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): **August 8, 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)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, no par value	RMTI	Nasdaq Global Market

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 August 8, 2019, Rockwell Medical, Inc. issued a press release announcing its financial results for the quarter ended June 30, 2019. 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 August 8, 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: August 8, 2019

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

Exhibit 99.1

FOR IMMEDIATE RELEASE

Rockwell Medical, Inc. Reports Second Quarter 2019 Financial Results

— Company Records First Commercial Sales of Dialysate Triferic®;
FDA Accepts New Drug Application for I.V. Triferic with PDUFA date of March 28, 2020—

WIXOM, Mich., August 8, 2019 — Rockwell Medical, Inc. (NASDAQ:RMTI) ("Rockwell Medical" or the "Company"), a biopharmaceutical company dedicated to improving outcomes for patients with anemia, with an initial focus on end-stage renal disease (ESRD) and chronic kidney disease (CKD), today reported business updates and financial results for the three and six months ended June 30, 2019.

Recent Business and Financial Highlights:

- Launched the initial product in the Triferic (ferric pyrophosphate citrate) portfolio, Dialysate Triferic, on May 6, 2019 and recorded its first commercial sales. The Company's goal for 2019 is to drive adoption by providing medical education to healthcare providers, while increasing awareness and understanding of Triferic's potential benefits.

- Submitted a New Drug Application ("NDA") for I.V. Triferic in the U.S. during the second quarter and received notice of acceptance for filing from the U.S. Food and Drug Administration ("FDA") on August 2, 2019 with a PDUFA date of March 28, 2020.

- Announced positive results of two clinical pharmacology trials of Triferic in China. Rockwell Medical and its partner in China expect to request a meeting with the National Medical Products Administration ("NMPA") to review the results of these studies and discuss whether these studies are sufficient to support a submission for regulatory approval for Dialysate Triferic.

- Received a new J-Code from the Centers for Medicare and Medicaid Services ("CMS"), effective July 1, 2019, for the powder packet formulation of Dialysate Triferic.

- Intends to provide comments supporting eligibility of I.V. Triferic for TDAPA in response to the recently announced CMS ESRD Proposed Rule for 2020.

- Sales were $14.8 million and $30.4 million for the three and six months ended June 30, 2019, a decrease of 0.5% and increase of 1.8% over the same periods last year, respectively. The Company's sales during the quarter and to date have substantially consisted of sales of dialysis concentrate products to DaVita, Baxter and international customers. The Company recently signed a new Products Purchase Agreement with DaVita with an initial term

through December 31, 2023 and supplies approximately 25% of the U.S. market for dialysis concentrates.

- Completed a public offering of common stock, with gross proceeds of $18.8 million.

- As of June 30, 2019, the Company had cash, cash equivalents and investments available-for-sale of $35.2 million. Additionally, the Company has approximately $38 million remaining under its at-the-market equity offering facility, pursuant to which the Company may sell, at such times and amounts as it deems appropriate, shares of common stock to support its business plan, subject to certain restrictions on use.

“During the second quarter, we accomplished two critical milestones: commercializing Dialysate Triferic and submitting our NDA for the I.V. Triferic formulation. We are pleased with the progress we have made in a relatively short time. Through our medical education, sales and marketing efforts, we have begun the process of converting U.S. dialysis clinics to commercial use of Dialysate Triferic, and we believe these efforts will support our launch of I.V. Triferic next year, if approved by the FDA,” stated Stuart Paul, President and Chief Executive Officer of Rockwell Medical.

“Our recent financing strengthens our balance sheet and supports our global commercialization and research and development efforts around Triferic. And, while we are disappointed with CMS’s proposed revisions as set forth in the ESRD Proposed Rule for 2020, we remain confident about Triferic’s future and potential to change the standard of care in anemia management for hemodialysis patients,” continued Mr. Paul.

Second Quarter 2019 Financial Results

Net loss for the second quarter of 2019 was $10.3 million, or $0.18 per basic and diluted share, compared to a net loss of $12.2 million, or $0.24 per basic and diluted share, in the second quarter of 2018. The reduction in net loss for the second quarter of 2019 compared to the second quarter of 2018 was driven primarily by an increase in gross profit and reduction in settlement expense, net of reimbursement, partially offset by an increase in sales and marketing expenses and research and product development expenses. The net loss for the second quarter of 2019 included a $1.3 million NDA application fee for I.V. Triferic and a $0.4 million accrual for the settlement of shareholder class action litigation.

Net sales for the second quarter of 2019 were $14.8 million compared to sales of $14.9 million during the second quarter of 2018.

