
**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): **June 22, 2018**

ROCKWELL MEDICAL, INC.

(Exact name of registrant as specified in its charter)

Michigan
(State or other
jurisdiction of
incorporation)

000-23661
(Commission File
Number)

38-3317208
(IRS Employer
Identification No.)

30142 Wixom Road, 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))

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 4.01 **Changes in Registrant’s Certifying Accountant.**

Resignation of Current Independent Registered Public Accounting Firm

On June 22, 2018, Rockwell Medical Inc.’s (the “Company”) independent accountant, Plante & Moran, PLLC (“Plante”), notified the Chair of the Audit Committee of the Board of Directors that it was resigning as the Company’s independent registered public accounting firm, effective immediately.

Plante’s reports on the Company’s financial statements for the years ended December 31, 2016 and December 31, 2017 did not contain an adverse opinion or a disclaimer of opinion, nor were they qualified or modified as to uncertainty, audit scope, or accounting principles.

During the two most recent years ended December 31, 2016 and December 31, 2017 and through June 22, 2018 (the date of Plante’s resignation), the Company had no disagreements with Plante on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreements, if not resolved to Plante’s satisfaction, would have caused it to make reference to the subject matter of the disagreements in connection with its reports.

In its letter to the Audit Committee dated June 22, 2018, which is attached hereto as Exhibit 99.2 and was issued by Plante in conjunction with its resignation letter, Plante identified certain reportable events, as described in Item 304(a)(1)(v) of Regulation S-K, relating to the Company’s financial statements and disclosures contained in the Company’s Quarterly Report on Form 10-Q for the period ended March 31, 2018 (the “Form 10-Q”). The terms of this letter are incorporated herein by reference.

The Chairman of the Audit Committee as well as another member of the Audit Committee, the Chairman of the Board, discussed with Plante the reasons for its resignation and has authorized Plante to respond fully to the inquiries of the Company’s successor independent registered public accounting firm concerning the reasons for Plante’s resignation.

The Company has provided Plante with a copy of the disclosures made in this Current Report on Form 8-K prior to the time this report was filed with the Securities and Exchange Commission. The Company has requested that Plante furnish a letter addressed to the Securities and Exchange Commission stating whether it agrees with the Company’s statements made in this report. A copy of Plante’s letter dated June 26, 2018, is attached as Exhibit 16.1 hereto.

Plante has not provided notice to the Company that disclosure should be made or action should be taken to prevent future reliance on the completed interim review related to the previously issued financial statements contained in the Form 10-Q. The Audit Committee is in the process of reviewing the concerns set forth in Plante’s correspondence and has not made a determination as to whether the financial statements in the Form 10-Q should not be relied upon. If the Audit Committee determines that the financial statements should not be relied upon, this conclusion will be reported in a separate Current Report on Form 8-K.

Engagement of New Independent Registered Public Accounting Firm

As of the date of this report, the Audit Committee has not yet retained a new independent registered public accounting firm. The Audit Committee is in the process of identifying and selecting a new independent registered public accounting firm and will disclose the selection when made on a subsequent Current Report on Form 8-K.

Item 9.01 **Financial Statements and Exhibits.**

(d) *Exhibits.* The following exhibits are being filed herewith:

EXHIBIT INDEX

Exhibit No.	Description
16.1	Letter from Plante & Moran, PLLC to Audit Committee of the Company, dated June 26, 2018.
99.1	Letter from Plante & Moran, PLLC to John Cooper, Audit Committee Chair, dated June 22, 2018
99.2	Letter from Plante & Moran, PLLC to the Audit Committee of the Company, dated June 22, 2018.

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: June 27, 2018

By: /s/ Benjamin Wolin
Benjamin Wolin
Chairman of the Board



Plante & Moran, PLLC
Suite 30C
19176 Hall Road
Clinton Township, MI 48038
Tel: 586.416.490C
Fax: 586.416.4901
plantemoran.com

June 26, 2018

Audit Committee of the Board of Directors
Rockwell Medical, Inc. and Subsidiary
30142 Wixom Rd.
Wixom, MI 48393

Dear Audit Committee Members:

We have read Item 4.01 to be included in the Form 8-K of Rockwell Medical, Inc. to be filed with the Securities and Exchange Commission regarding its change in auditors. We are in agreement with the statements made regarding our firm. We have no basis to agree or disagree with other statements made under Item 4.01.

Very truly yours,

PLANTE & MORAN, PLLC





Plante & Moran, PLLC
Suite 300
19176 Hall Road
Clinton Township, MI 48038
Tel: 586.416.4900
Fax: 586.416.4901
plantemoran.com

June 22, 2018

Mr. John Cooper
Audit Committee Chair
Rockwell Medical, Inc.
30142 Wixom Rd.
Wixom, MI 48393

Dear Mr. Cooper:

This letter is to inform you that, pursuant to the terms of the engagement letter for audit services (the "Engagement") dated March 27, 2018 between Plante & Moran, PLLC ("Plante Moran") and Rockwell Medical, Inc., Plante Moran has decided, effective as of the date of this letter, to terminate the Engagement. As a result, the client-auditor relationship between Rockwell Medical, Inc. (Commission File Number 000-23661) has ceased.

Plante Moran agrees to give your new auditors access to Plante Moran's workpapers (if access is requested) as Plante Moran deems appropriate. Notwithstanding the foregoing, Plante Moran's workpapers are and shall remain the exclusive property of Plante Moran.

Very truly yours,

PLANTE & MORAN, PLLC

A handwritten signature in black ink, appearing to read "Thomas J. Clement".

