
Proceeds from Issuance of Common Shares and Purchase Warrants	80,161	2,780,187
Cash Provided By Financing Activities	80,161	2,780,187
Effects of exchange rate changes	(671)	—
(Decrease) Increase In Cash	(14,017,588)	(34,602,269)
Cash At Beginning Of Period	31,198,182	65,800,451
Cash At End Of Period	\$ 17,180,594	\$ 31,198,182

Michael Rice,
Investor Relations;
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