

**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 9, 2020**

ROCKWELL MEDICAL, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

000-23661
(Commission File Number)

38-3317208
(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:

<u>Title of Each Class</u>	<u>Trading Symbol</u>	<u>Name of Each exchange on which registered</u>
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 9, 2020, Rockwell Medical, Inc. issued a press release and earnings presentation announcing its financial results for the quarter ended September 30, 2020. 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated November 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: November 9, 2020

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

Rockwell Medical, Inc. Provides Third Quarter 2020 Financial and Operational Update

-Ended the quarter with \$67.3 million in cash, cash equivalents and investments –

-Q3 2020 revenue of \$15.3 million-

-U.S. commercial launch of Triferic® AVNU expected in Q1 2021-

-Poised to enroll first patient in Phase 3 clinical trial of Triferic in China-

-Unveiled plans to develop FPC platform in new indications-

WIXOM, Mich., November 9, 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 iron deficiency 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, 2020.

“Rockwell Medical is sufficiently capitalized to drive value creation now, in the near-term and into the future, and we are working across three tracks concurrently: maximizing U.S. sales of Triferic and soon-to-be-launched Triferic AVNU; expanding the global commercial reach of Triferic through our key partners; and strategically developing new indications for our FPC platform,” said Russell Ellison, M.D., M.Sc., President and Chief Executive Officer of Rockwell Medical. “I am pleased to report that we have made important progress across all three tracks in the third quarter of 2020.”

Third Quarter 2020 Operational Highlights

U.S. Sales - Triferic Dialysate and Concentrates

- Net sales for the concentrates business were \$15.0 million and net sales for Triferic were \$0.3 million in the third quarter of 2020.
- There were approximately 3,400 contracted patients on therapy in the third quarter, representing approximately 500,000 annualized treatments.
- Rockwell continues to implement appropriate COVID-19 precautions to reduce the risk of possible exposure to employees. The Company has experienced no material impact on its supply chain to date. The Company continued to experience an impact on its sales and marketing efforts for Triferic Dialysate due to the restrictions put in place because of COVID-19.

Triferic AVNU – United States

Rockwell Medical expects to commercially launch Triferic AVNU in the United States in Q1 2021. Triferic AVNU will be reimbursed within the End Stage Renal Disease (“ESRD”) bundle payment that has been established for Medicare patients.

Triferic – Global Development and Commercialization

- Wanbang Biopharmaceutical, Rockwell’s partner in China, is poised to enroll the first patient in a pivotal Phase 3 trial for Triferic in China to support a filing for regulatory approval. Hemodialysis in China has continued to increase at a rapid rate in recent years, with over 600,000 hemodialysis patients in China, making it the largest single market in the world.
- Sun Pharma, Rockwell’s partner in India, submitted all regulatory appeal process documents to the Indian Central Drugs Standard Control Organization’s Technical Committee. Sun Pharma is navigating next steps due to the country’s temporary suspension of regulatory review due to COVID-19. India is a potentially attractive market for Triferic, with over 120,000 hemodialysis patients.
- In September 2020, Rockwell Medical entered into an exclusive license agreement with Jeil Pharmaceutical Co., Ltd. (“Jeil”), for the rights to commercialize Triferic in South Korea. Under the terms of the license agreement, Jeil will be the exclusive development and commercialization partner for Triferic in South Korea. In consideration for the license, Rockwell Medical received an upfront fee of \$200,000 and will be eligible for milestone payments and royalties on net sales. South Korea represents a sizable and growing market opportunity, with over 78,000 patients receiving hemodialysis annually.

New Indications for Ferric Pyrophosphate Citrate (“FPC”) Platform:

- In September 2020, the Rockwell Medical management team, in conjunction with leading key opinion leaders (“KOLs”), announced the Company’s growth plan and new therapeutic opportunities for its FPC platform:
 - The Company’s priority new indication to pursue is FPC for the treatment of iron deficiency in patients requiring home infusion therapy, a rapidly growing area of medicine, with more than 3.2 million patients served in 2019. Iron deficiency anemia (“IDA”) is a common co-morbidity in many sub-groups of patients receiving home infusion therapy, particularly in those receiving long-term home parenteral nutrition (“HPN”). Rockwell Medical believes that FPC is uniquely suited for the treatment of IDA in the home infusion population based upon its kinetic profile and outstanding safety profile in both clinical trials and post-marketing use, and may fill an unmet clinical need as a uniquely suitable home infusion therapy for treatment of IDA. Rockwell Medical intends to hold a Type C meeting with the FDA in Q1 2021 to discuss the pathway for clinical development and anticipates conducting a Phase II observational study and a

dose scheduling study to achieve proof-of-concept, with data expected to report around the end of 2021.

