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): **November 15, 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)

N/A
(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 November 15, 2021, Rockwell Medical, Inc. issued a press release and earnings presentation announcing its financial results for the quarter ended September 30, 2021. The press release and earnings presentation are furnished as Exhibit 99.1 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 Exhibit 99.1 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 Exhibit 99.1 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 November 15, 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: November 15, 2021

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

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

- Third quarter net sales of $16.0 Million, up 6% sequential quarter-over-quarter and 5% year-over-year -

- Company recently submitted Investigational New Drug application with FDA for its proposed clinical trial of FPC as a treatment for iron deficiency anemia in patients receiving home infusion -

- Company recently presented Triferic® real world evidence update at ASN Kidney Week 2021; results from pilot observational analysis demonstrate maintenance of hemoglobin and reduction of total IV iron requirement in adult patients on Triferic receiving chronic hemodialysis -

-Q3 2021 conference call and webcast scheduled for today at 4:30 p.m. ET-

WIXOM, Mich., November 15, 2021 (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 reported financial results and a business update for the three months ended September 30, 2021.

"Driven by accelerating growth in dialysis concentrates products, Rockwell Medical delivered a strong third quarter, which saw an increase in net sales versus both the second quarter of 2021 and third quarter of last year," said Russell Ellison, M.D., M.Sc., President and Chief Executive Officer of Rockwell Medical. "We continue to make steady progress to develop and deliver innovative treatment to patients with iron deficiency anemia (IDA). We recently submitted an Investigational New Drug application (IND) for our proposed clinical trial of Ferric Pyrophosphate Citrate (FPC) as a treatment for IDA in patients receiving home infusion, which is the first potential study of its kind in this patient population. At ASN Kidney Week 2021 in early November, we presented a real-world evidence update reflecting results from a pilot observational analysis, which demonstrated maintenance of hemoglobin and reduction of total IV iron requirement in adult patients on Triferic receiving chronic hemodialysis," concluded Dr. Ellison.

Third Quarter 2021 Operational Highlights

Dialysis Business

- Third quarter revenue from hemodialysis concentrates was approximately $15.7 million. The Company is in the process of analyzing its supply chain to identify efficiencies, while actively exploring U.S. and international expansion of this business with its customers.

- Revenue from Triferic was approximately $280,000 in the third quarter. Rockwell Medical continues to generate data in clinics showing the benefits of Triferic when integrated into anemia management protocols. As part of this initiative and due to the current economic environment, the Company has adjusted its sales and marketing efforts for Triferic and Triferic AVNU and is seeking a commercial partner within the

United States. This decision was based on the dynamics of the hemodialysis market, including provider consolidation, the effects of the CMS bundled payment system and competitive product bundling tactics.

Home Infusion Program

- The Company submitted an IND application with the U.S. Food and Drug Administration (FDA) in support of its proposed Phase 2 clinical trial of FPC, designed for the treatment of iron deficiency anemia and maintenance of hemoglobin in patients receiving infusion therapy in the home setting. Following IND submittal, a sponsor must wait 30 calendar days before initiating any clinical trials. During this time, the FDA has an opportunity to review the IND for safety to assure that research subjects will not be subjected to unreasonable risk.

- Home infusion represents a large and rapidly growing segment of healthcare. According to the National Home Infusion Association, the number of patients served by home infusion therapy has grown from approximately 800,000 in 2010 to over 3,000,000 in 2019. The home infusion setting is expected to continue to expand, which has been further accelerated by the COVID-19 pandemic and the desire to reduce or eliminate hospital and or clinic exposure. Many patient groups requiring home infusion therapies suffer from diseases that are associated with an incidence of iron deficiency and anemia. For example, it is estimated that 40% to 55% of all home parenteral nutrition patients are iron deficient. Management believes, based on the Company's the Company's data with hemodialysis patients, that FPC as a home infusion therapy for iron deficiency anemia may have distinct advantages over currently available iron replacement therapy options.

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 expects to have a meeting with the FDA in the first half of 2022 to discuss the pathway for a potential clinical development program.

Third Quarter 2021 Selected Financial Highlights

The following discussion and analysis should be read in conjunction with our condensed consolidated financial statements and related notes on Form 10-Q for the third quarter ended September 30, 2021.

Net sales for the third quarter were $16.0 million compared to net sales of $15.3 million for the same period last year and $15.1 million in the second quarter of this year. The increase was primarily due to an increase in sales of dialysis concentrates products.

Net sales of hemodialysis concentrates were approximately $15.7 million in the third quarter of 2021, which was approximately $713,000 higher compared to the third quarter of 2020 and approximately $845,000 higher than the second quarter 2021. Total sales of Triferic were approximately $280,000, roughly flat versus the third quarter of 2020 and second quarter 2021.

Cost of sales for the third quarter of 2021 was $16.3 million, resulting in gross loss of $0.3 million, compared to cost of sales of $14.9 million and a gross profit of $0.3 million for the third quarter of 2020. Gross profit decreased by $0.6 million, primarily due to an increase in costs related to protocols implemented because of the ongoing COVID-19 pandemic and an increase in shipping, fuel, and labor costs.

Research and product development expenses were $1.2 million for the third quarter of 2021 compared to $1.7 million for the third quarter of 2020. The decrease of $0.5 million was primarily due to the timing of investments the Company is continuing to make in its medical and scientific programs to support the continued advancement of its FPC technology platform.

Selling and marketing expenses were $1.5 million for the third quarter of 2021 compared to $1.7 million for the third quarter of 2020. The decrease of $0.2 million is primarily due to a decrease in marketing costs related to Triferic (dialysate).

