

**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 14, 2022**

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 Road, 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:

<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 Capital 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 14, 2022, Rockwell Medical, Inc. issued a press release and earnings presentation announcing its financial results for the quarter ended September 30, 2022. 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated November 14, 2022
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 14, 2022

By: /s/ Mark Strobeck
Mark Strobeck
Chief Executive Officer

Rockwell Medical Provides Business Strategy Update and Announces Third Quarter 2022 Financial and Operational Results

- *Rockwell is restructuring its business in the short-term to drive revenue and expansion opportunities in the growing hemodialysis market and through international pharmaceutical sales*
- *By making this strategic shift, Rockwell expects to achieve profitability in 2024, strengthen its overall financial position, and reduce the Company's reliance on the capital markets to fund future business growth*
- *Rockwell amended its long-term debt agreement to align with its updated strategic direction; Reduced debt from \$15 million to \$10 million*
- *Revenue was \$18.7 million for the third quarter 2022, which represents the highest quarterly revenue to-date for Rockwell*
- *Cash used in operating activities was \$1.1 million for the third quarter 2022, an 81% decrease over the second quarter 2022*

Wixom, Michigan, November 14, 2022 – Rockwell Medical, Inc. (“Rockwell” or the “Company”) (Nasdaq: RMTI), a commercial healthcare company focused on providing life-sustaining products for patients suffering from blood disorders and diseases associated with the kidney, today provided an update on its overall business strategy and announced its financial and operational results for the third quarter ended September 30, 2022.

BUSINESS STRATEGY UPDATE

During the third quarter of 2022, Rockwell Medical evaluated its businesses and the potential for short- and long-term value. Going forward, Rockwell will focus its efforts on growing the Company's revenue-generating businesses, which currently include its hemodialysis concentrates business and international partnerships for TRIFERIC[®], pausing further investment in capital-intensive pharmaceutical development programs, and achieving profitability to put the Company in a stronger and more stable financial position. As a result of these efforts, Rockwell expects to achieve profitability in 2024. Once the Company achieves profitability and sustains cash flow from its revenue-generating businesses, it will then consider investments in higher value, longer-term products to develop a broader kidney care products portfolio.

Subsequent to the third quarter of 2022, Rockwell announced that it is reacquiring its distribution rights to its hemodialysis concentrates products from Baxter and has agreed to terminate the exclusive distribution agreement dated October 2, 2014. Rockwell will acquire more than 700 hemodialysis concentrates customers including hospitals, medical centers, dialysis centers, and health systems, and will begin selling directly to new customers throughout the United States and internationally. With Rockwell's current customers and projected growth, the Company believes that it will be able to achieve \$100 million in revenue annually in the next few years. Furthermore, this transaction allows Rockwell to drive its overall business to profitability, to improve the Company's financial position, to maximize revenue, and to unlock the value of its manufacturing and distribution capabilities.

Exhibit 99.1

Rockwell is the second largest supplier of life-sustaining hemodialysis concentrates products to dialysis clinics in the United States. Collectively, this strategic focus affords Rockwell the opportunity to expand its leadership position within a large market opportunity, which currently is valued at \$380 million and is anticipated to grow to approximately \$500 million by 2026 in the United States alone.

“In light of a very challenging macroeconomic environment, we are pleased with our performance for the third quarter of 2022. We generated our largest quarterly revenue to date, significantly reduced our cash burn rate, and reduced our outstanding debt,” said [Mark Strobeck, Ph.D.](#), Rockwell Medical's President and CEO. “The decisions we have made, and continue to make, are consistent with our strategy going forward, which is focused on growing Rockwell’s revenue-generating businesses and achieving profitability in 2024 to put the Company in a stronger and more stable financial position. If successful, we expect that our cash balance will be sufficient to fund operations going forward, thereby reducing our reliance on raising money in the capital markets to fund our operations.”