- The Company is evaluating the potential of FPC to improve cardiac function in hospitalized acute heart failure patients. Heart failure in the U.S. has a large and growing patient population, with more than one million patients hospitalized each year with acute decompensated heart failure; iron deficiency (“ID”) is a common co-morbidity.

Third Quarter 2020 Corporate Updates

- In September 2020, Rockwell Medical appointed Russell L. Skibsted, M.B.A., as Executive Vice President, Chief Financial Officer and Chief Business Officer. Mr. Skibsted is a seasoned executive with more than 25 years of experience in finance, global business development, capital raising, investor relations, and operations. He has worked with a variety of both public and private life sciences companies, from commercial stage, development stage and start up.

Third Quarter 2020 Selected Financial Highlights

The following discussion and analysis should be read in conjunction with our unaudited condensed consolidated financial statements and related notes on Form 10-Q for the third quarter ended September 30, 2020.

Net sales for the third quarter of 2020 were \$15.3 million, a decrease of 0.8% compared to net sales of \$15.4 million for the third quarter of 2019. The decrease was primarily due to a decrease in international sales of our dialysis concentrates products. Triferic net sales for the three months ended September 30, 2020, were approximately \$0.3 million. Triferic was launched in Q2 2019 via the sample evaluation program and there were nominal revenues during the three months ended September 30, 2019.

Cost of sales for the third quarter of 2020 was \$14.9 million, resulting in gross profit of \$0.3 million, compared to cost of sales of \$15.4 million and a nominal gross loss during the third quarter of 2019. Gross profits are primarily related to our concentrates business at this time.

Selling and marketing expenses were \$1.7 million for the third quarter of 2020 compared to \$1.8 million for the third quarter of 2019.

General and administrative expenses were \$3.6 million for the third quarter of 2020 compared to \$4.6 million for the third quarter of 2019. The decrease of \$1.0 million was primarily due to a decrease in incentive compensation from forfeited equity awards associated with the departure of our former Chief Financial Officer in July 2020, a decrease in consulting expense relating to strategic development, a decrease in accounting costs relating to a decrease in internal audit fees; partially offset by severance pay related to our former President and Chief Executive Officer.

Research and product development expenses were \$1.7 million for the third quarter of 2020 compared to \$1.5 million for the third quarter of 2019. The increase in costs relate to our scientific programs. The Company is continuing to invest in its medical and scientific programs to support the global launch of Triferic and the advancement of our FPC technology platform.

Net loss for the third quarter of 2020 was \$7.4 million, or \$0.10 per basic and diluted share, compared to a net loss for third quarter of 2019 of \$7.9 million, or \$0.12 per basic and diluted share.

Cash, cash equivalents, and investments available-for-sale totaled \$67.3 million as of September 30, 2020, compared to \$40.0 million on June 30, 2020. Working capital was \$65.2 million as of September 30, 2020, compared to \$40.0 million as of June 30, 2020.

On September 25, 2020, Rockwell Medical closed a registered direct offering of 23,178,809 of its shares of common stock (or common stock equivalents in lieu thereof) and short-term warrants to purchase up to an aggregate of 23,178,809 shares of common stock to several healthcare-focused and other institutional investors. The gross proceeds from the registered direct offering were \$35.0 million before deducting placement agent fees and other offering expenses. The Company intends to use the net proceeds to advance the development of FPC, currently indicated for the maintenance of hemoglobin in dialysis, in new indications, including for the treatment of anemia in the home infusion setting, as well as for working capital and general corporate purposes.

Additionally, 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 September 30, 2020, there were 93,573,165 shares of common stock outstanding versus 70,156,922 shares outstanding as of June 30, 2020.