General and administrative expenses were $3.8 million for the third quarter of 2021 compared to $3.6 million for the third quarter of 2020. The increase of $0.2 million is due primarily to an increase in premiums for the Company’s director and officer insurance policy.

Net loss for the third quarter of 2021 was $7.5 million, or $0.08 per basic and diluted share, compared to a net loss of $7.4 million during the third quarter of 2020, or $0.10 per basic and diluted share.

Cash, cash equivalents and investments totaled approximately $33.2 million at the end of the third quarter 2021. Net cash used in operating activities was $7.1 million for the three months ended September 30, 2021, compared to net cash used in operating activities of $2.1 million for the three months ended September 30, 2020. Net cash used in operating activities was $24.5 million for the nine months ended September 30, 2021, compared to net cash used in operating activities of $21.1 million for the nine months ended September 30, 2020. The increase in cash used in operating activities in the first nine months of 2021 was primarily due to changes in current balance sheet accounts in the ordinary course of business of approximately $3.2 million, including an increase in net accounts receivable of $1.9 million and an increase in accounts payable and accrued expense of approximately $0.2 million.

As of September 30, 2021, there were 93,882,142 shares of common stock outstanding compared to 93,811,381 shares outstanding as of June 30, 2021.

Third Quarter 2021 and Business Update Conference Call and Webcast

Rockwell Medical's management team will host a conference call and audio webcast today at 4:00 p.m. ET to discuss Q3 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 7697945. 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 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 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. The Company is developing FPC for the treatment of iron deficiency in patients outside of dialysis, who are receiving intravenous medications in the home infusion setting, a large and rapidly growing segment of healthcare, and where these patients suffer from chronic diseases associated with high incidence of iron deficiency and anemia. 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.

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.

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 development plans and timing for Rockwell Medical’s FPC pipeline candidates, the timing and outcome of meetings with the FDA, including meetings regarding use of our FPC platform for the treatment of hospitalized patients with acute heart failure, the potential expansion of our hemodialysis concentrates business, the potential market for home infusion, and the benefit of FPC for the treatment of hospitalized patients with acute heart failure. 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 continuation 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 regulatory approval for Triferic (dialysate) and Triferic AVNU; 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; macroeconomic conditions; 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

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ROCKWELL MEDICAL, INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets
(unaudited)

	September 30, 2021 (Unaudited)	December 31, 2020
ASSETS		
Cash and Cash Equivalents	$ 23,390	$ 48,682
Investments Available-for -Sale	9,813	9,997
Accounts Receivable, net of a reserve	6,036	4,171
Inventory	4,028	3,913
Prepaid and Other Current Assets	2,815	2,706
Total Current Assets	**46,082**	**69,469**
Property and Equipment, net	2,507	2,642
Inventory, Non-Current	1,526	1,176
Right of Use Assets, net	6,934	2,911
Goodwill	921	921
Other Non-current Assets	729	629
Total Assets	$ **58,699**	$ **77,748**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts Payable	$ 4,834	$ 4,155
Accrued Liabilities	4,371	5,013
Lease Liability - Current	1,832	1,167
Deferred License Revenue	2,176	2,175
Insurance Financing Note Payable	1,312	—
Term Loan, Net of Issuance Costs	7,131	—
Customer Deposits	100	152
Other Current Liability - Related Party	—	131
Total Current Liabilities	**21,756**	**12,793**
Lease Liability - Long Term	5,226	1,821
Term Loan, Net of Issuance Costs	14,094	20,949
Deferred License Revenue	6,529	8,015
Total Liabilities	**47,605**	**43,578**
Stockholders' Equity:		
Preferred Shares, $0.0001 par value, 2,000,000 shares authorized, no shares issued and outstanding at September 30, 2021 and December 31, 2020	—	—
Common Stock, $0.0001 par value,170,000,000 shares authorized, 93,966,381 and 93,573,165 shares issued and outstanding at September 30, 2021 and December 31,2020, respectively	9	9
Additional Paid-in Capital	372,168	371,510
Accumulated Deficit	(361,139)	(337,406)
Accumulated Other Comprehensive Income	56	57
Total Stockholders' Equity	**11,094**	**34,170**
Total Liabilities And Stockholders' Equity	$ **58,699**	$ **77,748**

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

	Three Months Ended September 30, 2021	Three Months Ended September 30, 2020	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020
Net Sales	$ 15,988	$ 15,280	$ 46,599	$ 47,033
Cost of Sales	16,317	14,934	46,788	44,693
Gross (Loss) Profit	(329)	346	(189)	2,340
Research and Product Development	1,221	1,745	5,445	5,183
Selling and Marketing	1,541	1,669	4,860	5,738
General and Administrative	3,881	3,622	11,483	11,767
Operating Loss	(6,972)	(6,690)	(21,977)	(20,348)
Other (Expense) Income				
Realized Gain on Investments	—	4	(1)	8
Warrant Modification Expense	—	—	—	(837)
Interest Expense	(609)	(666)	(1,772)	(1,289)
Interest Income	—	2	17	239
Total Other Expense	(609)	(660)	(1,756)	(1,879)
Net Loss	$ (7,581)	$ (7,350)	$ (23,733)	$ (22,227)
Basic and Diluted Net Loss per Share	$ (0.08)	$ (0.10)	$ (0.26)	$ (0.32)
Basic and Diluted Weighted Average Shares Outstanding	93,882,142	71,811,322	93,726,629	69,594,167

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