

Rockwell Medical, Inc. Q1 2019 Earnings Call

MAY 9, 2019

Forward Looking Language

Certain statements in this presentation 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," "plan," "potential," "predict," "forecast," "project," "plan", "intend" or 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: statements about the preliminary recommendation of CMS relating to an unique J code for our Triferic Powder Packet; timing and success of our planned NDA submission for I.V. Triferic; the potential market opportunity for I.V. Triferic and other Rockwell products; pricing and reimbursement status for I.V. Triferic, Triferic and other Rockwell products, including eligibility for add-on reimbursement under TDAPA; liquidity and capital resources; expected duration of Rockwell Medical's existing working capital; success of our recently announced commercialization plans for Dialysate Triferic; and timing and success of our efforts to renegotiate economic terms of our concentrate business Rockwell Medical expressly disclaims any obligation to update or alter any statements whether as a result of new information, future events or otherwise, except as required by law.

Recent Business Highlights

Advancing the potential of



TRIFERIC[®]
ferric pyrophosphate citrate

to address anemia
management in hemodialysis
patients

- Announced **launch of first formulation of Triferic**, Dialysate Triferic[®], on May 6, 2019
- Assembled **team of commercial and medical professionals** to support launch of Triferic
- Poised to **file U.S. New Drug Application for I.V. Triferic** in the second quarter of 2019
- Received **preliminary recommendation from CMS for separate J-Code** for powder packet formulation of Dialysate Triferic
- Presented **positive data from two studies** evaluating intravenous and peritoneal dialysate formulations of Triferic at the 39th Annual Dialysis Conference in March 2019

Triferic Highlights

- Novel therapy for the treatment of anemia that mimics the body's natural process of iron absorption
- Platform technology that can potentially be applied for treatment of anemia in a number of disease states
- Multiple formulations developed for the treatment of anemia in hemodialysis patients worldwide
- Our initial formulation, Dialysate Triferic, is now commercially available in the U.S.

