Initiating Coverage
July 22, 2015

Rockwell Medical, Inc. (RMTI)
Initiation Report

LifeSci Investment Abstract

Rockwell Medical (NasdaqGM: RMTI) is an established commercial biopharmaceutical company offering innovative products and services for hemodialysis. The Company received FDA approval on January 26th for Triferic, the only treatment indicated to replace iron and maintain hemoglobin in hemodialysis patients. Triferic has the potential to transform iron management in dialysis, and is especially well positioned in the bundled payment system. Rockwell has an established core business selling dialysis concentrates in partnership with Baxter (NYSE: BAX). Triferic and a generic vitamin D supplement for dialysis, Calcitriol, are expected to launch in the summer of 2015.

Key Points of Discussion

- **Triferic is the Only FDA Approved Therapy for Delivering Iron and Maintaining Hemoglobin in Hemodialysis Patients.** Iron deficiency is a common consequence of dialysis treatment. Delivered via dialysate, Triferic is specifically designed to replace the 5-7 mg of iron that dialysis patients lose during each session. Triferic binds to apo-transferrin upon entering the blood and is transported to the bone marrow without increasing ferritin, similar to how the body uses dietary iron. This stands in contrast to the IV iron products that are associated with severe safety problems, leaving an unmet need among dialysis patients for iron maintenance therapy. Triferic was approved in January with a strong safety profile, including no anaphylaxis in more than 100,000 administrations. Triferic is expected to create a new paradigm for managing anemia in hemodialysis patients. It has an active Q-code for reimbursement that became effective on July 1.

- **Triferic Addresses an Unmet Need.** Current IV iron products are not well suited for maintaining iron in dialysis patients. IV iron products contain carbohydrates that are metabolized by the liver, and the iron gets trapped and then blocked from release to transferrin due to hepcidin mobilization. As a result, just 2-5% of IV iron actually binds to transferrin. IV iron use increases the risk of infection, causes oxidative stress, promotes cardiovascular disease and leads to iron overload. In addition, IV iron preparations can cause life-threatening anaphylactic reactions without warning, requiring a monitoring period after each administration. Triferic overcomes the problems of IV iron use by delivering iron slowly over the course of the dialysis session in a form that is readily bioavailable for hemoglobin formation and without the safety concerns of IV iron.

Expected Upcoming Milestones

- Q3 2015 – Commercial launch for Triferic.
- Q3 2015 – Commercial launch for Calcitriol.
- **Triferic Benefits Patients, Providers and Physicians.** We expect a strong market for Triferic based on the fact that all parties in the dialysis treatment market stand to benefit from its introduction, especially considering the ability to deliver improved patients outcomes safely. Patients have reported better quality of life when receiving small maintenance doses of iron during each dialysis session, rather than waiting until they become anemic and experience fatigue and other symptoms before receiving IV iron, which in turn causes adverse effects. Physicians we spoke to are interested in using Triferic for its ability to deliver iron in a physiologic manner with the absence of anaphylactic risk. Dialysis providers stand to benefit due to the potential for significant cost reduction, such as eliminating IV iron and related administration cost and reducing expensive ESAs, as well as freeing up valuable nursing time from administering IV iron enabling greater time to focus on improved patient care.

- **Rockwell’s Commercial Experience Portends a Robust Launch for Triferic.** Under current management, Rockwell has grown from the ground up to be a leading provider of dialysis concentrates, with a $50 million revenue base business. The Company has launched eight successful renal products over 20 years, four of which have become the standard of care. Rockwell acquired soluble ferric pyrophosphate, now known as Triferic, in 2002 and has methodically executed its goal of bringing this important iron maintenance therapy through clinical development and FDA approval. Management has extensive experience selling in the renal market and has cultivated well-established relationships with the major dialysis providers. The US market is very concentrated, where just 9 service providers control approximately 83% of the dialysis centers. DaVita, Rockwell’s largest customer, controls approximately 35% of the market, and in 2013 renewed a 5-year supply contract with Rockwell. The 4 largest dialysis providers in the US participated in the long-term Triferic clinical studies, and therefore have comfort and experience administering the drug. The Company doesn’t have to hire an expensive sales force. Rockwell’s unique strength is an established, successful commercial enterprise that is able to lower cost to a highly concentrated customer base that has strong incentivize to use clinically superior products such as Triferic that help deliver cost effective patient care.

- **Triferic Clinical Trials Published in Leading Peer-Reviewed Journals.** Rockwell recently announced that results from its Phase II PRIME study were published in the journal *Kidney International*. The paper details the drug’s ability to significantly reduce ESA use, including among hypo-responsive patients who do not respond well to ESAs. There was an overall 35% reduction in ESA use for treated patients compared to placebo, and a greater than 74% reduction in ESA use in patients considered to be ESA hypo-responders. Additionally, data from the Phase III CRUISE clinical program, the CRUISE 1 and 2 studies, were recently published in the journal *Nephrology Dialysis Transplantation (NDT)*. The publication emphasizes the key results from the Phase III trials, including Triferic’s ability to maintain patients’ hemoglobin without increasing ferritin. Patients who received Triferic in the trial experienced a statistically significant difference in hemoglobin relative to baseline as compared to the placebo group.

