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 31, 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)

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 2.02 Results of Operations and Financial Condition.

On March 31, 2021, Rockwell Medical, Inc. issued a press release and earnings presentation announcing its financial results for the quarter and year ended December 31, 2020. 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 31, 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: March 31, 2021

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

Exhibit 99.1

Rockwell Medical Provides Fourth Quarter and Full Year 2020 Financial and Operational Update

- 2020 revenue of $62.2 million-

-Ended the year with $58.7 million in cash, cash equivalents and investments –

-Conference call and webcast on Wednesday, March 31st at 4:30 p.m. ET-

WIXOM, Mich., March 31, 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 and full year ended December 31, 2020.

“2020 was an important year for us as we evolved our strategy to become a more medically-, scientifically- and data-driven company. There has been an evolution of both our management and Board, providing us with greater relevant experience,” said Russell Ellison, M.D., M.Sc., President and Chief Executive Officer of Rockwell Medical. “We believe these changes support an improved execution of our strategy to accelerate Rockwell Medical’s growth by creating and developing pharmaceutical products based on our Ferric Pyrophosphate Citrate ("FPC") technology for disease states where patients can benefit the most from an effective treatment for iron deficiency, while concurrently strengthening our dialysis business to drive incremental growth and efficiencies.”

Dr. Ellison added: “We’ve identified two areas beyond dialysis where we believe FPC will have the biggest impact: iron deficiency anemia in the home infusion setting and acute heart failure in hospitalized patients.”

Recent Operational Highlights

Dialysis Business

- Revenue from hemodialysis concentrates were $61.1 million in 2020.
- Revenue from Triferic were approximately $1.1 million in 2020.
- Results from a study, conducted by New York University and reported in Critical Care Medicine, showed $296,000 in cost savings from Triferic.

  The study, which was independent of Rockwell, reviewed the effects of long-term use of Triferic in a large outpatient dialysis clinic. The results showed substantial cost savings due to reductions in ESA and macromolecular IV iron use without impacting patient safety or hemoglobin targets. In a retrospective data review of 100 patients that were followed before and after implementation of Triferic dialysate, there was a relative

reduction in average weekly ESA dose of 26.4%, total use of IV iron replacement therapy decreased with a relative reduction in the use of all iron products (iron sucrose 65.7%, sodium ferric gluconate 98.2%) while anemia targets were met. This clinic determined that the reduction of these agents resulted in a net savings of more than $296,000 in one fiscal year.

- Triferic AVNU (ferric pyrophosphate citrate injection), the IV formulation of Triferic, was made commercially available to patients in the United States.
- Korea: In September 2020, Rockwell Medical partnered with Jeil Pharmaceutical Co., Ltd. for exclusive rights. In February 2021, Jeil filed a New Drug Application for Triferic (dialysate) and Triferic AVNU in Korea.
- China: In January 2021, Wanbang Biopharmaceuticals enrolled the first patient in a pivotal Phase 3 trial.
- India: In January 2020, Rockwell Medical and Sun Pharma entered into a licensing agreement, and Sun Pharma is in the regulatory process in India.
- Canada: In May 2020, Rockwell Medical announced the filing of a New Drug Submission with Health Canada for Triferic AVNU.

Home Infusion Program

- The U.S. Food and Drug Administration (FDA) has accepted our 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. Subsequent to a successful pre-investigational new drug meeting with the FDA, the Company plans to initiate a clinical study during the second half of 2021.

Pipeline Development

- Rockwell Medical is exploring the use of its FPC platform for the treatment of hospitalized patients with acute heart failure. Management 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 hold a Type C meeting with the FDA in the second half of 2021.

2020 Corporate Updates

- In December 2020, Rockwell Medical appointed industry leader and renowned life science industry executive, Ms. Andrea Heslin Smiley, to its Board of Directors. Ms. Smiley brings commercial experience and a deep expertise in clinical nurse educators.

- In September 2020, the Company appointed Russell L. Skibsted, M.B.A., as Executive Vice President, Chief Financial Officer and Chief Business Officer. Mr. Skibsted brings more than 25 years of experience in finance, global business development, capital raising, investor relations and operations.

- In June 2020, Rockwell Medical appointed industry leader and renowned authority on kidney disease, Allen R. Nissenson, M.D., F.A.C.P., to its Board of Directors. Dr. Nissenson brings clinical, regulatory and public policy expertise, combined with his senior executive experience at a large dialysis organization.

- In April 2020, the Company appointed Russell H. Ellison, M.D., M.Sc., as President and Chief Executive Officer. Dr. Ellison, who continues to serve as a member of the Rockwell Medical Board of Directors, brings broad medical, clinical development and corporate leadership experience to the role.

- In March 2020, Rockwell Medical appointed Robert S. Radie to its Board of Directors. Mr. Radie brings more than three decades of industry experience, working in senior executive roles with both public and private pharmaceutical and biotech companies.

Fourth Quarter and Full Year 2020 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.

Revenues were $15.2 million and $62.2 million for the three months and year ended December 31, 2020, respectively, compared to $15.5 million and $61.3 million for the three months and year ended December 31, 2019, respectively. Triferic revenue was $0.5 million and $1.1 million for the three months and year ended December 31, 2020, respectively. Triferic was launched in Q2 2019 via the sample evaluation program.

Cost of sales were $14.8 million and $59.5 million for the three months and year ended December 31, 2020, respectively, compared to $14.4 million and $58.5 million for the three months and year ended December 31, 2019, respectively. Cost of sales for the year ended December 31, 2020 resulted in gross profit of $2.7 million, compared to a gross profit of $2.8 million for the year ended December 31, 2019.