macromolecular IV iron

For dialysis-associated anemia,

TRIFERIC IS 3X SMART

True iron maintenance with
a refined approach



Donates iron directly and completely to transferrin



Mimics natural iron homeostasis



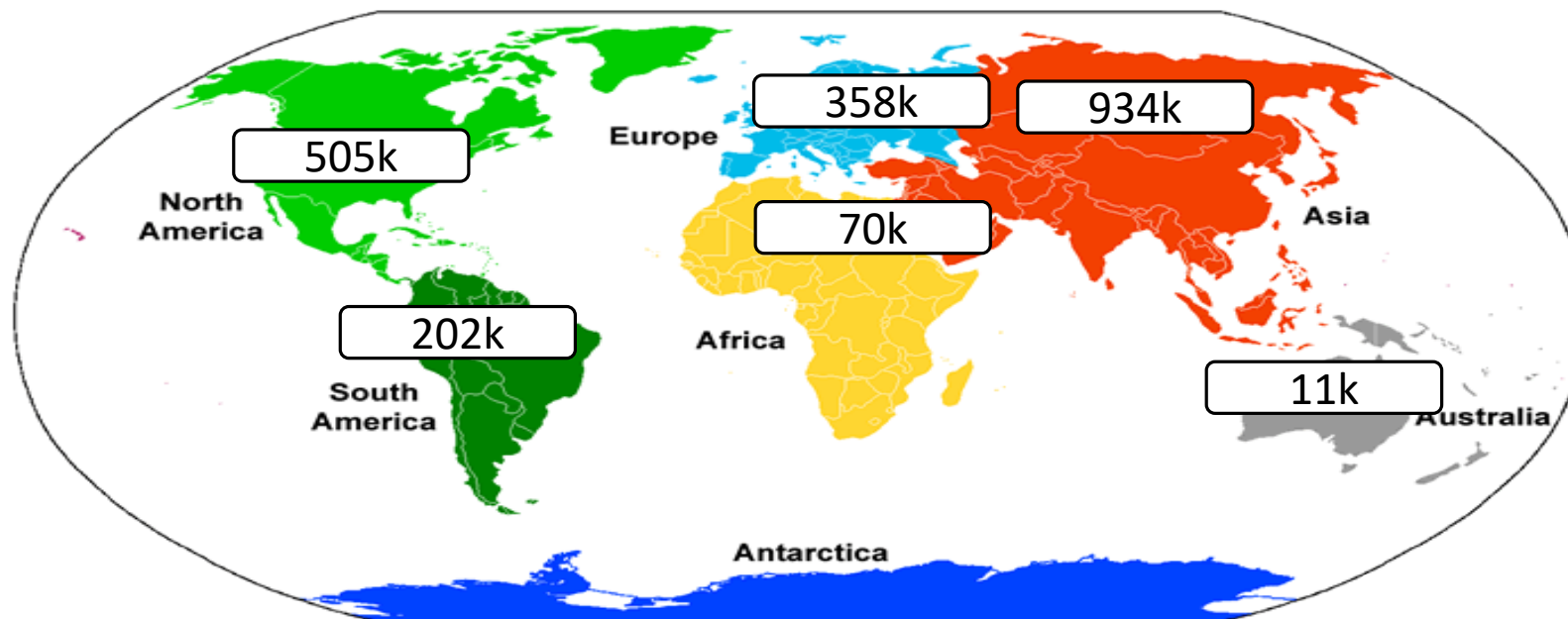
Safety profile similar to placebo

Large Global Market Opportunity

Global market opportunity for Triferic potentially exceeds \$1 billion

- 2+ million people receive hemodialysis annually⁽¹⁾, worldwide
- 250+ million estimated annual hemodialysis treatments, and growing because of increased rates of diabetes, obesity, and hypertension

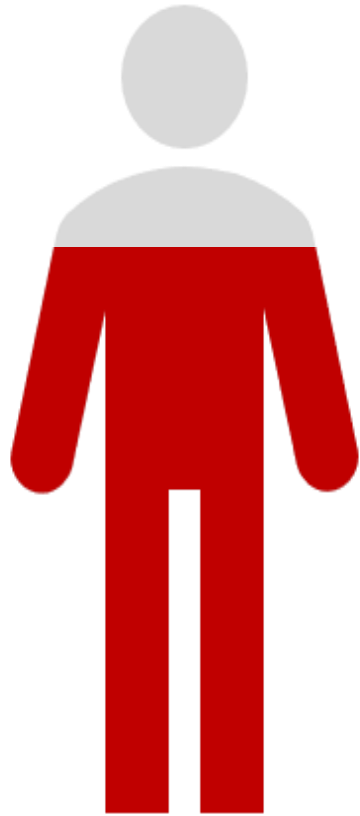
Hemodialysis Patients by Continent⁽¹⁾



(1) For selected countries listed in United States Renal Data System 2018 Annual Data Report. Table N.7.a “Yearly counts of all patients treated with in-center hemodialysis as of the end of the calendar year, 2003-2016.” and European Renal Association.

Unmet Need in Iron Maintenance Therapy

Current treatment approaches overload the body with iron rather than providing true iron maintenance

