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): **May 17, 2021**

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.)

30142 S. Wixom Avenue, Wixom, Michigan 48393
(Address of principal executive offices, including zip code)

(248) 960-9009
(Registrant's telephone number, including area code)

411 Hackensack Avenue, Suite 501, Hackensack, New Jersey, 07601
(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 2.02 Results of Operations and Financial Condition.

On May 17, 2021, Rockwell Medical, Inc. issued a press release and earnings presentation announcing its financial results for the quarter ended March 31, 2021. The press release and earnings presentation are furnished as Exhibit 99.1 and Exhibit 99.2, respectively, to this Current Report on Form 8-K.

As provided in General Instruction B.2 of Form 8-K, the information in this Item 2.02 and Exhibits 99.1 and 99.2 incorporated in this Form 8-K shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, nor shall such information or Exhibits 99.1 and 99.2 be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

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 May 17, 2021
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: May 17, 2021

By: /s/ Russell Ellison
Russell Ellison
Chief Executive Officer

Rockwell Medical, Inc. Provides First Quarter 2021 Financial and Operational Update

-Home Infusion FPC Program expected to initiate Phase 2 trial in second half of 2021-

-Company received marketing approval in Canada for Triferic AVNU™-

-Conference call and webcast on Monday, May 17th at 4:30 p.m. ET-

WIXOM, Mich., May 17, 2021 (GLOBE NEWSWIRE) -- Rockwell Medical, Inc. (Nasdaq: RMTI), a biopharmaceutical company dedicated to transforming the treatment of iron deficiency and anemia management and improving outcomes for patients around the world, today reported financial results and a business update for the three months ended March 31, 2021.

“We continued to drive our business forward in the first quarter,” said Russell Ellison, M.D., M.Sc., President and Chief Executive Officer of Rockwell Medical. “We believe our Home Infusion FPC program remains on track for a pre-IND meeting with the FDA expected in the third quarter of this year, with multiple upcoming milestones, including our current expectation that the subsequent initiation of our Phase 2 clinical trial of FPC for the treatment of iron deficiency anemia in adult patients in the home infusion setting will commence in the second half of 2021. We also received marketing approval of Triferic AVNU in Canada, the first international regulatory approval for our intravenous therapy, and continued to generate solid revenue from concentrates, our base business, ending the quarter in a strong cash position.”

First Quarter 2021 Operational Highlights

Dialysis Business

- Revenue from hemodialysis concentrates was approximately $15.2 million.
- Revenue from Triferic was approximately $283,000 thousand. Rockwell Medical continues to generate data in clinics showing the benefits of Triferic in real world protocols.
- The Company announced in April that Triferic AVNU (ferric pyrophosphate citrate injection) received a Notice of Compliance (marketing approval) from Health Canada for the replacement of iron to maintain hemoglobin in adult patients with hemodialysis-dependent chronic kidney disease. Rockwell Medical expects Triferic AVNU to become commercially available in Canada during 2022.

Home Infusion Program

- As previously announced, the U.S. Food and Drug Administration (FDA) accepted the Company’s proposed development strategy to pursue an approval via the 505(b)(1)

pathway as a novel new drug application (NDA) for FPC for treatment of iron deficiency anemia (IDA) in adult patients in the home infusion setting. Subject to a successful outcome of Rockwell Medical's pre-investigational new drug meeting with the FDA, the Company plans to initiate a Phase 2 clinical trial in the second half of 2021.

- In April, the Company presented data from a clinical feasibility study reviewing the practice patterns of iron deficiency anemia (IDA) in home parenteral nutrition patients at the National Home Infusion Association's (NHIA) 2021 Annual Conference. The study found that although approximately half of the patients in the home infusion setting suffer from IDA, and oral iron is indicated as a first-line therapy, many patients may not tolerate it, or may have unsatisfactory results with this option. The study results support the Company's initial assumptions that management of IDA in the home infusion population is suboptimal and remains an unmet clinical need.

Pipeline Development

- Rockwell Medical continues to explore the use of its FPC platform for the treatment of hospitalized patients with acute heart failure. Management currently believes that FPC may deliver rapidly bioavailable iron to the heart and improve cardiac energetics. This effect could help patients recover faster, resulting in shorter hospital stays and fewer 30-day re-admissions. The Company plans to have a meeting with the FDA in the second half of 2021.

First Quarter 2021 Selected Financial Highlights

The following discussion and analysis should be read in conjunction with our audited condensed consolidated financial statements and related notes on Form 10-K for the year ended December 31, 2020, and Form 10-Q for the quarter ended March 31, 2021.

Revenues were $15.5 million for the three months ended March 31, 2021, compared to $15.9 million for the three months ended March 31, 2020. Triferic revenue was $0.3 million for the three months ended March 31, 2021.