Cost of sales for the second quarter of 2019 was $14.1 million, resulting in gross profit of $0.7 million, compared to cost of sales of $18.9 million and a gross loss of $4.0 million during the second quarter of 2018. Gross profit increased in the second quarter of 2019 compared to the second quarter of 2018 due primarily to an inventory reserve expense of $0.2 million during the second quarter of 2019 compared to an inventory reserve expense of $5.4 million during the second quarter of 2018, partially offset by a decrease in gross profit in our dialysis concentrates products of $0.6 million. The decrease in gross profit for our dialysis concentrates products was primarily attributable to increased labor, materials and overhead costs.

Selling and marketing expenses were $2.2 million for the second quarter of 2019 compared to $0.2 million in the second quarter of 2018. The increase was due primarily to marketing costs to support the launch of Triferic and an increase in sales and marketing headcount.

General and administrative expenses were $5.5 million during each of the second quarter of 2019 and 2018, respectively.

Settlement expense, net of reimbursement, was $0.4 million in the second quarter of 2019, compared to $1.0 million in the second quarter of 2018. Settlement expense for the second quarter of 2018 reflected the terms of the confidential settlement agreement and mutual release entered into with the Company's former CEO, former CFO and a former and then current director, while Settlement expense for the second quarter of 2019 reflected an accrual for the settlement of shareholder class action litigation.

Research and product development expenses were $3.0 million for the second quarter of 2019 compared to $1.6 million for the second quarter of 2018. The increase was due primarily to the $1.3 million NDA application fee for I.V. Triferic, costs associated with new clinical studies for Triferic, and an increase in headcount to support the launch of Triferic, partially offset by the elimination of Calcitriol development and the reduction in testing costs on Triferic from the same period in 2018.

Other income, net, for the three months ended June 30, 2019 was $0.1 million, consisting of interest income. Other income for the three months ended June 30, 2018 was $0.1 million, consisting of $0.2 million of interest income, offset by $0.1 million of realized gains on investments.

The Company encourages shareholders to also review its Form 10-Q for the quarter ended June 30, 2019, as filed by the Company with the United States Securities and Exchange Commission ("SEC").

Key Objectives for 2019

- Drive adoption of Dialysate Triferic in the U.S. by raising awareness in the dialysis community of its unique benefits.
- Gather and analyze real-world data to support medical education and commercial efforts for Triferic.
- Interact with the FDA to support potential approval of I.V. Triferic in March 2020 and begin preparation for potential launch of I.V. Triferic.
- Use results from recently completed clinical pharmacology studies in China to support future regulatory submission to NMPA (formerly, the CFDA).
- Advance international opportunities for the Triferic portfolio through strategic partnerships and licensing agreements.
- Expand and improve operating margin for the Company's concentrates business.

Conference Call

As previously announced, Rockwell Medical management will host its second quarter 2019 conference call as follows:

Date	Thursday, August 8, 2019
Time	4:30 PM EDT
Telephone U.S:	(877) 383-7438
International:	(678) 894-3975
Webcast (live and archive)	https://edge.media-server.com/mmc/p/w4hd4fhc

About Triferic

Triferic is the only FDA-approved therapy indicated to replace iron and maintain hemoglobin in hemodialysis patients via dialysate during each dialysis treatment. Triferic delivers approximately 5-7 mg iron with every hemodialysis treatment to the bone marrow and maintains hemoglobin without increasing iron stores (ferritin). Unlike traditional IV iron products, Triferic donates iron immediately and completely to transferrin (carrier of iron in the body) upon entry into the blood and is then transported directly to the bone marrow to be incorporated into hemoglobin, with no increase in ferritin (stored iron and inflammation) and no reports of anaphylaxis in over 1,000,000 patient administrations, addressing a significant medical need in overcoming Functional Iron Deficiency (FID) in ESRD patients. The Company has developed multiple formulations of Triferic: (1) FDA-approved Dialysate Triferic; and (2) I.V. Triferic, for which the Company filed a New Drug Application in May 2019 with a PDUFA date of March 28, 2020. 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 biopharmaceutical company dedicated to improving outcomes for patients with anemia, with an initial focus on end-stage renal disease (ESRD) and chronic kidney disease (CKD). Rockwell Medical's exclusive renal drug therapy, Triferic, supports disease management initiatives to improve the quality of life and care of dialysis patients and is intended to deliver safe and effective therapy, while decreasing drug administration costs and improving patient convenience. The Company has developed multiple formulations of Triferic: (1) Dialysate Triferic; and (2) I.V. Triferic. Dialysate Triferic is the only FDA-approved therapeutic indicated for iron replacement and maintenance of hemoglobin in hemodialysis patients. The Company's strategy is to bring its therapeutics to market in the United States and to utilize partners to develop and commercialize such therapeutics in international markets. Rockwell Medical is also an established manufacturer, supplier and leader in delivering high-quality hemodialysis concentrates/dialysates to dialysis providers and distributors in the U.S. and abroad. Please visit www.rockwellmed.com for more information.