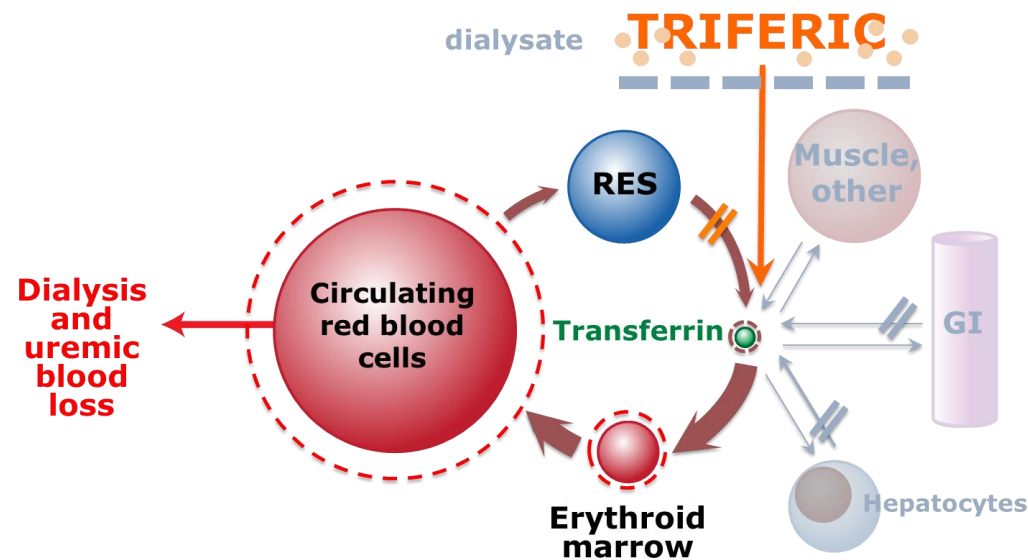


- Blood loss and iron sequestration are leading causes of anemia in hemodialysis (HD) patients
- 5-7 mg iron loss during every HD treatment
- The current standard of care for anemia management in hemodialysis patients is costly and associated with significant safety risks
 - ESAs are costly (~\$30 per treatment on average) and carry cardiovascular risks (black box warning)
 - I.V. Iron – not indicated for iron maintenance; increases ferritin and hepcidin levels
 - >75% of patients in the U.S. exceed KDIGO guidelines for ferritin levels as a result of increased I.V. iron dosing
 - Risk of hypersensitivity reactions, anaphylaxis, iron overload, increase in infections and functional iron deficiency

Triferic[®] Platform

Novel therapy that addresses the daily iron needs of dialysis patients and avoids iron toxicity

Triferic Replaces Iron Losses by Directly Donating Iron to Transferrin, Bypassing the Hepcidin Block



