

# ROCKWELL MEDICAL, INC.

## **FORM 8-K** (Current report filing)

Filed 08/09/17 for the Period Ending 08/09/17

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

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

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**FORM 8-K**

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**CURRENT REPORT**

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

Date of Report (Date of earliest event Reported): August 9, 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))

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.

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

On August 9, 2017, the Company issued the press release attached hereto as Exhibit 99.1, announcing its financial results for the quarter ended June 30, 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 August 9, 2017

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**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: August 9, 2017

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

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EXHIBIT INDEX

Exhibit    Description

[99.1](#)        Press Release dated August 9, 2017

## Rockwell Medical Reports Second Quarter Results

WIXOM, Mich., Aug. 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 and six months ended June 30, 2017.

### Q2 2017 Financial Highlights

- Sales were \$13.2 million compared to \$13.4 in Q2 2016.
- Gross profit was \$1.5 million, unchanged compared to Q2 2016.
- SG&A expense was \$6.5 million compared \$5.0 million in Q2 2016.
- R&D expense was \$1.7 million compared to \$2.1 million in Q2 2016.
- Net loss was \$7.1 million or (\$0.14) per share compared to a \$5.4 million loss or (\$0.11) per share in Q2 2016.
- Cash and investments were \$43.2 million as of June 30, 2017.
- Net working capital was \$56.1 million as of June 30, 2017.

### Q2 YTD 2017 Financial Highlights

- Sales were \$27.8 million, an increase of \$0.8 million or 2.8% over the first six months of 2016.
- Gross profit was \$3.9 million, an increase of \$0.7 million or 21.1% over the first six months of 2016.
- SG&A expense was \$12.6 million compared to \$10.0 million in the first six months of 2016.
- R&D expense was \$2.9 million compared to \$3.4 million in the first six months of 2016.
- Net Loss was \$11.8 million or (\$0.23) per share compared to \$10.2 million or (\$0.20) per share in the first six months of 2016.

“Our immediate priority is to secure add-on reimbursement for Triferic and we continue to make solid progress in our efforts,” stated Mr. Robert L. Chioini, chairman and chief executive officer of Rockwell. “We are working with key leadership within the new administration including Health and Human Services and Centers for Medicare and Medicaid Services, and we continue to receive outstanding congressional support. Feedback reported from our Triferic drug sample program continues to be very favorable and there is clearly recognition in the medical community of the value that Triferic can bring to patient outcomes. Calcitriol manufacture is progressing well and we remain on track with our FDA submission.”

### **Conference Call Information**

Rockwell Medical will be hosting a conference call to review its 2017 second quarter and year to date results on Wednesday, August 9, 2017 at 4:30 p.m. EDT. Investors are encouraged to call a few minutes in advance at (888) 487-0354, or for international callers (719) 325-2301, passcode #3956742 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](http://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](http://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.

Michael Rice, Investor Relations; 646-597-6979

Triferic<sup>®</sup> is a registered trademark of Rockwell Medical, Inc.

## ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

### CONSOLIDATED INCOME STATEMENTS

For the three and six months ended June 30, 2017 and June 30, 2016

(Unaudited)

	<b>Three Months Ended June 30, 2017</b>	<b>Three Months Ended June 30, 2016</b>	<b>Six Months Ended June 30, 2017</b>	<b>Six Months Ended June 30, 2016</b>
Sales	\$ 13,243,107	\$ 13,452,517	\$ 27,835,361	\$ 27,079,565
Cost of Sales	11,744,819	11,962,989	23,979,601	23,895,111
Gross Profit	1,498,288	1,489,528	3,855,760	3,184,454
Selling, General and Administrative	6,541,179	5,014,370	12,641,894	10,001,111
Research and Product Development	1,675,494	2,063,324	2,890,345	3,377,754
Operating Income (Loss)	(6,718,385)	(5,588,166)	(11,676,479)	(10,194,411)
Interest and Investment Income	(364,599)	227,020	(148,528)	413,582
Income (Loss) Before Income Taxes	(7,082,984)	(5,361,146)	(11,825,007)	(9,780,829)
Income Tax Expense	—	—	—	(404,527)
Net Income (Loss)	<u>\$ (7,082,984)</u>	<u>\$ (5,361,146)</u>	<u>\$ (11,825,007)</u>	<u>\$ (10,185,356)</u>
Basic Earnings (Loss) per Share	\$ (0.14)	\$ (0.11)	\$ (0.23)	\$ (0.20)
Diluted Earnings (Loss) per Share	\$ (0.14)	\$ (0.11)	\$ (0.23)	\$ (0.20)

## ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

### CONSOLIDATED BALANCE SHEETS

As of June 30, 2017 and December 31, 2016

(Unaudited)

	<b>June 30, 2017</b>	<b>December 31, 2016</b>
<b>ASSETS</b>		
Cash and Cash Equivalents	\$ 8,327,695	\$ 17,180,594
Investments Available for Sale	34,914,331	40,759,703
Accounts Receivable, net of a reserve of \$7,000 in 2017 and \$5,000 in 2016	4,880,969	6,393,228
Inventory	13,774,065	12,141,072
Other Current Assets	1,907,270	2,034,598
Total Current Assets	<u>63,804,330</u>	<u>78,509,195</u>
Property and Equipment, net	1,529,639	1,391,575
Inventory, Non-Current	2,725,958	1,826,554
Intangible Assets	4,205	4,382
Goodwill	920,745	920,745

Other Non-current Assets	490,738	501,187
Total Assets	<u>\$ 69,475,615</u>	<u>\$ 83,153,638</u>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Accounts Payable	\$ 3,869,646	\$ 5,858,234
Accrued Liabilities	3,585,198	4,210,151
Customer Deposits	212,320	77,217
Total Current Liabilities	<u>7,667,164</u>	<u>10,145,602</u>
Deferred License Revenue	17,962,468	20,051,737
Shareholders' Equity:		
Common Shares, no par value, 51,740,040 and 51,527,711 shares issued and outstanding	270,302,780	268,199,939
Accumulated Deficit	(226,166,099)	(214,341,092)
Accumulated Other Comprehensive Income	(290,698)	(902,548)
Total Shareholders' Equity	<u>43,845,983</u>	<u>52,956,299</u>
Total Liabilities And Shareholders' Equity	<u>\$ 69,475,615</u>	<u>\$ 83,153,638</u>

## ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

### CONSOLIDATED STATEMENTS OF CASH FLOWS

For the six months ended June 30, 2017 and June 30, 2016

(Unaudited)

	<u>2017</u>	<u>2016</u>
Cash Flows From Operating Activities:		
Net (Loss)	<b>\$ (11,825,007)</b>	<b>\$ (10,185,356)</b>
Adjustments To Reconcile Net Loss To Net Cash Used In Operating Activities:		
Depreciation and Amortization	259,084	395,990
Share Based Compensation—Non-employee	88,487	—
Share Based Compensation—Employees	4,301,585	5,222,723
Loss on Disposal of Assets	3,634	258
Loss (gain) on Sale of Investments Available for Sale	368,519	(3,302)
Changes in Assets and Liabilities:		
Decrease (Increase) in Accounts Receivable	343,993	(2,543,404)
(Increase) in Inventory	(2,532,397)	(3,137,896)
Decrease (Increase) in Other Assets	349,378	(54,132)
Increase (Decrease) in Accounts Payable	(1,988,717)	980,981
Increase (Decrease) in Other Liabilities	(489,857)	106,441
(Decrease) in Deferred License Revenue	(996,240)	(963,372)
Increase (Decrease) in Deferred Drug License Revenue	(136,362)	3,886,365
Changes in Assets and Liabilities	<u>(5,450,202)</u>	<u>(1,725,017)</u>
Cash (Used In) Operating Activities	<b>(12,253,900)</b>	<b>(6,294,704)</b>
Cash Flows From Investing Activities:		
Purchase of Investments Available for Sale	(27,262,362)	(9,259,648)
Sale of Investments Available for Sale	33,351,339	8,328,987
Purchase of Equipment	(401,055)	(229,287)
Proceeds on Sale of Assets	450	1,000
Cash Provided by (Used In) Investing Activities	<u>5,688,372</u>	<u>(1,158,948)</u>
Cash Flows From Financing Activities:		
Proceeds from Issuance of Common Shares	—	77,250
Restricted Stock Retained in Satisfaction of Tax Liabilities	(2,287,231)	—
Cash Provided By (Used In) Financing Activities	<u>(2,287,231)</u>	<u>77,250</u>

Effects of exchange rate changes	(140)	—
(Decrease) Increase In Cash	(8,852,899)	(7,376,402)
Cash At Beginning Of Period	17,180,594	31,198,182
Cash At End Of Period	<u>\$ 8,327,695</u>	<u>\$ 23,821,780</u>