

Improving patient outcomes with innovative critical care drug therapies.

Rockwell Medical (NASDAQ: RMTI) is a fully-integrated biopharmaceutical company providing innovative products and services initially targeting end-stage renal disease (ESRD), chronic kidney disease (CKD) and iron deficiency anemia.

Rockwell's lead investigational drug, soluble ferric pyrophosphate (SFP), is designed to provide dialysis patients with continuous iron therapy, delivering physiologic benefits not found with current intravenous iron (IV) administration. Rockwell's SFP and other drug candidates are intended to support disease management initiatives that enhance the quality of life and care of dialysis patients, delivering safe and effective therapy while decreasing drug administration costs.

Rockwell's growing renal product franchise has been built through the manufacture and distribution of high-quality hemodialysis concentrates, supplying dialysis providers and distributors throughout the U.S. and abroad. Rockwell's marketed products are used to maintain human life, removing toxins and replacing critical nutrients in dialysis patient's blood.

Rockwell has a history of successfully addressing unmet needs in the renal market.

Treating Anemia in Dialysis Patients

The majority of the estimated 400,000 ESRD patients in the U.S. and 2 million worldwide receiving hemodialysis require treatment for iron deficiency anemia. Dialysis patients lose approximately 5 to 7 milligrams of iron during each dialysis session, and this is a primary cause of their anemia. Anemia leaves them feeling exhausted, tired and unable to perform simple daily tasks. In an effort to treat this problem, approximately \$560M is spent on administering iron to dialysis patients each year.

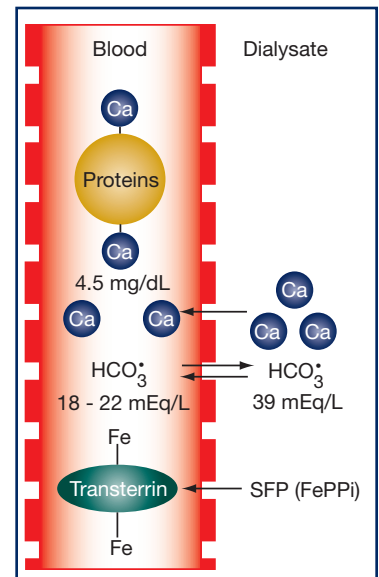
In addition, dialysis patients' kidneys do not produce erythropoietin, the body's natural hormone that drives the production of red blood cells. As a result, dialysis patients receive an erythropoiesis-stimulating agent (ESA), which is a synthetic substitute for erythropoietin. As ESA stimulates red blood cell formation it increases the demand for iron, also contributing to functional iron deficiency. Since ESA and iron work together, iron must be present when ESA is dosed, otherwise ESA will not be as effective and new red blood cell generation will be compromised, requiring greater ESA doses.

Soluble Ferric Pyrophosphate (SFP)

SFP is a proprietary, investigational drug in clinical development and is designed to treat iron deficiency anemia. It is the first and only drug to continuously deliver iron to dialysis patients, via dialysate, during their dialysis treatment. As all dialysis patients lose 5 to 7 milligrams of iron during each treatment, which is a primary driver of their anemia, SFP's mode of delivery enables that iron loss to be replaced "real-time," thereby maintaining optimal iron balance in the patient.

SFP versus IV Iron

SFP is a small iron salt with an extremely tight bond, much different than the larger IV iron carbohydrates. SFP lacks carbohydrate, and is not treated as a foreign particulate in the body, and therefore is also not expected to trigger anaphylactoid reactions. As SFP is administered



Delivered in small doses during each hemodialysis session, SFP (FePPi) is intended to provide a safe and efficacious pathway to maintaining hemodialysis patients' iron levels within a desired target range.



EXECUTIVE MANAGEMENT:

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Thomas E. Klema

Chief Financial Officer and Secretary

Ajay Gupta, M.D.

Chief Scientific Officer

Richard C. Yocum, M.D.