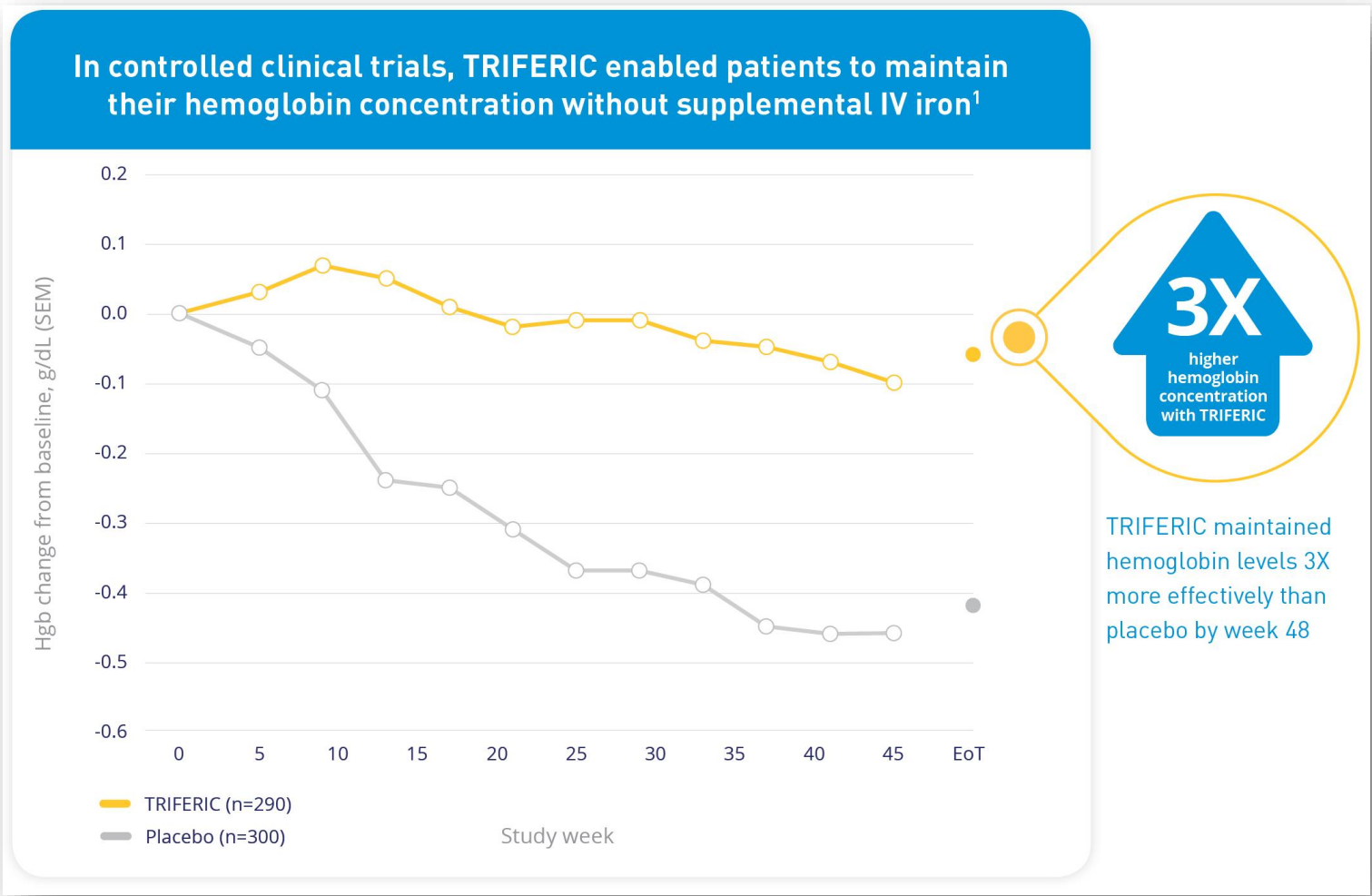
Brittenham GM. Chapter 34. Disorders of Iron Homeostasis: Iron Deficiency and Iron Overload. In Hoffman R. and Furie B. eds. Hematology: Basic Principles and Practice. Saunders, 6th ed., 2013.

*Gupta et al. - *Kidney International* – 2015

- **Unique, physiologic mechanism of action** – donates iron directly and completely to transferrin
 - **FIRST and ONLY** FDA-approved product indicated to maintain hemoglobin in hemodialysis-dependent CKD patients
 - Maintains hemoglobin with no increase in ferritin level
 - Replaces recurring iron loss during dialysis
 - Safety profile similar to placebo
- Initially developed multiple formulations of Triferic for the treatment of anemia in hemodialysis patients - **delivers iron every dialysis treatment**

