ROCKWELL MEDICAL, INC.

FORM 8-K
(Current report filing)

Filed 05/10/17 for the Period Ending 05/09/17

Address	30142 S WIXOM RD
	WIXOM, MI 48393
Telephone	2489609009
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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): May 9, 2017

Rockwell Medical, Inc.

(Exact Name of Registrant as Specified in Charter)

Michigan	**000-23661**	**38-3317208**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2). Emerging growth company [ ]

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. [ ]

Item 2.02. Results of Operations and Financial Condition.

On May 9, 2017, the Company issued the press release attached hereto as Exhibit 99.1, announcing its financial results for the quarter ended March 31, 2017.

Item 9.01. Financial Statements and Exhibits.

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

Exhibit	Description
99.1	Press Release dated May 9, 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: May 9, 2017

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

EXHIBIT INDEX

Exhibit	Description
99.1	Press Release dated May 9, 2017.

Exhibit 99.1

Rockwell Medical Reports First Quarter Results

WIXOM, Mich., May 09, 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 for the treatment of iron replacement, secondary hyperparathyroidism and hemodialysis, reported results for the quarter ended March 31, 2017.

Q1 2017 Financial Highlights

- Sales were $14.6 million, or $1.0 million higher than Q1 2016, primarily due to higher domestic sales.
- Sequentially, sales increased approximately 9% over the fourth quarter 2016.
- Gross profit increased to $2.4 million compared to $1.7 million in Q1 2016.
- SG&A expense was $6.1 million compared $5.0 million in Q1 2016.
- R&D expense was $1.2 million compared to $1.3 million in Q1 2016.
- Net loss was $4.7 million or ($0.09) per share compared to a $4.8 million loss or ($0.10) per share in Q1 2016.
- Cash and investments were $52.7 million as of March 31, 2017.
- Net working capital was $64.4 million as of March 31, 2017.

2017 Corporate Highlights

- Nominated pharmaceutical executive David T. Domzalski to the Board of Directors to strengthen the Board, contribute to the Company's growth and development and facilitate shareholder value.
- Received allowance for a Triferic ESA sparing patent in China with claims also covering composition and use.
- Triferic presentations featured at the National Kidney Foundation (NKF) 2017 Spring Clinical Meetings in Orlando, Florida covering Triferic in peritoneal dialysis and pharmacokinetic studies of Triferic in support of other indications.
- Presented data on Triferic intravenous (IV) administration at the 19th International Conference on Dialysis.
- Selected to present Triferic (ferric pyrophosphate citrate) as an innovative, unique mode-of-action therapy at the 7th International Congress of the International BioIron Society (IBIS) in Los Angeles, at UCLA.

Mr. Robert L. Chioini, chairman and chief executive officer of Rockwell stated, "We continue to be pleased with the progress we are making in our commercialization efforts for both Triferic and Calcitriol. With regards to gaining add-on reimbursement for Triferic, we are working with all key stakeholders and we feel strongly that our efforts will result in Triferic receiving this proper designation. Feedback reported from our Triferic drug sample program continues to be favorable and impressive relating to improving patient outcomes and lowering cost. Calcitriol manufacture is progressing nicely. Lab tests are meeting product specification and we remain on track with our FDA submission."

Conference Call Information
Rockwell Medical will be hosting a conference call to review its first quarter 2017 results on Tuesday, May 9, 2017 at 4:30 p.m. EDT. Investors are encouraged to call a few minutes in advance at (888) 203-7667, or for international callers (719) 457-2617, passcode #5087785 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 ended March 31, 2017 and March 31, 2016

(Unaudited)

	Three Months Ended March 31, 2017	Three Months Ended March 31, 2016
Sales	$ 14,592,254	$ 13,627,048
Cost of Sales	12,234,782	11,932,122
Gross Profit	2,357,472	1,694,926
Selling, General and Administrative	6,100,715	4,986,741
Research and Product Development	1,214,851	1,314,430
Operating Income (Loss)	(4,958,094)	(4,606,245)
Interest and Investment Income	216,071	186,562
Income (Loss) Before Income Taxes	(4,742,023)	(4,419,683)
Income Tax Expense	—	(404,527)
Net Income (Loss)	$ (4,742,023)	$ (4,824,210)
Basic Earnings (Loss) per Share	$ (0.09)	$ (0.10)
Diluted Earnings (Loss) per Share	$ (0.09)	$ (0.10)