Research and product development expenses were $1.9 million and $7.1 million for the three months and year ended December 31, 2020, respectively, compared to $2.0 million and $6.9 million for the three months and year ended December 31, 2019, respectively. The increase of $0.2 million year over year is related to clinical trials and other product development expenses for Triferic. 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 $2.1 million and $7.9 million for the three months and year ended December 31, 2020, respectively, compared to $1.9 million and $9.1 million for the three months and year ended December 31, 2019, respectively. The decrease of $1.2 million year over year is due primarily to the decrease in marketing costs of $2.3 million, partially offset by an increase in costs associated with hiring, training and educating new employees of $1.1 million. The fluctuation in these costs is mainly due to the timing of the Triferic (dialysate) launch in the third quarter of 2019. We expect lower quarter-to-quarter fluctuations in sales and marketing costs going forward.

General and administrative expenses were $4.4 million and $16.2 million for the three months and year ended December 31, 2020, respectively, compared to $4.7 million and $21.0 for the three months and year ended December 31, 2019, respectively. The $4.8 million decrease year over year was driven primarily by decreases to stock compensation, legal, recruiting and consulting fees, partially offset by an increase in labor costs. The decrease in stock compensation primarily relates to the resignation of our former President and Chief Executive Officer, Stuart Paul, in April 2020 and former Chief Financial Officer effective July 2020.

Net loss was $8.7 million, or $(0.09) basic and diluted net loss per share, and $30.9 million, or $(0.41) basic and diluted net loss per share, for the three months and year ended December 31, 2020, respectively, compared to net loss of $7.3 million, or $(0.11) basic and diluted net loss per share, and $34.1 million, or $(0.56) basic and diluted net loss per share, for the three months and year ended December 31, 2019, respectively.

Cash, cash equivalents, and investments available-for-sale totaled $58.7 million as of December 31, 2020, compared to $67.3 million on September 30, 2020. Working capital was $56.7 million as of December 31, 2020, compared to $65.2 million as of September 30, 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 December 31, 2020, there were 93,573,165 shares of common stock outstanding.

Fourth Quarter and Full Year 2020 and Business Update Conference Call and Webcast

Rockwell Medical's management team will host a conference call and audio webcast today, March 31, 2021, at 4:30 p.m. ET to discuss Q4 and Full Year 2020 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 6154055. 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 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. Rockwell Medical's exclusive renal drug therapies, Triferic (ferric pyrophosphate citrate) Dialysate and Triferic AVNU, are the only FDA-approved therapeutics indicated for 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.

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 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)
(Unaudited)

	December 31, 2020	December 31, 2019
ASSETS		
Cash and Cash Equivalents	$ 48,682	$ 11,795
Investments Available-for-Sale	9,997	14,250
Accounts Receivable, net of a reserve of $9 for both 2020 and 2019	4,171	4,203
Inventory	3,913	3,647
Prepaid and Other Current Assets	2,706	2,979
Total Current Assets	**69,469**	**36,874**
Property and Equipment, net	2,642	2,433
Inventory, Non-Current	1,176	441
Right of Use Assets, net	2,911	3,213
Goodwill	921	921
Other Non-current Assets	629	435
Total Assets	$ 77,748	$ 44,317
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts Payable	$ 4,155	$ 3,018
Accrued Liabilities	5,013	4,518
Settlement Payable	—	104
Lease Liability - Current	1,167	1,493
Deferred License Revenue	2,175	2,234
Insurance Financing Note Payable	—	763
Customer Deposits	152	55
Other Current Liability - Related Party	131	189
Total Current Liabilities	**12,793**	**12,374**
Lease Liability - Long Term	1,821	1,781
Term Loan, Net of Issuance Costs	20,949	—
Deferred License Revenue	8,015	9,842
Total Liabilities	**43,578**	**23,997**
Stockholders' Equity:		
Preferred Shares, $0.0001 par value, 2,000,000 shares authorized, no shares issued and outstanding at December 31, 2020 and 2019	—	—
Common Stock, $0.0001 par value,170,000,000 shares authorized, 93,573,165 and 65,378,890 shares issued and outstanding at December 31,2020 and 2019, respectively	9	7
Additional Paid-in Capital	371,510	326,777
Accumulated Deficit	(337,406)	(306,516)
Accumulated Other Comprehensive Income	57	52
Total Stockholders' Equity	**34,170**	**20,320**
Total Liabilities And Stockholders' Equity	$ 77,748	$ 44,317

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Operations
(Dollars in Thousands, except per share amounts)
(Unaudited)

	Three Months Ended December 31, 2020	Three Months Ended December 31, 2019	Year Ended December 31, 2020	Year Ended December 31, 2019
Net Sales	$ 15,164	$ 15,490	$ 62,197	$ 61,308
Cost of Sales	14,780	14,379	59,472	58,464
Gross Profit (Loss)	384	1,111	2,725	2,839
Research and Product Development	1,909	1,956	7,092	6,886
Selling and Marketing	2,133	1,901	7,871	9,050
General and Administrative	4,416	4,657	16,182	20,998
Settlement Expense, net of Reimbursement	—	—	—	430
Operating Loss	(8,074)	(7,403)	(28,420)	(34,525)
Other (Expense) Income				
Realized Gain on Investments	—	6	8	30
Warrant Modification Expense	—	—	(837)	—
Interest Expense	(588)	(8)	(1,879)	(25)
Interest Income	(2)	103	238	392
Total Other Income	(590)	101	(2,470)	397
Net Loss	$ (8,664)	$ (7,302)	$ (30,890)	$ (34,128)
Basic and Diluted Net Loss per Share	$ (0.09)	$ (0.11)	$ (0.41)	$ (0.56)
Basic and Diluted Weighted Average Shares Outstanding	93,573,165	64,450,030	75,621,674	60,918,544

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