- **Rockwell’s drugs Triferic and Calcitriol are Innovative Products Geared to Excel in the Bundled Payment Environment.** The amount that providers are paid per dialysis patient session is fixed and carefully controlled by regulators, so the clinics must work hard to make sure all of their costs fit within that limit. Rockwell has experience selling into this market, and Triferic and Calcitriol are both intended to maximize this cost-reduction advantage. When considering Calcitriol, most dialysis patients receive some form of IV vitamin D. Rockwell’s Calcitriol is a generic version of the hormonally active metabolite of vitamin D₃, also known as 1,25-dihydroxyvitamin D₃ or calcijex. Calcitriol is expected to be priced lower than competing branded products, giving customers a strong incentive to switch.

Regarding Triferic, in addition to its positive attributes for patient health, the pharmacoeconomic argument is robust. Introduction of Triferic has the potential to help clinics achieve significant savings by eliminating IV iron as a maintenance therapy and by significantly reducing ESA usage. Moreover, it is expected to help providers meet the
Centers for Medicare and Medicaid Services’ (CMS) Quality Incentive Program (QIP). This program gives providers an additional 2% on their payment when certain standards of care are met. Anemia management is an important aspect of the QIP, meaning Triferic has the potential to impact clinics’ ability to achieve these extra payments. A 2% rebate for the QIP gives providers about $5 extra per patient per session or $780 per patient annually. Making it easier for providers to achieve the QIP and the subsequent payment is another incentive that should help drive adoption.

**Rockwell Entered into an Exclusive Licensing Agreement with Baxter International.** On October 3, 2014, Rockwell Medical announced an exclusive licensing agreement with Baxter International (NYSE: BAX) for Rockwell’s hemodialysis product line. The deal included a $20 million up-front cash payment and a $15 million equity investment in Rockwell at a premium to the price at that time ($11.39/share) by Baxter. In addition to the up-front payment and equity investment, the Company is expected to receive an additional $10 million for the expansion of manufacturing capabilities. Rockwell is exploring a manufacturing site in the west that is expected to help access and open up significant additional future sales. The agreement has a 10 year lifespan with the option for Baxter to extend the term by 5 years for an additional $7.5 million payment. Notably, the deal did not include Calcitriol or Triferic.

**Baxter Deal Improves Rockwell’s Financials and De-Risks its Business.** Baxter will purchase Rockwell’s concentrate products at a predetermined price per unit that will lock in a higher gross margin and will trend higher over the course of the deal. Topline sales dollars will be reduced, but Rockwell will increase profit margins immediately and in the years ahead. Additionally, Rockwell will continue to manage customer service and delivery operations and pass that cost onto Baxter, charging a slight mark-up. The deal eliminates Rockwell’s variable freight cost, which has been the greatest expense in its gross margin. The deal with Baxter enabled Rockwell to monetize and de-risk their concentrate business while still maintaining sole ownership.

**Additional Opportunities for Triferic.** In addition to the expected US launch of Triferic into the dialysis market, Rockwell has multiple other opportunities to expand the market for this product. The Company has the potential to announce one or more distribution and marketing agreements giving a partner access to Triferic in foreign markets. Rockwell could also license the compound to a partner for development in additional indications outside of dialysis, and potentially as an intravenous or subcutaneous formulation. We would not be surprised to see Rockwell announce a deal in one or more of these areas in the future.

**Financial Discussion**

For the first quarter of 2015 Rockwell reported sales of $13.9 million, a 7% increase over the same period in 2014, and gross profit of $2.3 million, a 38% increase over 2014. Notably, research and development expenses tumbled from $3.8 million in the first quarter of 2014 to $0.8 million in 2015. This decrease is due to the completion of the Triferic clinical trials and regulatory applications, so this expense is expected to stay near current levels in the near future. The company reduced its net loss from the same period in 2014 from $7.8 million or $0.20/share to $3.7 million or $0.07/share. The Company completed a financing in late 2014, selling 6.5 million shares at $9.00/share for gross proceeds of $58.5 million and net proceeds to the company of $54.7 million. Rockwell subsequently finished the first quarter of 2015 with $83.3 million in cash on hand.
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Company Description

Rockwell Medical (NasdaqGM: RMTI) is a fully-integrated biopharmaceutical company offering innovative products and services initially targeting end-stage renal disease (ESRD), chronic kidney disease (CKD), and iron deficiency anemia. As an established manufacturer and leader in delivering high-quality hemodialysis concentrates to dialysis providers and distributors in the US and abroad, Rockwell provides products used to maintain human life, removing toxins and replacing critical nutrients in the dialysis patient's bloodstream. The Company markets unique, proprietary renal drug therapies. These exclusive renal drug therapies support disease management initiatives to improve the quality of life and care of dialysis patients and are designed to deliver safe and effective therapy, while decreasing drug administration costs and improving patient convenience and outcome.