Thomas J. Clement





Plante & Moran, PLLC
 Suite 300
 19176 Hall Road
 Clinton Township, MI 48038
 Tel: 586.416.4900
 Fax: 586.416.4901
 plantemoran.com

June 22, 2018

Audit Committee of the Board of Directors
 Rockwell Medical, Inc. and Subsidiary
 30142 Wixom Rd.
 Wixom, MI 48393

Dear Audit Committee Members:

We have been made aware of the attached e-mail received by Rockwell Medical, Inc. (Rockwell) on March 27, 2018 in connection with its ongoing pursuit of Triferic special reimbursement status. This e-mail was not disclosed to us in the course of our review procedures related to the financial statements for the quarter ended March 31, 2018 (Q1) included in Rockwell's form 10Q filed on May 15, 2018. This e-mail and its contents are inconsistent with representations made to us by Rockwell, orally and in writing, in connection with our review procedures. Had we been made aware of this e-mail, we would have informed you of the following matters:

Uncorrected Misstatements

Management's estimate of reserves for slow-moving and obsolete Triferic inventory is determined based on a weighted average probability model that considers anticipated product launch dates, current sales projections, and product expiration dates. Rockwell management represented that the factors used in its determination of the Q1 reserves reflected the best information and estimates available as of the 10Q filing date. In estimating these reserves for Q1, Rockwell assigned a 50 percent probability weighting to outcomes dependent on near-term approval of Triferic special reimbursement status. Elimination of those outcomes from the Q1 reserve analysis model would have suggested additional reserves recognizable in Q1 totaling approximately \$400,000.

Internal Control Matters

The above-referenced e-mail provides significant evidence regarding Rockwell's ongoing pursuit of Triferic special reimbursement status that was not given consideration in determining inventory reserves, classification and disclosures. This failure to consider all known facts and evidence regarding these matters is a deficiency in operation and effectiveness of Rockwell's financial reporting and disclosure controls that we consider to be a material weakness in those controls.

Inconsistencies in 10Q Filing

We call your attention to the following matters in Rockwell's form 10Q filing for the quarter ended March 31, 2018, that we believe to be inconsistent with the facts in existence at the time of filing:

- Certification Pursuant to Rule 13a-14(a) – Robert L. Chioni
- Certification Pursuant to Rule 13a-14(a) – Thomas E. Klema
- Note 2 to the Q1 financial statements, Basis of Presentation (specifically, 2nd paragraph)



June 22, 2018

- Item 4. Controls and Procedures (specifically, 2nd and 3rd paragraphs)

In addition, had this e-mail been disclosed to us, our communications to you resulting from our pre-filing review of the Q1 10Q would have included our view that the disclosures in the Overview section of Item 2 regarding Triferic should be clearer and more transparent regarding the status of Rockwell's request for separate reimbursement with CMS and the prospects for reversal of CMS's decisions.

Very truly yours,

PLANTE & MORAN, PLLC



Thomas J. Clement



David J. Kristick

Attachment

To: Steven Stranne[SStranne@Polsinelli.com]
From: Shah, Anand (CMS/CMMI)
Sent: Tue 3/27/2018 2:43:15 PM
Subject: RE: Innovation Demo for ESRD

Hi Steve –

Thank you for your note on Rockwell's proposal.

We have carefully reviewed your concept and submitted materials. Unfortunately, given the other initiatives CMS has underway, we will not be able to pursue this model.

I appreciate you and Rob Chioini coming to CMMI to present Rockwell's idea, as well as the continued follow up with us.

Anand

Anand Shah, MD, MPH
Chief Medical Officer
Center for Medicare & Medicaid Innovation
Centers for Medicare & Medicaid Services

From: Steven Stranne [mailto:SStranne@Polsinelli.com]
Sent: Saturday, March 24, 2018 4:51 PM
To: Shah, Anand (CMS/CMMI) <Anand.Shah1@cms.hhs.gov>
Subject: Innovation Demo for ESRD

Dr. Shah, I am writing to follow up on the proposal we submitted in October of 2017 for a potential CMMI project for new, transformative therapies that are likely to significantly control overall costs and improve care for Medicare beneficiaries with end stage renal disease (ESRD). Thanks again for meeting with us, along with your colleagues in the Innovation Center, in November, 2017.

As time continues to pass, I urge you and the CMS leadership team to adopt and expedite this proposal. The demonstration would enable the Agency to select, evaluate, and support transformative innovations like Triferic that have reasonable pricing and that show promise to improve care, reduce complications, and save the Medicare program money. The Agency would retain significant control over decisions involving the innovations to be selected for the demonstration and the ongoing payment policies. We need to break down barriers to innovations that can deliver value, save federal resources, and improve care in this vulnerable and expensive patient population. Our proposal would result in good policy that would disrupt and refine the counterproductive aspects of the status quo.

As you may recall, there is significant support for our proposal in the ESRD community and in Congress. Although this list is not inclusive, recall that well-respected patient advocacy groups such as the American Association of Kidney Patients (AAKP) and Dialysis Patient Citizens (DPC) support this proposal. In addition to a number of other stakeholders in the provider and ESRD communities, many Members of Congress in the House and Senate have communicated their support through letters and other means, including but not limited to Chairman Brady and his staff.

Please let us know what we can do to be helpful. This proposal provides a straightforward way to ensure that the Medicare program can identify and harness reasonably-priced innovation in a way that improves lives and holds down overall health costs. That seems to fall squarely within the Administration's objectives and the Innovation Center's mission. We encourage you to adopt this proposal and to do so quickly. Thanks again for your help, Steve

Steven Stranne, MD, JD
Shareholder, Polsinelli PC
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sstranne@polsinelli.com
<http://www.polsinelli.com/ssstranne/>
1401 Eye Street, NW
Suite 800
Washington, DC 20005

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