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 14, 2019**

ROCKWELL MEDICAL, INC.

(Exact name of registrant as specified in its charter)

Michigan	**000-23661**	**38-3317208**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

30142 Wixom Road, Wixom, Michigan 48393
(Address of principal executive offices, including 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 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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 March 14, 2019, Rockwell Medical, Inc. issued a press release announcing its financial results for the quarter and year ended December 31, 2018. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) *Exhibits*. The following exhibit is being furnished herewith:

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release, dated March 14, 2019

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 14, 2019

By: /s/ Stuart Paul
Stuart Paul
Chief Executive Officer

Exhibit 99.1

FOR IMMEDIATE RELEASE

Rockwell Medical, Inc. Reports Fourth Quarter and Full Year 2018 Financial Results

— Company is poised to advance multiple formulations of Triferic®, the first and only FDA-approved therapy indicated to replace iron and maintain hemoglobin levels in adult hemodialysis patients —

WIXOM, Mich., March 14, 2019 — Rockwell Medical, Inc. (NASDAQ:RMTI) (the "Company"), a biopharmaceutical company targeting end-stage renal disease (ESRD) and chronic kidney disease (CKD), today reported financial results for the three months and full year ended December 31, 2018.

Recent Business Updates:

- **Launch of Dialysate Triferic** — The Company has developed a long-term, strategic plan for the Triferic portfolio. As part of this plan, the Company expects to launch Dialysate Triferic in the U.S. during the second quarter of 2019.

- **I.V. Triferic Update** — The Company expects to file a New Drug Application ("NDA") for I.V. Triferic during the second quarter of 2019. I.V. Triferic was developed pursuant to a Special Protocol Assessment with the U.S. Food and Drug Administration ("FDA") through which an equivalence approach to Dialysate Triferic was deemed acceptable by the FDA. Data from a previously completed equivalence study will be presented at the 39th Annual Dialysis Conference on March 18, 2019.

- **International Triferic Updates** — In January 2019, the Company received the first international approval for Dialysate Triferic in Peru, and expects to receive regulatory approval for Dialysate Triferic in Chile in 2019. The Company plans to file for regulatory approval for Dialysate Triferic in China, and I.V. Triferic in Canada during 2019, pending completion of any required clinical trials and discussions with local regulators. The Company is actively pursuing international licensing opportunities with a primary focus on Europe and Japan.

- **Strengthened Management Team** — During the fourth quarter of 2018, the Company added seasoned executives with extensive experience in pharmaceuticals and the renal sector to manage a strategic worldwide business plan to develop and commercialize the Triferic portfolio.

Selected Financial Highlights for the Three and Twelve Months ended December 31, 2018:

- Sales for the fourth quarter of 2018 were $16.9 million compared to $14.8 million for the fourth quarter of 2017, an increase of 14%; for the full year 2018, sales were $63.4 million compared to $57.3 million for 2017, an increase of 11%.

- Net loss for the fourth quarter of 2018 was $9.4 million compared to a net loss of $9.0 million for the fourth quarter of 2017.

- Cash used in operating activities for the fourth quarter of 2018 was $5.8 million. As of December 31, 2018, the Company had cash, cash equivalents and investments available-for-sale of $33.5 million and working capital of $33.6 million.

“In a short time, we have made significant progress in developing a focused, disciplined strategy for the launch of Dialysate Triferic in the U.S. and the filing of our NDA for I.V. Triferic. We see a tremendous global opportunity for Triferic to deliver a much-needed alternative to the more than two million patients worldwide who receive in-center hemodialysis treatments each year,” stated Stuart Paul, President and Chief Executive Officer of Rockwell Medical.

“As the first and only FDA-approved therapy to replace iron and maintain hemoglobin levels, Triferic has the potential to change, over time, the standard of care in anemia management in hemodialysis patients. With a compelling clinical profile and the recent additions to the management team, we are well-positioned to bring our innovative formulations of Triferic to market,” concluded Mr. Paul.

Fourth Quarter 2018 Financial Results

Sales for the fourth quarter of 2018 were $16.9 million compared to sales of $14.8 million for the fourth quarter of 2017. The increase was due primarily to higher international sales, an increase in revenue from distribution and management fees billed to Baxter, and increased sales to Baxter and DaVita. Revenue recognized from licensing fees was $0.7 million for both the fourth quarters of 2018 and 2017, respectively.

Cost of sales for the fourth quarter of 2018 was $15.7 million, resulting in a gross profit of $1.2 million in the fourth quarter of 2018, compared to a gross loss of $1.2 million in the fourth quarter of 2017. The year-over-year change in gross profit was positively impacted by a decrease in inventory reserves and higher sales volumes, partially offset by higher distribution costs and higher variable costs due to the increase in sales volume. Gross profit for the Company’s concentrates business for each of the three months ended December 31, 2018 and December 31, 2017 was $1.6 million.

Selling, general and administrative expenses were $7.9 million for the fourth quarter of 2018 compared with $5.9 million for the fourth quarter of 2017. The $2.0 million increase was primarily due to increases in stock-based compensation, higher consulting expenses, recruiting fees, bonus and insurance expenses, offset by lower legal and annual reporting expenses.