Triferic Efficacy: Phase 3 Clinical Trials

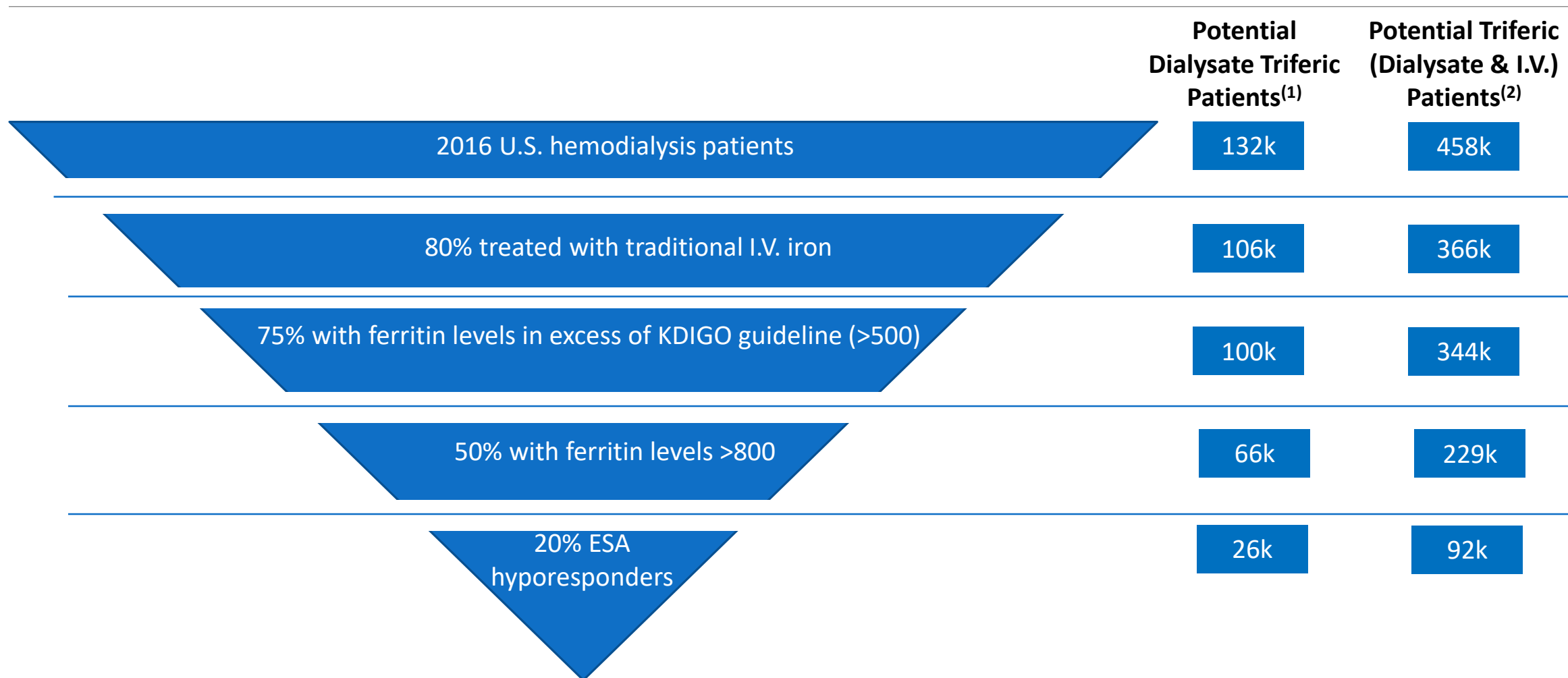
Iron maintenance with Triferic provided bioavailable iron, effectively raising hemoglobin levels during 48-week trials



1) Fishbane SN, Singh AK, Cournoyer SH, et al. Ferric pyrophosphate citrate (Triferic™) administration via the dialysate maintains hemoglobin and iron balance in chronic hemodialysis patients. *Nephrol Dial Transplant.* 2015;30(12):2019-2026.

U.S. Market Potential

Estimated U.S. Market Opportunity of \$400 million



1) Represents initial targets of in-center hemodialysis patients treated at medium, small and independent dialysis organizations as of 2016.

2) Represents all in-center hemodialysis patients as of 2016.

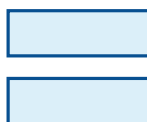
Pricing Dynamics – Existing Therapies

Traditional I.V. Iron

272 mg / month⁽¹⁾



\$0.23 / mg ASP⁽²⁾⁽³⁾



\$63 / month / patient

\$5 / treatment / patient⁽⁴⁾

WAC to ASP discount ~35%

Erythropoiesis Stimulating Agents (ESAs)

Long & Short Acting Formulations

Avg Dose: ~10,000 short-acting units / week⁽¹⁾

\$25 - \$40 / treatment / month⁽⁵⁾

- 1) DOPPS Practice Monitor, February 2018.
- 2) Average Selling Price for Iron Sucrose, April 2019.
- 3) Per CMS ASP Drug Pricing Files.
- 4) Assumes 12 treatments per patient per month.
- 5) MedPac; CMS ASP Drug Pricing Files April 2019.

