ROCKWELL MEDICAL, INC.
Form 8-K
November 07, 2014

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 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 6, 2014**

ROCKWELL MEDICAL, INC.

(Exact name of registrant as specified in its charter)

Michigan	**000-23661**	**38-3317208**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

30142 Wixom Road, Wixom, Michigan	**48393**
(Address of principal executive offices)	(Zip Code)

Registrant s telephone number, including area code **(248) 960-9009**

(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 (see General Instruction A.2. below):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events

Rockwell Medical, Inc. (the Company) announced that on November 6, 2014, the Oncologic Drugs Advisory Committee (ODAC) of the U.S. Food & Drug Administration recommended that the Phase 3 efficacy and safety results for the Company s lead investigational drug, Triferic, support a positive benefit/risk to treat iron loss to maintain hemoglobin in patients with hemodialysis-dependent stage 5 chronic kidney disease. The ODAC voted in favor of Triferic by a vote of 8 to 3.

The ODAC reviewed safety and efficacy data from Rockwell s overall clinical program. During the clinical program more than 1,400 patients were treated with Triferic and more than 100,000 individual administrations were given. The results from the clinical trials have shown Triferic to be an effective and highly-differentiated iron delivery therapy with a safety profile similar to placebo.

SIGNATURES

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 7, 2014

By: /s/ Thomas E. Klema
Thomas E. Klema
Its: Chief Financial Officer