Third Quarter 2020 and Business Update Conference Call and Webcast

Rockwell Medical's management team will host a conference call and audio webcast today at 4:30 p.m. ET to discuss Q3 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 7679074. 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 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 ($\geq 3\%$ 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 impact of COVID-19 on Rockwell Medical’s business and operations, the commercialization of Triferic Dialysate, the launch of Triferic AVNU, expected reimbursement for Triferic AVNU, the development plans and timing for Rockwell Medical’s FPC pipeline candidates, the patient enrollment in a clinical trial and regulatory filings in China, regulatory approval in India and estimated market sizes. 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, including our supply chain, dialysis concentrates business and the commercial launch of Triferic AVNU; the challenges inherent in new product development and other indications and therapeutics areas for our products; the success of our commercialization strategy; the success and timing of our commercialization of Triferic Dialysate; the success and timing of international clinical trials for Triferic Dialysate; the success and timing 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 results 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 Quarterly Report on Form 10-Q for the period ended September 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.

Financial Tables Follow

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

	September 30, 2020 (Unaudited)	December 31, 2019
ASSETS		
Cash and Cash Equivalents	\$ 56,614	\$ 11,794
Investments Available-for-Sale	10,702	14,250
Accounts Receivable, net	4,129	4,203
Inventory, net	3,877	3,647
Prepaid and Other Current Assets	2,621	2,980
Total Current Assets	77,943	36,874
Property and Equipment, net	2,785	2,433
Inventory, Non-Current	859	441
Right of Use Assets, net	2,099	3,213
Goodwill	921	921
Other Non-Current Assets	629	435
Total Assets	\$ 85,236	\$ 44,317
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts Payable	\$ 4,190	\$ 3,018
Accrued Liabilities	4,968	4,518
Settlement Payable	-	104
Lease Liability - Current	1,155	1,493
Deferred License Revenue - Current	2,180	2,234
Insurance Financing Note Payable	-	763
Customer Deposits	73	55
Other Current Liability - Related Party	142	188
Total Current Liabilities	12,708	12,373
Lease Liability - Long-Term	1,039	1,781
Term Loan, Net of Issuance Costs	20,856	-
Deferred License Revenue - Long-Term	8,558	9,843
Total Liabilities	43,161	23,997
Stockholders' Equity:		
Preferred Stock, \$0.0001 par value, 2,000,000 shares authorized; no shares issued and outstanding at September 30, 2020 and December 31, 2019	-	-
Common Stock, \$0.0001 par value; 170,000,000 shares authorized; 93,573,165 and 65,378,890 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	9	7
Additional Paid-in Capital	370,760	326,777
Accumulated Deficit	(328,743)	(306,516)
Accumulated Other Comprehensive Income	49	52
Total Stockholders' Equity	42,075	20,320
Total Liabilities and Stockholders' Equity	\$ 85,236	\$ 44,317

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

<i>In thousands of US dollars (\$) except per share amounts</i>	Three Months Ended September 30, 2020	Three Months Ended September 30, 2019	Nine Months Ended September 30, 2020	Nine Months Ended September 30, 2019
Net Sales	\$ 15,280	\$ 15,407	\$ 47,033	\$ 45,812
Cost of Sales	14,934	15,424	44,693	44,085
Gross Profit	346	(17)	2,340	1,727
Selling and Marketing	1,669	1,827	5,738	7,149
General and Administrative	3,622	4,623	11,767	16,341
Settlement Expense	-	-	-	430
Research and Product Development	1,745	1,475	5,183	4,930
Operating Loss	(6,690)	(7,942)	(20,348)	(27,123)
Other Income (Expense)				
Realized Gain on Investments	4	6	8	24
Warrant Modification Expense	-	-	(837)	-
Interest Expense	(666)	(16)	(1,289)	(16)
Interest Income	2	97	239	289
Total Other Income	(660)	87	(1,879)	297
Net Loss	\$ (7,350)	\$ (7,855)	\$ (22,227)	\$ (26,826)
Basic and Diluted Net Loss per Share	\$ (0.10)	\$ (0.12)	\$ (0.32)	\$ (0.45)
Basic and Diluted Weighted Average Shares Outstanding	71,811,322	63,796,723	69,594,167	59,728,446

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