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): **September 9, 2020**

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 Avenue, Suite 501, Hackensack, New Jersey 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:

☐ 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**	**Name of Each exchange on which registered**
Common Stock, par value $0.0001	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 8.01 Other Events.

On September 9, 2020, Rockwell Medical, Inc. (the "Company") issued a press release announcing that the Company has entered into an exclusive license agreement with Jeil Pharmaceutical Co., Ltd. for the rights to commercialize Triferic (ferric pyrophosphate citrate) in South Korea. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

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 September 9, 2020
104	Cover Page Interactive Data File, formatted in INline XBRL and included as Exhibit 101.

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: September 9, 2020

By: /s/ Russell Ellison

Russell Ellison

Chief Executive Officer

Exhibit 99.1

Rockwell Medical Enters into Exclusive License Agreement with Jeil Pharmaceutical Co., Ltd., for the Rights to Commercialize Triferic® in South Korea

-Sizable and growing market opportunity with over 78,000 patients receiving hemodialysis annually-

WIXOM, Mich., September 09, 2020 (GLOBE NEWSWIRE) -- Rockwell Medical, Inc. (Nasdaq: RMTI) ("Rockwell Medical" or the "Company"), a biopharmaceutical company dedicated to transforming the treatment of iron deficiency and anemia management and improving outcomes for patients around the world, today announced that it has entered into an exclusive license agreement with Jeil Pharmaceutical Co., Ltd. ("Jeil"), for the rights to commercialize Triferic (ferric pyrophosphate citrate) in South Korea.

Under the terms of the license agreement, Jeil will be the exclusive development and commercialization partner for Triferic in South Korea and Rockwell Medical will supply the product to Jeil. In consideration for the license, Rockwell Medical will receive an upfront fee, and will be eligible for milestone payments and royalties on net sales.

Jeil has developed and supplied pharmaceutical products and contributed to the growth and development of the pharmaceutical industry in Korea since its founding in 1959. Jeil, listed on the Korea Composite Stock Price (KOSPI) index since 1988, has approximately 1,000 employees and more than $576 million is sales for the year ended 2019. Jeil will leverage its strong development and commercialization capabilities and local market expertise to promote Triferic to nephrologists in South Korea. A Joint Alliance Committee, comprised of members from Rockwell Medical and Jeil, will guide the development and execution for Triferic in South Korea. Jeil will be responsible for all regulatory and commercialization activities. Product sales are anticipated to begin in early 2022, subject to regulatory approval.

"We are pleased to announce the license agreement with Jeil and the establishment of a relationship between our two companies," said Russell Ellison, M.D., President and Chief Executive Officer of Rockwell Medical. "With its substantial development and commercialization capabilities and local market expertise, Jeil is well positioned to ensure that hemodialysis patients have access to our innovative therapeutic across South Korea. Today's news marks another meaningful advancement for Triferic, as we expand our global footprint and drive the long-term value of Triferic."

"We welcome this opportunity to collaborate with Rockwell Medical to provide Triferic to patients on hemodialysis in South Korea," said Suk-Je Sung, President and Chief Execute Officer of Jeil. "There remains a significant unmet need for innovative medicine to address iron deficiency in these patients, with more than 78,000 patients receiving hemodialysis every year and we expect the number of CKD dialysis patients to continue to increase and double by 2030."

Torreya Partners acted as a financial advisor to Rockwell Medical for this transaction.

About Rockwell Medical

Rockwell Medical is a biopharmaceutical company dedicated to transforming iron deficiency and anemia management in a wide variety of therapeutic areas and across the globe, improving the lives of very sick patients. The Company's initial focus is the treatment of anemia in end-stage kidney disease (ESKD). Rockwell Medical's exclusive renal drug therapies, Triferic (ferric pyrophosphate citrate) Dialysate and

Triferic AVNU, are the only FDA-approved therapeutics 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 to dialysis providers and distributors in the U.S. and abroad.

About Triferic Dialysate and Triferic AVNU

Triferic Dialysate and Triferic AVNU are the only FDA-approved therapies in the U.S. indicated to replace iron and maintain hemoglobin in hemodialysis patients during each dialysis treatment. Triferic Dialysate and Triferic AVNU have a unique and differentiated mechanism of action, which has the potential to benefit patients and health care economics. Triferic Dialysate and Triferic AVNU represent a potential innovative medical advancement in hemodialysis patient iron management - with the potential to become the future standard of care.

Triferic Dialysate and Triferic AVNU both deliver approximately 5-7 mg iron with every hemodialysis treatment to the bone marrow and maintain hemoglobin without increasing iron stores (ferritin). Both formulations donate iron immediately and completely to transferrin (carrier of iron in the body) upon entry into the blood which 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 ESKD patients.

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%).

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, the receipt of an upfront fee and milestone payments and royalties by Rockwell Medical, the timing of product sales in South Korea, the receipt of regulatory approvals in South Korea and the potential market opportunity for Triferic in South Korea. Words such as, “may,” “might,” “will,” “should,” “believe,” “expect,” “anticipate,” “estimate,” “continue,” “could,” “can,” “would,” “develop,” “plan,” “potential,” “predict,” “forecast,” “project,”

"intend" or the negative of these terms, and 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, but are not limited to: the impact of the COVID-19 pandemic (including, applicable federal, state or local orders) on business and operating results; receipt of regulatory approval for Triferic in South Korea; our ability to achieve milestones and receive royalty payments; anticipated market opportunity in South Korea; and those risks more fully discussed in the "Risk Factors" section of our Quarterly Report on Form 10-Q for the period ended June 30, 2020 and of our Annual Report on Form 10-K for the year ended December 31, 2019, as such description may be amended or updated in any future reports we file with the SEC. Rockwell Medical expressly disclaims any obligation to update our forward-looking statements, except as may be required by law.

Triferic® is a registered trademark of Rockwell Medical, Inc. Triferic AVNU is pending with the U.S. Patent and Trademark Office. All other product names, logos, and brands are property of their respective owners in the United States and/or other countries. All company, product and service names used on this website are for identification purposes only. Use of these names, logos, and brands does not imply endorsement.

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