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): **October 24, 2019**

ROCKWELL MEDICAL, INC.

(Exact name of registrant as specified in its charter)

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

411 Hackensack Ave., Suite 501, Hackensack, NJ 07601
(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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o 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, par value $0.0001 per share	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 o

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. o

Item 2.02 Results of Operations and Financial Condition.

On October 24, 2019, Rockwell Medical, Inc. issued a press release announcing its financial results for the quarter ended September 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 October 24, 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: October 24, 2019

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

Exhibit 99.1

FOR IMMEDIATE RELEASE

Rockwell Medical, Inc. Provides Business Update

– Encouraging progress for Triferic® portfolio –
– Conference call at 8:30 am ET on Friday, October 25, 2019 –

WIXOM, Mich., October 24, 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), today provided a business update and information related to the launch of Dialysate Triferic® (ferric pyrophosphate citrate), and reported preliminary third quarter 2019 financial results. The Company will host a conference call on Friday, October 25, 2019 at 8:30 am ET to review these updates.

"Our mission is to transform anemia management in a wide variety of disease states across the globe while improving patients' lives. We believe Triferic is one of the most innovative advancements in patient iron management over the last two decades. Accordingly, we are building the foundation to become a leading medical and commercial organization in the field of dialysis, which we believe will enable Triferic to become the standard of care for ESRD patients. To that end, we are pleased with the early progress we are making with the commercialization of our Triferic portfolio," stated Stuart Paul, President and Chief Executive Officer of Rockwell Medical.

Dialysate Triferic U.S. Market Introduction Highlights

Key highlights and early learnings include:

- Most clinics require a three month product trial before committing to commercial purchase. As a result, the Company launched an Evaluation Program to enable clinics to utilize Dialysate Triferic at no cost for up to three months.

- The sales cycle to convert a new account has been approximately 5-6 months on average, which includes initial contact, the Evaluation Program, and on-boarding.

- Key metrics for Dialysate Triferic adoption include:

    - Entered into contracts with 13 clinics for the purchase of Dialysate Triferic as of September 30, 2019, representing more than 1,000 patients. This translates to more than 150,000 annualized treatments with Dialysate Triferic;

    - More than 15 additional clinics, representing over 1,300 patients, are at various stages of an Evaluation Program; and

- To date, more than 75% of clinics that initiated and completed an Evaluation Program since launch have entered into contracts to purchase Dialysate Triferic.

Building a Leading Medical Platform

Rockwell Medical is committed to and focused on enhancing its medical capabilities. Key highlights and progress to date include:

- The Company entered into its first contract with a Center of Excellence for the purchase of Dialysate Triferic during the third quarter of 2019. The Company defines Centers of Excellence as leading independent academic institutions that operate their own clinics or leading nephrology practices that are recognized as thought leaders in dialysis.

- Rockwell Medical is working with early adopters of Dialysate Triferic, including Centers of Excellence, to collect and analyze real-world data. The Company expects to generate an ongoing stream of data publications, case studies and white papers to enhance the value proposition for Triferic.

    - The Company is collecting real-world data from seven dialysis clinics totaling more than 500 patients, including five clinics associated with a medium dialysis organization and two clinics affiliated with a Center of Excellence, as of September 30, 2019.

    - The Company expects the first meaningful data readouts from these relationships to occur during the first quarter of 2020.

- Rockwell Medical expects to announce updates to its Medical Advisory Board during the fourth quarter of 2019, including the addition of world-renowned experts in anemia and ESRD.

Other Business Updates

- The Company submitted comments to the Centers for Medicare & Medicaid Services (CMS) on the 2020 Proposed Rule for the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS), highlighting the innovative nature of I.V. Triferic, as well as the importance of the Transitional Drug Add-On Payment Adjustment (TDAPA) to incentivize innovation and competition. A final ruling from CMS is expected in early November 2019.

- Rockwell Medical is engaged with the U.S. Food and Drug Administration (FDA) on normal course review activities regarding the I.V. Triferic New Drug Application. The Company remains on track for a PDUFA date of March 28, 2020.

Preliminary Financial Results

The Company estimates net sales for the three months ended September 30, 2019 will be in the range of $15.0 million to $15.4 million. Net sales of Dialysate Triferic are estimated to be in the range of $90,000 to $100,000 for the third quarter of 2019. Ending cash, cash equivalents and investments as of September 30, 2019 were approximately $29.0 million. The change in cash,

cash equivalents and investments for the three months ending September 30, 2019 was approximately ($6.2) million.

These current preliminary, estimated results of operations are based on management's initial review of operations for the three months ended September 30, 2019, and remain subject to completion of the Company's customary closing and review procedures, final adjustments and other developments that may arise between now and the time the financial results for the three months ended September 30, 2019 are finalized. It is possible that the final reported results for the three months ended September 30, 2019 may differ materially from the estimates provided in this release.

"Our efforts to drive adoption of our Triferic portfolio include: the U.S. market introduction of Dialysate Triferic, building a leading medical platform in the field of dialysis, the potential approval of I.V. Triferic in the U.S. in 2020, and continued progress in international market development. We are especially encouraged that more than 75% of the dialysis centers that have initiated and completed our Evaluation Program since launch have now converted to commercial customers who purchase Triferic," concluded Mr. Paul.

Conference Call

Rockwell Medical management will host a conference call to discuss the business update and preliminary third quarter 2019 financial results with dial-in details as follows:

Date	Friday, October 25, 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/mmc/p/5myjode4

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.

Important Safety Information

Serious hypersensitivity reactions, including anaphylactic-type reactions, some of which have been life-threatening and fatal, have been reported in patients receiving parenteral iron products. Patients may present with shock, clinically significant hypotension, loss of consciousness, and/or collapse. Monitor patients for signs and symptoms of hypersensitivity during and after hemodialysis until clinically stable. Personnel and therapies should be immediately available for the treatment of serious hypersensitivity reactions. Hypersensitivity reactions have been reported in 1 (0.3%) of 292 patients receiving Triferic in two randomized clinical trials.

Iron status should be determined on pre-dialysis blood samples. Post dialysis serum iron parameters may overestimate serum iron and transferrin saturation.

The most common adverse reactions (≥3% and at least 1% greater than placebo) in controlled clinical studies include: procedural hypotension (21.6%), muscle spasms (9.6%), headache (9.2%), pain in extremity (6.8%), peripheral edema (6.8%), dyspnea (5.8%), back pain (4.5%), pyrexia (4.5%), urinary tract infection (4.5%), asthenia (4.1%), fatigue (3.8%), arteriovenous (AV) fistula thrombosis (3.4%), and AV fistula site hemorrhage (3.4%).

For more information, including full prescribing information, visit: http://www.triferic.com.

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 timing of data readouts; the timing for the ruling from CMS; 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
Investor Relations:
Lisa M. Wilson, In-Site Communications, Inc.
T: 212-452-2793
E: lwilson@insitecony.com

Source: Rockwell Medical, Inc.