# 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): **December 14, 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 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 8.01 Other Events.**

On December 14, 2021, Rockwell Medical, Inc. (the "Company") issued a press release regarding the Company's receipt of a request from the U.S. Food and Drug Administration for additional data supporting its Investigational New Drug application for its proposed Phase 2 clinical trial of Ferric Pyrophosphate Citrate. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

**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 December 14, 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: December 14, 2021

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

**Exhibit 99.1**

**Rockwell Medical Receives Important Feedback from FDA on its IND Application for Phase 2 Trial of Ferric Pyrophosphate Citrate in Home Infusion**

**WIXOM, Mich., December 14, 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 announced that it received feedback from the U.S. Food and Drug Administration (FDA) regarding its Investigational New Drug (IND) application in support of its proposed Phase 2 clinical trial of Ferric Pyrophosphate Citrate (FPC), designed for the treatment of iron deficiency anemia and maintenance of hemoglobin in patients receiving infusion therapy in the home setting.

“We are breaking new ground with this study, which is the first of its kind, evaluating the use of parenteral iron in treating iron deficiency anemia in the rapidly-growing home infusion setting. The study proposal includes a novel dosing regimen, one that is fine-tuned to match the preferences of caregivers and patients receiving health care at home. We are working closely with FDA to ensure that our planned approach is well suited for this patient population,” said Russell Ellison, M.D., President and Chief Executive Officer of Rockwell Medical.

FDA requested that additional data related to the microbiology and short-term stability of FPC be submitted to further support the drug administration method proposed for the study. The company expects to run these additional studies, complete the required analysis, and provide the requested data in the first half of 2022. “We have a clear understanding of the request from FDA, and we believe there is a well-defined path forward to generate the data. The effort will help us refine our study approach, which is carefully designed for the home infusion application. We expect that these activities will have a minimal impact on the timing of our planned dosing of the first patient in this study,” said Marc Hoffman, M.D., Chief Medical Officer of Rockwell Medical.

“This important feedback from FDA strengthens our confidence in the potential value of this therapy. We are working to ensure that this product is studied with the patient and caregiver preferences in mind. The ultimate success of our project would mean patients will have access to a treatment for iron deficiency anemia in the home, so they could potentially avoid visits to an office or clinic to receive iron. We believe this may be a significant advance in the care of chronically ill patients with iron deficiency anemia who wish to avoid visits to healthcare facilities and the associated risks,” said Dr. Ellison.

Once the additional data is submitted, Rockwell must wait 30 calendar days before treating any patients in the clinical trial. During this time, FDA has an opportunity to review the IND and the additional data that is submitted.

**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. 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.

**Rockwell Medical Forward-Looking Statements**

Certain statements in this press release, including without limitation statements relating to the timing of completion of response activities, the impact of the response activities on the timing of dosing the first patient in the trial and the path forward to resolve the FDA's questions, 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" 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: Rockwell's ability to timely lift the clinical hold for the planned home infusion trial, the impact of the COVID-19 pandemic on Rockwell's business, including any clinical trials, and the FDA's response time, the risks of current treatment patterns in the home infusion setting for iron deficiency anemia and whether the FDA will raise any additional issues with the IND during its review period; 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, 2021 and 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.

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**ROCKWELL MEDICAL CONTACTS**

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