

ROCKWELL MEDICAL, INC.

FORM 8-K (Current report filing)

Filed 11/08/17 for the Period Ending 11/08/17

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): November 8, 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.

Item 2.02. Results of Operations and Financial Condition.

On November 8, 2017, the Company issued the press release attached hereto as Exhibit 99.1, announcing its financial results for the quarter ended September 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 November 8, 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: November 8, 2017

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

EXHIBIT INDEX

Exhibit Description

[99.1](#) Press Release dated November 8, 2017.

Rockwell Medical Reports Third Quarter Results

Conference Call and Webcast Today at 4:30 p.m. EST.

WIXOM, Mich., Nov. 08, 2017 (GLOBE NEWSWIRE) -- Rockwell Medical, Inc. (NASDAQ:RMTI), reported results for the three and nine months ended Sept. 30, 2017.

Q3 2017 Financial Highlights

- Sales were \$14.6 million, an increase of 14.1% or \$1.8 million over third quarter of 2016.
- Gross profit was \$1.1 million, compared to \$1.6 million in Q3 2016.
- SG&A expense was \$4.8 million, compared \$5.1 million in Q3 2016.
- R&D expense was \$1.3 million, same as Q3 2016.
- Net loss was \$5.1 million or (\$0.10) per share compared to a \$4.6 million loss or (\$0.09) per share in Q3 2016.
- Cash and investments were \$38.9 million as of September 30, 2017.
- Net working capital was \$53.6 million as of September 30, 2017 compared to \$56.1 million at June 30, 2017.

Q3 YTD 2017 Financial Highlights

- Sales were \$42.5 million, an increase of 6.4% or \$2.6 million over first nine months of 2016.
- Gross profit was \$4.9 million, compared to \$4.8 million in first nine months of 2016.
- SG&A expense was \$17.4 million compared to \$15.1 million in first nine months of 2016.
- R&D expense was \$4.2 million compared to \$4.6 million in first nine months of 2016.
- Net Loss was \$16.9 million or (\$0.33) per share compared to \$14.7 million or (\$0.29) per share in first nine months of 2016.

Mr. Robert L. Chioini, Chairman and Chief executive Officer of Rockwell, stated, "Our operating business results were in-line with our expectations. Regarding our progress on gaining separate reimbursement for Triferic, we have had further productive interaction with the Centers for Medicare and Medicaid Services (CMS) and with the Center for Medicare and Medicaid Innovation (CMMI). As requested, we have provided a comprehensive package of information that highlights the clinical benefits and cost savings advantages for separate reimbursement for Triferic. We believe we are well positioned to gain a favorable decision."

Conference Call Information

Rockwell Medical will be hosting a conference call to review its 2017 third quarter and year to date results today Wednesday, Nov. 8, 2017 at 4:30 p.m. EST. Investors are encouraged to call a few minutes in advance at (888) 282-4591, or for international callers (719) 325-2491, Conference ID #8182379. To listen to the call via webcast, please go to 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.

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ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED INCOME STATEMENTS

For the three and nine months ended September 30, 2017 and September 30, 2016

(Unaudited)

	<u>Three Months Ended September 30, 2017</u>	<u>Three Months Ended September 30, 2016</u>	<u>Nine Months Ended September 30, 2017</u>	<u>Nine Months Ended September 30, 2016</u>
Sales	\$ 14,626,904	\$ 12,814,815	\$ 42,462,265	\$ 39,894,380
Cost of Sales	<u>13,555,853</u>	<u>11,234,934</u>	<u>37,535,454</u>	<u>35,130,045</u>
Gross Profit	1,071,051	1,579,881	4,926,811	4,764,335
Selling, General and Administrative	4,791,636	5,070,127	17,433,530	15,071,238
Research and Product Development	<u>1,304,658</u>	<u>1,261,863</u>	<u>4,195,003</u>	<u>4,639,617</u>
Operating Income (Loss)	(5,025,243)	(4,752,109)	(16,701,722)	(14,946,520)
Interest and Investment Income	<u>(31,751)</u>	<u>188,847</u>	<u>(180,279)</u>	<u>602,429</u>
Income (Loss) Before Income				
Taxes	(5,056,994)	(4,563,262)	(16,882,001)	(14,344,091)
Income Tax Expense	<u>—</u>	<u>—</u>	<u>—</u>	<u>(404,527)</u>
Net Income (Loss)	<u>\$ (5,056,994)</u>	<u>\$ (4,563,262)</u>	<u>\$ (16,882,001)</u>	<u>\$ (14,748,618)</u>
Basic Earnings (Loss) per Share	\$ (0.10)	\$ (0.09)	\$ (0.33)	\$ (0.29)
Diluted Earnings (Loss) per Share	\$ (0.10)	\$ (0.09)	\$ (0.33)	\$ (0.29)