Research and product development expenses were $1.6 million for the fourth quarter of 2018 compared to $2.1 million for the fourth quarter of 2017. The $0.5 million decrease in the fourth quarter of 2018 was largely related to lower clinical trial and product testing expenses for

Triferic, partially offset by higher labor costs. Research and product development expenses for the fourth quarter of 2018 also included a $0.7 million inventory write-down for Calcitriol.

Research and development — licenses acquired (related party) was $1.1 million for the fourth quarter of 2018 compared to nil for the fourth quarter of 2017. The increase was related to the Master Services and Intellectual Property Agreement entered into with Charak, LLC and Dr. Ajay Gupta in October 2018.

Net loss for the fourth quarter of 2018 was $9.4 million, or $0.17 per basic and diluted share, compared to a net loss of $9.0 million, or $0.18 per basic and diluted share, in 2017.

Full Year 2018

For the year ended December 31, 2018, sales were $63.4 million compared to $57.3 million for the year ended December 31, 2017. The increase of $6.1 million was primarily due to higher international sales of $2.1 million, or a 31% increase, compared to the year ended December 31, 2017, as well as increased revenue from distribution and management fees billed to Baxter. Revenue recognized from licensing fees was $2.4 million and $2.3 million for the years ended December 31, 2018 and 2017, respectively.

Cost of sales for the year ended December 31, 2018 was $65.0 million, resulting in a gross loss of $1.6 million in 2018, compared to a gross profit of $3.7 million in 2017. Gross profit declined by $5.3 million in 2018 compared to 2017, due primarily to an increase in inventory reserves and write-offs of Triferic inventory of $4.6 million and a gross profit decrease of $0.6 million in the Company's dialysis concentrates products. The decrease in gross profit for the Company's dialysis concentrates products was primarily attributable to increased distribution costs and lower pricing under the Company's distribution agreement with Baxter, partially offset by increased unit volume growth.

Selling, general and administrative expenses were $23.1 million for the year ended December 31, 2018 compared to $23.3 million for the year ended December 31, 2017. The decrease is due to reduced salaries and stock compensation offset by increases in legal, insurance and outside consulting expenses.

Settlement expenses were $1.0 million for the year ended December 31, 2018 compared to nil for the year ended December 31, 2017. The increase was related to the settlement agreement with the Company's former CEO, former CFO and certain former directors in August 2018.

Research and product development expenses were $5.6 million for the year ended December 31, 2018 compared to $6.3 million for the year ended December 31, 2017. The decrease was largely related to lower Triferic development costs.

Research and development — licenses acquired (related party) was $1.1 million for the year ended December 31, 2018 compared to nil for the year ended December 31, 2017. The increase was related to the Master Services and Intellectual Property Agreement entered into with Charak, LLC and Dr. Ajay Gupta in October 2018.

Net loss for the year end December 31, 2018 was $32.1 million, or $0.61 per basic and diluted share, compared to a net loss of $25.9 million, or $0.51 per basic and diluted share, in 2017.

Decision on Calcitriol (Active Vitamin D) Injection

Following a strategic review of Calcitriol, including pricing, commercial distribution and marketing, manufacturing efficiencies and capacity (including potential capital investment), the Company determined commercialization of Calcitriol in the U.S. is not viable at this time. The decision is based, in part, on the fact that prevailing market prices for similar Vitamin D products are lower than the cost to produce Calcitriol on a dose-equivalent basis, and as a result it would be difficult for the Company to market Calcitriol profitably. As a result of this decision, the Company recorded an inventory reserve of $0.7 million for the fourth quarter of 2018, reflecting the remainder of its Calcitriol inventory. The Company is continuing to evaluate the potential commercialization of Calcitriol in China with its partner, Wanbang Biopharmaceutical, including the market opportunity and regulatory pathway.

Key Objectives for 2019

- Launch Dialysate Triferic in the U.S. in the second quarter of 2019;
- File an NDA with the FDA for I.V. Triferic in the second quarter of 2019;
- Accelerate global development of Triferic through existing partners and identify new partners for key geographies, including Europe and Japan; and
- Grow and improve the profitability of the Company's concentrates business.

Conference Call

As previously announced, Rockwell Medical management will host its fourth quarter and full year 2018 conference call as follows:

Date	Thursday, March 14, 2019
Time	8:30 AM EDT
Telephone U.S:	(877) 383-7438
International:	(678) 894-3975
Webcast (live and archive)	https://edge.media-server.com/m6/p/hbjxp3dz

About Rockwell Medical, Inc.

Rockwell Medical is a biopharmaceutical company targeting end-stage renal disease (ESRD) and chronic kidney disease (CKD). Rockwell Medical'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's anemia drug Triferic is the only FDA-approved product indicated for iron replacement and maintenance of hemoglobin in hemodialysis patients. Rockwell Medical is also an established manufacturer, supplier and leader in delivering high-quality hemodialysis concentrates/dialysates (used to maintain human life by removing

toxins and replacing critical nutrients in the dialysis patient's bloodstream) to dialysis providers and distributors in the U.S. and abroad. Please visit www.rockwellmed.com for more information.