Forward-Looking Statements

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 Medical's intention to bring to market Triferic, and I.V. Triferic. 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 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), many of which are beyond our control and subject to change. Actual results could be materially different. Risks and uncertainties include: statements about the issuance of a unique J code for our Triferic Powder Packet; timing and regulatory approval process for Dialysate Triferic in China; timing and regulatory approval process of our NDA filing for I.V. Triferic as filed with the FDA; the potential market opportunity and commercialization of Dialysate Triferic in China; potential market opportunity for I.V. Triferic, as well as other Rockwell Medical products; pricing and reimbursement status for I.V. Triferic and other Rockwell Medical products, including the eligibility of I.V. Triferic for add-on reimbursement under TDAPA, pursuant to CMS’ preliminary proposed rules as announced by CMS on July 29, 2019; liquidity and capital resources; expected duration of Rockwell Medical’s existing working capital; success of our recently announced commercialization of Dialysate Triferic; and timing and success of our efforts to maintain, grow and improve the profit margin of the Company’s concentrate business. Rockwell Medical 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.

Triferic® is a registered trademark of Rockwell Medical, Inc.

Contact

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Source: Rockwell Medical, Inc.

Financial Tables Follow

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets

	June 30, 2019 (Unaudited)	December 31, 2018
ASSETS		
Cash and Cash Equivalents	$ 21,417,159	$ 22,713,980
Investments Available-for -Sale	13,816,079	10,818,059
Accounts Receivable, net	5,388,858	6,979,514
Insurance Receivable	—	371,217
Inventory	3,972,637	4,038,778
Prepaid and Other Current Assets	3,667,605	1,903,682
Total Current Assets	**48,262,338**	**46,825,230**
Property and Equipment, net	2,563,428	2,638,293
Inventory, Non-Current	1,445,000	1,637,000
Right of Use Assets, net	3,329,481	—
Goodwill	920,745	920,745
Other Non-current Assets	555,222	536,516
Total Assets	$ **57,076,214**	$ **52,557,784**
LIABILITIES AND SHAREHOLDERS' EQUITY		
Accounts Payable	$ 4,065,302	$ 4,492,071
Accrued Liabilities	4,071,341	5,129,761
Settlement Payable	430,000	416,668
Lease Liability - Current	1,637,481	—
Deferred License Revenue - Current	2,243,256	2,252,868
Insurance Financing Note Payable	1,908,554	—
Customer Deposits	128,654	63,143
Other Current Liability - Related Party	350,000	850,000
Total Current Liabilities	**14,834,588**	**13,204,511**
Lease Liability - Long-Term	1,690,310	—
Deferred License Revenue - Long-Term	10,959,577	12,076,399
Total Liabilities	**27,484,475**	**25,280,910**
Shareholders' Equity:		
Preferred Shares, no par value, no shares issued and outstanding at June 30, 2019 and December 31, 2018	—	—
Common Shares, no par value, 63,398,704 and 57,034,154 shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively	320,882,946	299,601,960
Accumulated Deficit	(291,358,764)	(272,388,234)
Accumulated Other Comprehensive Income	67,557	63,148
Total Shareholders' Equity	**29,591,739**	**27,276,874**
Total Liabilities And Shareholders' Equity	$ **57,076,214**	$ **52,557,784**

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

	Three Months Ended June 30, 2019	Three Months Ended June 30, 2018	Six Months Ended June 30, 2019	Six Months Ended June 30, 2018
Net Sales	$ 14,845,788	$ 14,913,363	$ 30,405,227	$ 29,861,943
Cost of Sales	14,112,639	18,930,371	28,661,686	34,599,442
Gross Profit (Loss)	733,149	(4,017,008)	1,743,541	(4,737,499)
Selling and Marketing	2,218,997	164,374	5,321,375	379,457
General and Administrative	5,496,670	5,526,575	11,717,169	8,643,449
Settlement Expense, net	430,000	1,030,000	430,000	1,030,000
Research and Product Development	2,958,276	1,558,946	3,455,552	3,225,302
Operating Loss	(10,370,794)	(12,296,903)	(19,180,555)	(18,015,707)
Other Income				
Realized Gain (Loss) on Investments	4,135	(122,095)	18,023	(124,987)
Interest Income	74,476	188,206	192,002	360,381
Total Other Income	78,611	66,111	210,025	235,394
Net Loss	$ (10,292,183)	$ (12,230,792)	$ (18,970,530)	$ (17,780,313)
Basic and Diluted Net Loss per Share	$ (0.18)	$ (0.24)	$ (0.33)	$ (0.35)
Basic and Diluted Weighted Average Shares Outstanding	58,216,066	51,288,424	57,660,947	51,288,424