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

As of September 30, 2017 and December 31, 2016

(Unaudited)

ASSETS

<u>September 30, 2017</u>	<u>December 31, 2016</u>
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Cash and Cash Equivalents	\$ 3,887,923	\$ 17,180,594
Investments Available for Sale	35,028,841	40,759,703
Accounts Receivable, net of a reserve of \$6,000 in 2017 and \$5,000 in 2016	5,374,390	6,393,228
Inventory	14,864,642	12,141,072
Other Current Assets	2,032,095	2,034,598
Total Current Assets	61,187,891	78,509,195
Property and Equipment, net	1,708,817	1,391,575
Inventory, Non-Current	1,494,175	1,826,554
Intangible Assets	4,117	4,382
Goodwill	920,745	920,745
Other Non-current Assets	490,655	501,187
Total Assets	<u>\$ 65,806,400</u>	<u>\$ 83,153,638</u>
LIABILITIES AND SHAREHOLDERS' EQUITY		
Accounts Payable	\$ 4,188,677	\$ 5,858,234
Accrued Liabilities	3,231,789	4,210,151
Customer Deposits	199,407	77,217
Total Current Liabilities	7,619,873	10,145,602
Deferred License Revenue	17,396,167	20,051,737
Shareholders' Equity:		
Common Shares, no par value, 51,761,040 and 51,527,711 shares issued and outstanding	272,055,391	268,199,939
Accumulated Deficit	(231,223,093)	(214,341,092)
Accumulated Other Comprehensive Income	(41,938)	(902,548)
Total Shareholders' Equity	40,790,360	52,956,299
Total Liabilities And Shareholders' Equity	<u>\$ 65,806,400</u>	<u>\$ 83,153,638</u>

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

For the nine months ended September 30, 2017 and September 30, 2016

(Unaudited)

	<u>2017</u>	<u>2016</u>
Cash Flows From Operating Activities:		
Net (Loss)	\$ (16,882,001)	\$ (14,748,618)
Adjustments To Reconcile Net Loss To Net Cash Used In Operating Activities:		
Depreciation and Amortization	384,835	583,501
Share Based Compensation—Non-employee	158,667	—
Share Based Compensation—Employees	5,874,769	7,794,690
Loss on Disposal of Assets	4,084	7,340
Loss on Sale of Investments Available for Sale	704,695	26,820
Changes in Assets and Liabilities:		
(Increase) in Accounts Receivable	(149,429)	(2,984,463)
(Increase) in Inventory	(2,391,191)	(3,888,489)
Decrease (Increase) in Other Assets	224,635	(1,376,042)
(Decrease) in Accounts Payable	(1,669,651)	(598,427)
(Decrease) in Other Liabilities	(863,034)	(179,856)
(Decrease) in Deferred License Revenue	(1,494,360)	(1,445,058)
(Decrease) Increase in Deferred Drug License Revenue	(204,543)	3,818,184

Changes in Assets and Liabilities	<u>(6,547,573)</u>	<u>(6,654,151)</u>
Cash (Used In) Operating Activities	(16,302,524)	(12,990,418)
Cash Flows From Investing Activities:		
Purchase of Investments Available for Sale	(34,235,347)	(23,158,809)
Sale of Investments Available for Sale	40,122,266	24,491,678
Purchase of Equipment	(706,346)	(328,322)
Proceeds on Sale of Assets	450	1,000
Cash Provided by Investing Activities	5,181,023	1,005,547
Cash Flows From Financing Activities:		
Proceeds from Issuance of Common Shares	116,105	80,161
Restricted Stock Retained in Satisfaction of Tax Liabilities	(2,287,231)	—
Cash (Used In) Provided By Financing Activities	(2,171,126)	80,161
Effects of exchange rate changes	(44)	(18)
(Decrease) In Cash	(13,292,671)	(11,904,728)
Cash At Beginning Of Period	17,180,594	31,198,182
Cash At End Of Period	<u>\$ 3,887,923</u>	<u>\$ 19,293,454</u>