Forward-Looking Statement

Certain statements in this press release may constitute "forward-looking statements" within the meaning of the federal securities laws, including, but not limited to, Rockwell's intention to bring to market Triferic, IV Triferic and Calcitriol. Words such as "may," "might," "will," "should," "believe," "expect," "anticipate," "estimate," "continue," "could," "plan," "potential," "predict," "forecast," "project," "plan", "intend" or similar expressions, or statements regarding intent, belief, or current expectations, are forward-looking statements. While Rockwell 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's SEC filings), many of which are beyond our control and subject to change. Actual results could be materially different. Risks and uncertainties include: statements about the timing and success of our planned NDA submission for IV Triferic; the potential market opportunity for IV Triferic and other Rockwell products; pricing and reimbursement status for IV Triferic, Triferic and other Rockwell products, including eligibility for add-on reimbursement under TDAPA; liquidity and capital resources; expected duration of Rockwell Medical's existing working capital; plans and timing relating to the planned commercialization of Triferic; and timing and success of our efforts to renegotiate economic terms of our concentrate business Rockwell expressly disclaims any obligation to update or alter any statements whether as a result of new information, future events or otherwise, except as required by law.

Contact

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Source: Rockwell Medical, Inc.

Financial Tables Follow

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets

	(unaudited)	
	December 31, 2018	**December 31, 2017**
ASSETS		
Cash and Cash Equivalents	$ 22,713,980	$ 8,406,917
Investments Available-for -Sale	10,818,059	24,648,459
Accounts Receivable, net of a reserve of $2,104 in 2018 and $11,000 in 2017	6,979,514	6,355,566
Insurance Receivable	371,217	—
Inventory	4,038,778	7,637,384
Prepaid and Other Current Assets	1,903,682	1,779,992
Total Current Assets	**46,825,230**	**48,828,318**
Property and Equipment, net	2,638,293	2,548,978
Inventory, Non-Current	1,637,000	5,986,752
Goodwill	920,745	920,745
Other Non-current Assets	536,516	494,847
Total Assets	$ **52,557,784**	$ **58,779,640**
LIABILITIES AND SHAREHOLDERS' EQUITY		
Accounts Payable	$ 4,492,071	$ 4,222,159
Accrued Liabilities	5,129,761	4,715,712
Settlement Payable	416,668	—
Deferred License Revenue	2,252,868	—
Customer Deposits	63,143	205,303
Other Current Liability - Related Party	850,000	—
Total Current Liabilities	**13,204,511**	**9,143,174**
Deferred License Revenue	12,076,399	16,723,318
Total Liabilities	**25,280,910**	**25,866,492**
Shareholders' Equity:		
Preferred Shares, no par value, no shares issued and outstanding at December 31, 2018 and 2017	—	—
Common Shares, no par value, 57,034,154 and 51,768,424 shares issued and outstanding at December 31, 2018 and 2017, respectively	299,601,960	273,210,907
Accumulated Deficit	(272,388,234)	(240,262,376)
Accumulated Other Comprehensive Income (Loss)	63,148	(35,383)
Total Shareholders' Equity	**27,276,874**	**32,913,148**
Total Liabilities And Shareholders' Equity	$ **52,557,784**	$ **58,779,640**

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Operations
(unaudited)

	Three Months Ended December 31, 2018	Three Months Ended December 31, 2017	Year Ended December 31, 2018	Year Ended December 31, 2017
Net Sales	$ 16,854,259	$ 14,838,016	$ 63,388,617	$ 57,300,281
Cost of Sales	15,670,109	16,062,936	64,973,157	53,598,390
Gross Profit (Loss)	1,184,150	(1,224,920)	(1,584,540)	3,701,891
Selling, General and Administrative	7,900,256	5,869,879	23,082,304	23,303,409
Settlement Expense, net of Reimbursement	—	—	1,030,000	—
Research and Product Development	1,608,823	2,126,397	5,642,317	6,321,400
Research and Development - Licenses Acquired (Related Party)	1,100,000	—	1,100,000	—
Operating Loss	(9,424,929)	(9,221,196)	(32,439,161)	(25,922,918)
Other Income (Expense)				
Realized Gain (Loss) on Investments	(325)	(87,514)	(222,338)	(792,207)
Interest Income	48,932	267,336	535,328	790,226
Other Expense	410	1,348	313	2,873
Foreign Currency Gain		742	—	742
Total Other Income (Expense)	49,017	181,912	313,303	1,634
Net Loss	$ (9,375,912)	$ (9,039,284)	$ (32,125,858)	$ (25,921,284)
Basic and Diluted Net Loss per Share	$ (0.17)	$ (0.18)	$ (0.61)	$ (0.51)
Basic and Diluted Weighted Average Shares Outstanding	56,041,350	51,260,975	52,824,486	51,067,412