Cost of sales was $15.1 million for the three months ended March 31, 2021, resulting in gross profit of $0.4 million, compared to $14.7 million for the three months ended March 31, 2020, resulting in gross profit of $1.1 million.

Research and product development expenses were $1.8 million for the three months ended March 31, 2021 and 2020. The Company is continuing to invest in its medical and scientific programs to support the continued data and phase 4 clinical programs for Triferic in dialysis and the advancement of our FPC technology platform.

Selling and marketing expenses were $1.9 million during the three months ended March 31, 2021, compared with $2.1 million during the three months ended March 31, 2020. The decrease of $0.2 million is primarily due to a decrease in marketing costs related to Triferic

(dialysate) partially offset by a slight increase in costs associated with the launch of Triferic AVNU.

General and administrative expenses were $3.9 million during the three months ended March 31, 2021, compared with $5.3 million during the three months ended March 31, 2020. The decrease of $1.4 million is due primarily to a decrease in stock compensation of $1.3 million, relating to a decrease in incentive compensation from forfeited equity awards and the change in probability relating to performance award achievement; a decrease in legal costs of $0.2 million, relating to previous litigation that has since been resolved; and a decrease in insurance costs of $0.1 million, relating to reduced premiums; partially offset by an increase of $0.2 million for increased headcount and severance pay related to our former President and Chief Executive Officer.

Net loss was $7.2 million, or $(0.08) basic and diluted net loss per share for the three months ended March 31, 2021, compared to net loss of $8.10 million, or $(0.12) basic and diluted net loss per share for the three months ended March 31, 2020.

Cash, cash equivalents, and investments available-for-sale totaled $46.1 million as of March 31, 2021, compared to $58.7 million on December 31, 2020. Working capital was $48.0 million as of March 31, 2021, compared to $56.7 million as of December 31, 2020.

The Company has a debt facility of $35.0 million of which the first tranche of $22.5 million was funded in March 2020 and is classified as long-term debt on the balance sheet. The Company may be eligible to draw on a third tranche of $7.5 million upon the achievement of certain additional milestones, including the achievement of certain Triferic sales thresholds.

As of March 31, 2021, there were 93,599,519 shares of common stock outstanding.

First Quarter 2021 Business Update Conference Call and Webcast

Rockwell Medical's management team will host a conference call and audio webcast today, May 17, 2021, at 4:30 p.m. ET to discuss Q1 2021 financial results and provide a business update.

To access the conference call, please dial (877) 383-7438 (local) or (678) 894-3975 (international) at least 10 minutes prior to the start time and refer to conference ID 7870946. A live webcast of the call will be available under "Events & Presentations" in the Investor section of the Company's website, https://ir.rockwellmed.com/. An archived webcast will be available on the Company's website approximately two hours after the event and will be available for 30 days.

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 replace the ongoing losses to maintain hemoglobin without increasing iron stores. Both formulations donate iron immediately and completely to transferrin (carrier of iron in the body), which is then transported to the bone marrow to be incorporated into hemoglobin. Because of this unique mechanism of action, there is no increase in ferritin (a measure of stored iron). Triferic and Triferic AVNU address a significant medical need in treating functional iron deficiency in end-stage kidney disease patients.

The safety profile of Triferic is similar to placebo in controlled clinical trials in patients with end-stage kidney disease. Since approval, there have been no safety related changes to the product labeling.

IMPORTANT SAFETY INFORMATION FOR TRIFERIC AND TRIFERIC AVNU

INDICATION

TRIFERIC and TRIFERIC AVNU are indicated for the replacement of iron to maintain hemoglobin in adult patients with hemodialysis-dependent chronic kidney disease (HDD-CKD).

Limitations of Use

TRIFERIC and TRIFERIC AVNU are not intended for use in patients receiving peritoneal dialysis. TRIFERIC and TRIFERIC AVNU have not been studied in patients receiving home hemodialysis.

Warnings and Precautions

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.

Adverse Reactions

Most common adverse reactions (incidence ≥3% and at least 1% greater than placebo) in controlled clinical studies include: headache, peripheral edema, asthenia, AV fistula thrombosis, urinary tract infection, AV fistula site hemorrhage, pyrexia, fatigue, procedural hypotension, muscle spasms, pain in extremity, back pain, and dyspnea.

To report an Adverse Events (AE) or Product Quality Control (PQC) please call the Medical Information Department at (855) 333-4315 or e-mail at rockwell.pharmacovigilance@propharmagroup.com.

For full Safety and Prescribing Information please visit www.Triferic.com and www.Trifericavnu.com.