FINANCIAL HIGHLIGHTS

- Revenue for the three months ended September 30, 2022 was \$18.7 million, which represents a slight increase over second quarter 2022 revenue and the highest quarterly revenue to-date for Rockwell, and a 16.9% increase year-over-year compared to \$16.0 million for the three months ended September 30, 2021. Revenue for the nine months ended September 30, 2022 was \$53.5 million, which represents a 14.8% increase year-over-year compared to \$46.6 million for the nine months ended September 30, 2021. The Company projects total annual revenue for 2022 to be between \$65 million and \$70 million, which would represent up to a 13% increase over \$61.9 million for 2021.
- Cash used in operating activities for the three months ended September 30, 2022 was \$1.1 million, compared to \$5.8 million for the three months ended June 30, 2022, representing an 81% decrease quarter-over-quarter.
- Cash and cash equivalents at September 30, 2022 was \$27.6 million compared to cash and cash equivalents of \$30.8 million at June 30, 2022 and \$22.4 million at December 31, 2021. The variance in cash used in operating activities and cash and cash equivalents for the three months ended September 30, 2022 is attributable to paying down debt over the quarter.
- Subsequent to the third quarter of 2022, Rockwell reduced its long-term debt to \$10 million following a pre-payment of \$5 million. This enables the Company to reduce its interest expense over the next year by agreeing to a ten-month interest-only period starting with its first payment on December 1, 2022 and ending on its last payment on September 1, 2023. Taking into account this debt prepayment, the Company’s cash and cash equivalents as of September 30, 2022 would have been \$22.6 million. This is compared to March 31, 2022 when Rockwell’s outstanding debt was \$19.5 million and cash balance was \$9.9 million.

OPERATING HIGHLIGHTS

- Over the third quarter of 2022, Rockwell’s ability to meet demands for its hemodialysis concentrates products remained consistent despite the Company’s suppliers experiencing raw materials, equipment, and fuel challenges. Demand for Rockwell’s products remains high as other companies continue to face challenges supplying customers.

Exhibit 99.1

- In the third quarter of 2022, Rockwell’s partner, Jeil Pharmaceutical, commercially launched TRIFERIC® in South Korea. Rockwell recognized revenue associated with its license and supply agreements with Jeil totaling \$5,200 and \$0.3 million for the three and nine months ended September 30, 2022, respectively. Rockwell remains focused on supporting its six international partnerships in China, India, Korea, Turkey, Peru, and Chile with organizations that have exclusive license agreements to develop and commercialize TRIFERIC® in their respective regions.
- To align with the Company’s updated strategic direction, Rockwell discontinued its New Drug Applications (“NDAs”) for TRIFERIC® and TRIFERIC® AVNU in the United States. Sustaining TRIFERIC® commercially in the United States resulted in a loss to Rockwell of approximately \$2 million to \$3 million, annually. The decision to discontinue the NDAs was not made lightly as the Company realizes the direct impact this action has on patients currently using these products. TRIFERIC® and its approved presentations were not discontinued for safety reasons.
- During the third quarter of 2022, Rockwell conducted a microbiological and short-term stability study of Ferric Pyrophosphate Citrate (“FPC”) for Home Infusion, in accordance with FDA guidance, to support the Company’s Investigational New Drug (“IND”) application. Preliminary results from the microbiology and short-term stability study indicated that the program would likely not meet the FDA’s requirements to support the IND application and would require significant capital expenditure and resources to conduct additional re-formulation work and a Phase 2 study. As a result, the Company has put development work associated with FPC for Home Infusion on hold.
- Rockwell will conduct a pre-IND meeting with the FDA in the fourth quarter of 2022 to discuss the development plan for FPC in Acute Heart Failure and once completed, Rockwell will determine the path forward for this program as the Company works towards profitability.
- During and subsequent to the third quarter of 2022, Rockwell undertook workforce reductions as part of its business restructuring.

Rockwell Medical’s Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2022 will provide a full analysis of the Company’s business strategy as well as its third quarter 2022 results.

CONFERENCE CALL AND WEBCAST DETAILS

Please call 10 minutes prior to the call to register.

Date: Monday, November 14, 2022

Time: 8:00am ET

Webcast: www.RockwellMed.com/Results

Live Number: (888) 660-6347 // (International) 1 (929) 201-6594

Replay Number: (800) 770-2030 // (International) 1 (647) 362-9199 *A replay will be available via the replay number and webcast through December 14, 2022.*

Access Code: 4944610

Exhibit 99.1

Speakers: Mark Strobeck, Ph.D., President and Chief Executive Officer; and Paul McGarry, SVP, Finance and Chief Accounting Officer

Format: Discussion of Rockwell Medical's overall business strategy and third quarter of 2022 operational and financial results followed by Q&A.

