



**Targeting end-stage renal disease (ESRD) and chronic kidney disease (CKD) with innovative products for the treatment of iron deficiency, secondary hyperparathyroidism and hemodialysis.**

**August 2017**

# Safe Harbor Statement

This presentation contains forward-looking statements. All statements, other than statements of historical facts, including, among others, statements regarding the Company's future plans, products (investigational or otherwise), financial position, business strategy, projected levels of growth, projected costs and projected financing needs, projected roll-out or approval dates, are forward-looking statements. Those statements include statements regarding the intent, belief or current expectations of Rockwell Medical and members of the Company's management team, as well as the assumptions on which such statements are based, and generally are identified by the use of words such as "may," "will," "seeks," "anticipates," "forecast," "upcoming," "believes," "estimates," "expects," "plans," "intends," "should", "potential" or similar expressions. Forward looking statements are not guarantees of future performance and involve risks and uncertainties, including those set forth in the Company's annual and quarterly reports filed with the SEC. Actual results may differ materially from those contemplated by such forward-looking statements.

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# Company Overview

- Corporate offices located in Wixom, Michigan USA
- 4 Manufacturing facilities (MI, TX, SC, IA)
- Approximately 330 employees
- We are committed to bringing new innovative therapies to the market to improve the lives of patients
  - Triferic<sup>®</sup> – transformative iron replacement and hemoglobin maintenance therapy
  - Calcitriol – generic vitamin D injection (packaged in vial)
  - CitraPure<sup>®</sup> – innovative dialysate lowers inflammation and cost

# Leader in Manufacturing and Delivering Innovative Dialysis Products

|   |                                       |
|---|---------------------------------------|
| <b>Triferic® – Innovative Iron Replacement Therapy for Dialysis Patients</b>  | Approx. \$300M US market; \$1B global |
| <ul style="list-style-type: none"> <li>○ The only FDA approved product indicated to replace iron and maintain hemoglobin in hemodialysis patients</li> <li>○ Novel iron molecule binds directly to transferrin</li> </ul> |                                       |
| <b>Calcitriol – Preparing to Launch FDA Approved Generic Drug</b>   | Approx. \$200M US Market              |
| <ul style="list-style-type: none"> <li>○ Original most potent lowest dose vitamin D injection</li> <li>○ Lower cost pure play for current US market Vitamin D Analogs</li> </ul>  |                                       |
| <b>Growing Concentrate Business</b>   | Revenue: \$50M cash flow positive     |
| <ul style="list-style-type: none"> <li>○ Strong, existing customer relationships with standard-of-care products</li> <li>○ One of two major concentrate suppliers in the US</li> </ul>                                    |                                       |
| <b>Experienced, Proven Management Team</b>  |                                       |
| <ul style="list-style-type: none"> <li>○ Successful with multiple product launches, product development, clinical development, marketing and sales</li> </ul>   |                                       |

# Experienced Management Team

## **Robert L. Chioini**

Founder, Chairman and CEO

## **Thomas E. Klema**

VP, CFO and Secretary

## **Ajay Gupta, M.D.**

Chief Scientific Officer

## **Raymond D. Pratt, M.D.**

Chief Medical Officer

### Product Development & Acquisitions

- Successful innovative product launches and strategic product acquisitions and in the dialysis space
  - Dri-Sate<sup>®</sup>, SteriLyte<sup>®</sup>, Renal Pure<sup>®</sup> and CitraPure<sup>®</sup> all developed in-house and have become the standard-of-care in the hemodialysis concentrate market
  - Triferic<sup>®</sup> and Calcitriol acquired; both offer clinical and cost benefit and positioned for success

### Clinical Development & Launch Success

- Successful FDA drug approval; completed clinical development of Triferic<sup>®</sup> executing large-scale clinical studies over 10 years
- Successfully launched multiple, industry-changing dialysis products over 20 years

### Marketing & Sales

- Created solid brand recognition with innovative standard-of-care products
- Developed loyal customer base and strong customer relationships
- Built \$50M+ operating business from the ground up

# Innovative, Cost Saving Products for Dialysis Patients in the Renal Space

## Drug Products

### Triferic<sup>®</sup>

- Replaces the iron loss that occurs to patients “real-time” during dialysis treatment session
- Iron binds directly to transferrin and is transported to bone marrow for Hgb incorporation; no increase in iron stores
- Delivered via dialysate saves significant nursing time
- Proven safety data: 350,000 human doses with no anaphylaxis
- ESA sparing study (PRIME) showed Triferic<sup>®</sup> reduces ESA use 35% overall and 74.4% in hypo-responders
- U.S. Commercial launch underway – Blockbuster Potential

### Calcitriol

- Original, most potent active vitamin-D injection
- The only Calcitriol injection offered in a vial
- Clinically equivalent in safety and efficacy to the two branded drugs
- Lower cost alternative
- FDA Approved, preparing for commercial launch

## Concentrate Products

CitraPure<sup>®</sup> Citric-Acid Concentrate

Renal Pure<sup>®</sup> Liquid Acid Concentrate

RenalPure<sup>®</sup> Powder Bicarbonate Concentrate

Dri-Sate<sup>®</sup> Dry Acid/Mixing System

SteriLyte<sup>®</sup> Liquid Bicarbonate Concentrate

Ancillary Products

# Triferic<sup>®</sup> - Transformative Iron Replacement; Key Growth Driver

Overcomes High-Ferritin, High-Infection and  
Functional Iron Deficiency (FID) in HD Patients

- **FDA Indicated for iron maintenance therapy**
- **Small 5-7 mg iron dose over 4 hours**
- **Iron binds completely to transferrin**
- **Consistently maintains hemoglobin**
- **No iron trapped in the liver**
- **No increase in ferritin (iron stores)**
- **No increase in inflammation**
- **No increase in infections (vs placebo)**
- **No anaphylaxis (vs placebo)**
- **Decrease in blood transfusions (vs placebo)**

# Product Pipeline





# Global Sales Initiative

- License Triferic® outside U.S. for HD with key partners world-wide – \$1B+ market opportunity; China secured
- License Triferic® worldwide for other clinical indications PD, TPN, Cancer and IRIDA (orphan); China secured



We Expect Triferic® to Become the Global Standard of Care for HD Patients