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

As of March 31, 2017 and December 31, 2016

(Unaudited)

	March 31, 2017	December 31, 2016
ASSETS		
Cash and Cash Equivalents	$ 11,899,710	$ 17,180,594
Investments Available for Sale	40,840,581	40,759,703
Accounts Receivable, net of a reserve of $4,000 in 2017 and $5,000 in 2016	7,249,928	6,393,228
Inventory	13,420,823	12,141,072
Other Current Assets	1,339,169	2,034,598
Total Current Assets	74,750,211	78,509,195

Property and Equipment, net	1,419,651	1,391,575
Inventory, Non-Current	2,837,912	1,826,554
Intangible Assets	4,293	4,382
Goodwill	920,745	920,745
Other Non-current Assets	524,011	501,187
Total Assets	$ 80,456,823	$ 83,153,638
LIABILITIES AND SHAREHOLDERS' EQUITY		
Accounts Payable	$ 3,943,575	$ 5,858,234
Accrued Liabilities	6,230,911	4,210,151
Customer Deposits	216,732	77,217
Total Current Liabilities	10,391,218	10,145,602
Deferred License Revenue	19,460,436	20,051,737
Shareholders' Equity:		
Common Shares, no par value, 52,057,711 and 51,527,711 shares issued and outstanding	270,478,325	268,199,939
Accumulated Deficit	(219,083,115)	(214,341,092)
Accumulated Other Comprehensive Income	(790,041)	(902,548)
Total Shareholders' Equity	50,605,169	52,956,299
Total Liabilities And Shareholders' Equity	$ 80,456,823	$ 83,153,638

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

For the three months ended March 31, 2017 and March 31, 2016

(Unaudited)

	2017	**2016**
Cash Flows From Operating Activities:		
Net (Loss)	**$ (4,742,023)**	**$ (4,824,210)**
Adjustments To Reconcile Net Loss To Net Cash Used In Operating Activities:		
Depreciation and Amortization	130,215	200,089
Share Based Compensation—Non-employee	19,071	—
Share Based Compensation—Employees	2,259,316	2,679,468
Loss on Disposal of Assets	3,350	506
Changes in Assets and Liabilities:		
(Increase) in Accounts Receivable	(344,500)	(1,176,787)
(Increase) in Inventory	(2,291,108)	(1,292,152)
(Increase) in Other Assets	160,406	(42,733)
(Decrease) in Accounts Payable	(1,914,780)	425,252
(Decrease) in Other Liabilities	2,160,268	(507,795)
Increase (decrease) in Deferred License Revenue	(498,120)	(481,686)
Increase (decrease) in Deferred Drug License Revenue	(93,181)	3,954,546
Changes in Assets and Liabilities	(2,821,015)	878,645
Cash (Used In) Provided By Operating Activities	**(5,151,086)**	**(1,065,502)**
Cash Flows From Investing Activities:		
Purchase of Investments Available for Sale	31,123	—
Purchase of Equipment	(162,003)	(202,430)
Proceeds on Sale of Assets	450	—
Cash (Used In) Investing Activities	**(130,430)**	**(202,430)**
Cash Flows From Financing Activities:		

Proceeds from Issuance of Common Shares and Purchase Warrants	—	77,250
Cash Provided By Financing Activities	**—**	**77,250**
Effects of exchange rate changes	632	—
(Decrease) Increase In Cash	(5,280,884)	(1,190,682)
Cash At Beginning Of Period	17,180,594	31,198,182
Cash At End Of Period	**$ 11,899,710**	**$ 30,007,500**

Michael Rice, Investor Relations; 646-597-6979