Dialysate Triferic Reimbursement

Medicare Reimbursement

- Medicare reimbursement for Dialysate Triferic will be “within the bundle”

J-Codes

- Currently, Triferic powder packet and 5 ml liquid ampule are grouped under J-Code 1443
- On April 26, CMS announced a preliminary recommendation to issue a new J-Code for the powder packet (1444)
- If finalized, the new J-Code would be effective on July 1, 2019 pursuant to the preliminary recommendation

WAC Pricing

- Powder packet: \$8.00 per treatment
- 5 ml liquid ampule: \$9.50 per treatment
- Realized price = WAC price less certain deductions (e.g. returns, customer discounts / rebates, distribution fees)

Dialysate Triferic Launch 2019

Focus on educating Nephrologists about Triferic® while continuing to generate real-world evidence

KOL Engagement

- Continue to build champions (10-15)
- Drive effective medical education programs (webinars, Peer2Peer)
- Capture KOL testimonials

KOL and HCP Publication Strategy

- Case studies and abstract submissions
- Scientific dossiers for VAC committees
- Capture real-world data to accelerate adoption in 2020

Conference Promotion

- Conferences promotion: ANNA, NKF NRAA, ASN
- Chapter support/participation (NKF)
- Society partnerships & Triferic Product Presentations

Sales Force Engagement

- Launch new sales campaign
- Effective account targeting
- Engage key centers of excellence

Digital Promotion

- Launch new Rockwell Medical and Triferic website (mid-May)
- Create new information videos: Mechanism of Action, Mix & Administration
- Social media postings to drive share of voice

Triferic International Updates

Estimated market potential >\$1 billion in international markets



China

- Partnered to commercialize Triferic® with Wanbang Biopharmaceutical
- Completed enrollment for 2 studies for Dialysate Triferic®
- Low-to-mid 20% royalty due to Rockwell on Net Sales; \$35 million potential milestone payments
- Estimated peak market opportunity in excess of \$400 million



LATAM

- Received Peru regulatory approval January 2019; expect Chile regulatory approval in 2019
- Estimated peak market opportunity of \$100 million across all countries



Canada

- Regulatory dossier nearly ready – expected submission in 2019
- Estimated peak market opportunity of \$25 million



Europe

- Discussions ongoing with potential partners for I.V. Triferic®
- Estimated peak market opportunity of \$400 million



Japan

- Early stage discussions ongoing with potential partners for I.V. Triferic®
- Clarify Japan I.V. Triferic® regulatory requirements
- Estimated peak market opportunity of \$200 - \$250 million

Q1 2019 Financial Results

3 months ended 3/31/19 compared to the three months ended 3/31/18

<i>(\$ in millions except YOY amounts)</i>	Q1 2019	Q1 2018	% Change
Net Sales	\$15.6	\$14.9	4%
Gross Profit	1.0	(0.7)	NM
Selling & Marketing	3.1	0.2	NM
General & Administrative	6.2	3.1	100%
Research & Development	0.5	1.7	-70%
Operating Income (Loss)	(8.8)	(5.7)	54%
Net Income (Loss)	(8.7)	(5.5)	56%

Selected Balance Sheet & Cash Flow Metrics

<i>(\$ in millions)</i>	As of 3/31/2019	As of 12/31/2018
Cash, Cash Equivalents and Investments	\$27.8	\$33.5
Debt	0.0	0.0
Working Capital	24.5	33.6

	Q1 2019	Q1 2018
Cash Flow from Operations	(5.4)	(4.6)
Total Change in Cash & Investments	(5.7)	(5.0)

Triferic 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%).

For more information, including full prescribing information, visit: <http://www.triferic.com>.