About Rockwell Medical

Rockwell Medical is a commercial healthcare company focused on providing life-sustaining products for patients suffering from blood disorders and diseases associated with the kidney. Rockwell is an innovative leader in producing and delivering a portfolio of hemodialysis products, including concentrates (solutions and powders) and related ancillaries, to dialysis providers in the United States and internationally. Rockwell is the second largest supplier of acid and bicarbonate concentrates for dialysis patients in the United States. The Company is dedicated to providing the hemodialysis community with the highest quality products supported by the most reliable delivery service in the industry. 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. Words such as, "may," "might," "will," "should," "believe," "expect," "anticipate," "estimate," "continue," "could," "can," "would," "develop," "plan," "potential," "predict," "forecast," "project," "intend," "look forward to," "remain confident" or the negative of these terms, and similar expressions, or statements regarding intent, belief, or current expectations, are forward looking statements. There can be no assurance that: Rockwell Medical will achieve its projected total annual revenue for 2022 and beyond; Rockwell Medical will be able to achieve planned cost savings to operate its concentrates business profitability or achieve the other components of its strategy; Rockwell Medical will achieve profitability; termination of the exclusive distribution agreement with Baxter will help improve Rockwell's balance sheet or long-term viability; or Rockwell Medical's future cash balance will be sufficient to fund operations going forward. 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 those risks more fully discussed in the "Risk Factors" section of our Annual Report on Form 10-K for the year ended December 31, 2021, 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.

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INVESTOR RELATION CONTACT:

Heather R. Hunter
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Financial Tables Follow
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ROCKWELL MEDICAL, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS

(Dollars In Thousands)

	September 30, 2022 (Unaudited)	December 31, 2021
Cash and Cash Equivalents	\$ 27,564	\$ 22,438
Total Assets	\$ 54,186	\$ 48,574
Total Liabilities	\$ 38,050	\$ 46,039
Total Stockholders' Equity	\$ 16,136	\$ 2,535
Common Stock Outstanding	11,152,673	8,544,225
Common stock and common stock equivalents*	20,056,596	11,511,666
*Common stock and common stock equivalents:		
Common stock	11,152,673	8,544,225
Preferred stock converted	1,363,636	—
Common stock warrants (pre-funded)	7,311,000	—
Common stock and pre-funded stock warrants	19,827,309	8,544,225
Options to purchase common stock	1,311,691	528,591
Restricted stock awards	891	7,118
Restricted stock units	125,000	29,289
Common stock warrants	9,944,378	2,402,442
Total common stock and common stock equivalents	31,209,269	11,511,666

ROCKWELL MEDICAL, INC. AND SUBSIDIARIES
UNAUDITED CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS

(In Thousands, Except Shares and Per Share Amounts)

	Three Months Ended September 30, 2022	Three Months Ended September 30, 2021	Nine Months Ended September 30, 2022	Nine Months Ended September 30, 2021
Net Sales	\$ 18,691	\$ 15,988	\$ 53,497	\$ 46,599
Cost of Sales	17,914	16,317	51,760	46,788
Gross Profit (Loss)	777	(329)	1,737	(189)
Research and Product Development	469	1,221	2,963	5,445
Selling and Marketing	762	1,541	1,743	4,860
General and Administrative	3,254	3,881	11,845	11,483
Operating Loss	(3,708)	(6,972)	(14,814)	(21,977)
Other (Expense) Income				
Realized Gain on Investments	—	—	4	(1)
Interest Expense	(476)	(609)	(1,497)	(1,772)
Interest Income	(6)	—	(10)	17
Total Other Expense	(482)	(609)	(1,503)	(1,756)
Net Loss	\$ (4,190)	\$ (7,581)	\$ (16,317)	\$ (23,733)
Basic and Diluted Net Loss per Share	\$ (0.40)	\$ (0.89)	\$ (1.75)	\$ (2.79)
Basic and Diluted Weighted Average Shares Outstanding	10,528,148	8,534,740	9,229,788	8,520,603