About Rockwell Medical

Rockwell Medical is a commercial-stage biopharmaceutical company developing and commercializing its next-generation parenteral iron technology platform, Ferric Pyrophosphate Citrate (FPC), which has the potential to lead to transformative treatments for iron deficiency in multiple disease states, reduce healthcare costs and improve patients' lives. The Company has two FDA-approved therapies indicated for patients undergoing hemodialysis, which are the first two products developed from the FPC platform. Rockwell Medical is also advancing its FPC platform by developing FPC for the treatment of iron deficiency anemia in patients outside of dialysis, who are receiving intravenous medications in the home infusion setting. In addition, Rockwell Medical is one of two major suppliers of life-saving hemodialysis concentrate products to kidney dialysis clinics in the United States. For more information, visit www.RockwellMed.com.

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 effectiveness of FPC in other indications, Triferic's ability to generate cost savings, our ability to grow our dialysis business, the development plans and timing for Rockwell Medical's FPC pipeline candidates, the timing and outcome of meetings with the FDA, the timing and outcome of foreign clinical trials and regulatory approval, the timing for the commencement of our clinical trial of FPC for treatment of IDA in adult patients in the home infusion setting and future trends related to our sales and marketing costs. Words such as, "may," "might," "will," "should," "believe," "expect," "anticipate," "estimate," "continue," "could," "can," "would," "develop," "plan," "potential," "predict," "forecast," "project," "intend" 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 continuance of the COVID-19 pandemic (including, applicable federal state or local orders) on business, labor availability and operating results, including our supply chain, dialysis concentrates business and the Company's commercialization of both pharmaceutical and medical device products; the challenges inherent in new product development, other new indications and therapeutics areas for our products; the success of our commercialization of Triferic (dialysate) and Triferic AVNU; the success and timing of international clinical trials for Triferic Dialysate; the success and timing of international regulatory and reimbursement approval for Triferic (dialysate) and Triferic AVNU; the success of our commercial launch of Triferic AVNU in the United States; the success and timing of the development of our FPC pipeline candidates, the risk that topline clinical data and real world data results may not demonstrate efficacy or may not be predictive of future results; expected financial performance, including cash flows, revenues, growth, margins, funding, liquidity and capital resources; and those risks more fully discussed in the "Risk Factors" section of our Annual Report on Form 10-K for the year ended December 31, 2020, 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.

Financial Tables Follow

ROCKWELL MEDICAL

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets
(Dollars in Thousands)

	March 31, 2021 (Unaudited)	December 31, 2020
ASSETS		
Cash and Cash Equivalents	$ 35,675	$ 48,682
Investments Available-for -Sale	10,464	9,997
Accounts Receivable, net of a reserve	6,597	4,171
Inventory	4,117	3,913
Prepaid and Other Current Assets	2,389	2,706
Total Current Assets	**59,242**	**69,469**
Property and Equipment, net	2,472	2,642
Inventory, Non-Current	1,325	1,176
Right of Use Assets, net	4,860	2,911
Goodwill	921	921
Other Non-current Assets	629	629
Total Assets	$ **69,449**	$ **77,748**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts Payable	$ 3,307	$ 4,155
Accrued Liabilities	4,032	5,013
Lease Liability - Current	1,417	1,167
Deferred License Revenue	2,170	2,175
Customer Deposits	135	152
Other Current Liability - Related Party	171	131
Total Current Liabilities	**11,232**	**12,793**
Lease Liability - Long Term	3,522	1,821
Term Loan, Net of Issuance Costs	21,041	20,949
Deferred License Revenue	7,476	8,015
Total Liabilities	**43,271**	**43,578**
Stockholders' Equity:		
Preferred Shares, $0.0001 par value, 2,000,000 shares authorized, no shares issued and outstanding at March 31, 2021 and December 31, 2020	—	—
Common Stock, $0.0001 par value,170,000,000 shares authorized, 93,599,519 and 93,573,165 shares issued and outstanding at March 31, 2021 and December 31,2020, respectively	9	9
Additional Paid-in Capital	371,274	371,510
Accumulated Deficit	(345,158)	(337,406)
Accumulated Other Comprehensive Income	53	57
Total Stockholders' Equity	**26,178**	**34,170**
Total Liabilities And Stockholders' Equity	$ **69,449**	$ **77,748**

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

	Three Months Ended March 31, 2021	Three Months Ended March 31, 2020
Net Sales	$ 15,473	$ 15,857
Cost of Sales	15,072	14,744
Gross Profit	401	1,113
Research and Product Development	1,809	1,822
Selling and Marketing	1,851	2,073
General and Administrative	3,923	5,273
Operating Loss	(7,182)	(8,055)
Other (Expense) Income		
Realized Gain on Investments	—	2
Interest Expense	(581)	(102)
Interest Income	11	171
Total Other (Expense) Income	(570)	71
Net Loss	$ (7,752)	$ (7,984)
Basic and Diluted Net Loss per Share	$ (0.08)	$ (0.12)
Basic and Diluted Weighted Average Shares Outstanding	93,591,053	67,518,240

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