Vice President, Drug Development and Medical Affairs

STOCK INFORMATION:

As of October 19, 2009

Ticker/exchange: NASDAQ/RMTI

Closing Price: \$7.82

52-week Range: \$1.06- \$9.39

Market Cap: ~\$133 million

Average Volume: 94,000 (3 months)

SELECTED FINANCIALS:

For the three months ended

June 30, 2009

Cash and Cash Equivalents

\$3.3 million

Net Loss: \$1.7million, or (\$0.12) per basic and

diluted share

YEAR FOUNDED: 1995 (successful IPO in 1998)

EMPLOYEES: 294

ANALYST COVERAGE: Morning Star, Wedbush

Securities and JMP Securities

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SFP CLINICAL DEVELOPMENT PROGRESS

Complete:

- ▶ Comprehensive pharmacology/toxicology program comprising of multiple studies
- ▶ Phase 2a dose range study
- ▶ SFP formulation GMP grade (patent pending)

Ongoing:

- ▶ Phase 2b dose range study (data expected Q1 2010)
- ▶ NIH-funded study SFP vs. IV iron (data expected late 2010)

Anticipated:

- ▶ Phase 3 clinical program
- ▶ File NDA with FDA
- ▶ Commercial launch U.S. (upon market approval)

continuously via dialysate it crosses the dialyzer membrane and enters the patient's blood. It then binds rapidly to apo-transferrin, the body's natural protein for transporting iron, where it is taken directly to the bone marrow, mimicking normal dietary iron uptake. This mode of delivery enables iron to travel directly to the bone marrow for incorporation into hemoglobin, avoiding storage in the liver and related toxicity and ensuring adequate red blood cell formation; and as a result, enabling ESA to be more effective in achieving hemoglobin in the target range.

Managing anemia in ESRD patients is necessary and can be improved over current IV iron administration. SFP has been designed to effectively address the ongoing challenges in anemia management by:

- ▶ Maintaining Hgb levels in the target range of 10-12 g/dL
- ▶ Improving response to ESA therapy while avoiding excessively high doses and potential risks
- ▶ Preventing iron from being stored in the liver thereby reducing the risk of liver toxicity
- ▶ Reducing current administration and drug-related costs

A successful Phase 2a study evaluated the short-term safety and efficacy of delivering SFP to dialysis patients by way of dialysate. In the results, the authors concluded that a slow, frequent delivery of iron was a safe and effective alternative to IV iron dextran delivery. In the Phase 2a study, hemodialysis patients were stabilized on regular IV iron dextran and split into two groups: 10 who received SFP via dialysate and a control group of 11 who continued on IV iron dextran. At the end of the study, IV iron was required by all 11 patients in the control group while 8 of the 10 patients in the SFP group did not need any IV iron (*Note: the 2 patients who received IV iron experienced excessive blood losses caused by amputation and bypass surgery which required hospitalization during the study*). The study demonstrated that patients receiving SFP regularly via dialysate did not require IV iron.¹

Market Opportunity

According to the USRDS 2007 Annual Data Report, approximately 90% of the nearly 400,000 patients currently on dialysis require iron supplementation. Sales of IV iron in the U.S. were approximately \$560 million in 2008 alone. Along with a move towards a government "bundled reimbursement" paid to dialysis providers starting in 2011, Rockwell's SFP value proposition of continuous iron delivery that maintains optimal iron balance and maximizes ESA response should provide a safer and more effective therapy for patients and less costly method of iron delivery and greater savings for dialysis providers, pending verification in clinical trials.

Pipeline

Rockwell is planning to further develop new drug opportunities in the areas of women's health, oncology and parenteral nutrition based on its SFP technology, as well as new drugs for other targeted renal therapies and indications.

Products/Indications	Preclinical	Phase 1	Phase 2	Phase 3
Soluble Ferric Pyrophosphate (SFP)				
Hemodialysis	→			
SFP Line Extensions				
Peritoneal Dialysis	→			
Oral Prescription	→			
Parenteral Nutrition Admixtures	→			
Carnitine + Vitamin	→			

¹Source: Gupta, A. et al. Dialysate iron therapy: Infusion of soluble ferric pyrophosphate via the dialysate during hemodialysis. *Kidney International* 1999; 55: 1891-1898