*Triferic*, which was recently approved by the FDA, is a novel iron salt capable of delivering iron in a physiological manner, providing continuous-iron-maintenance therapy for the treatment or prevention of iron deficiency anemia in dialysis patients. Unlike current IV iron treatment used in dialysis, *Triferic* travels directly to the bloodstream and transfers its iron load at a cellular level, similar to normal dietary iron uptake. *Triferic* generated a strong data package concerning its efficacy and safety as an iron maintenance therapy, leading to the drug’s approval in January 2015 following a positive FDA panel recommendation. Rockwell is preparing to launch this product as well as its generic Vitamin D supplement *Calcitriol* in the summer of 2015.

*Triferic*: The First Approved Agent for the Maintenance of Hemoglobin

*Triferic* (soluble ferric pyrophosphate) is the first agent approved by the FDA to replace iron and maintain hemoglobin in adult patients with hemodialysis-dependent chronic kidney disease (HDD-CKD). Rockwell licensed the compound in 2002 and successfully completed all stages of clinical development, garnering FDA approval on January 26, 2015. All patients undergoing dialysis naturally lose iron from their blood as part of the process. *Triferic* is administered as part of the dialysate, replacing lost iron. This reduces the number of erythropoietin stimulating agents (ESA) injections patients require and should lessen the burden of intravenous iron, which causes hypersensitivity reactions. *Triferic* possesses a profile that makes it a potential disruptive technology in the current dialysis market. It is complementary to Rockwell's core dialysate business and along with *Calcitriol* should help drive significant sales growth.

Mechanism of Action - Physiological Iron Delivery

*Triferic* contains an iron atom tightly complexed to a pyrophosphate ligand. When iron is strongly bound to pyrophosphate, which naturally exists in blood, the complex does not allow for significant release of iron. This in turn limits the toxicity associated with free iron when delivered intravenously. On the other hand, the pyrophosphate complex allows rapid transfer of the iron to plasma transferrin. Transferrin-bound iron is then moved to the bone marrow in a bioavailable form that can be incorporated into new red blood cells. Serum pyrophosphate further has been shown to promote the binding of iron ions to plasma transferrin. SFP is water soluble, which allows for effective delivery through the dialysate and ready transportation through the blood stream.

Iron Overload Remains a Concern for Dialysis Patients. A unique attribute of *Triferic* as an iron source is that while it increases hemoglobin, it does not increase ferritin. Increasing ferritin is a marker of stored iron and inflammation, and signifies that iron being delivered is not efficiently bound by transferrin. In September 2014, Keryx Biopharmaceuticals (NasdaqCM: KERX) announced that it had received FDA approval for its phosphate binder ferric
citrate, later named Auryxia. It was approved as a treatment for hyperphosphatemia, which is an unsafe elevation in serum phosphorous, in chronic kidney disease patients on dialysis. However, the FDA approved the drug with a warning label citing the risk of iron overload due to a significant increase in ferritin. Keryx originally touted this effect as an advantage of the drug over other phosphate binders, but it has since raised safety concerns. Excess iron can lead to undesirable long-term health effects.

Excess iron delivered to the liver from the iron carbohydrate products is believed to result in decreased iron available for the production of red blood cells (RBCs). IV iron increases iron stores in a patient's liver as the iron is incorporated into the reticuloendothelial (RE) system. In contrast, Triferic's absorption properties result in less iron accumulation in the liver relative to the traditional IV iron products. Iron overload of the liver increases the production of hepcidin, the key regulator of iron homeostasis. Hepcidin inhibits the release of iron from the liver to be taken to the bone marrow for the production of RBCs. It appears that Triferic bypasses the liver, and the deleterious hepcidin-induced blockade of iron release, and delivers iron directly to the bone marrow.

**Superior Safety Profile**

With approximately 100,000 doses of Triferic already delivered to patients, there have been no discernible drug-related effects of toxicity. In clinical trials, a comparison of the incidence of AEs for placebo versus Triferic dose groups did not suggest any AE’s were associated with treatment.

Safety has historically been the most important point of differentiation among the IV iron products. Early products induced high levels of anaphylaxis and were subsequently replaced by the safer iron-carbohydrate products. In contrast to these large, complexed preparations, Triferic is a monomeric iron salt that does not cause the allergic reactions associated with the carbohydrate-based IV iron products. Other toxicities associated with the conventional IV iron products have been ascribed to their release of free iron, which is similarly not a problem with Triferic.

**End Stage Renal Disease - Kidney Function, Iron Metabolism, & Disease Information**

The kidneys serve in several homeostatic functions, including the regulation of blood pressure, electrolytes, and the acid-base balance. The kidney, illustrated in Figure 1, is bean-shaped and is located behind the abdominal cavity in the lower-back portion of the human body. As blood enters the kidney from the renal artery, toxins are filtered out into the urine and the blood then exits the organ through the renal vein. The kidney contains approximately 1 million nephrons that carry out most of the kidney's filtration functions. The nephron acts as a filter as it reabsorbs and secretes solutes that include ions such as sodium, carbohydrates, and amino acids.
Another critical function of the kidney is the secretion of hormones that aid in many of the body’s biological systems. Erythropoietin is a hormone secreted by the kidneys in response to hypoxia, or low amounts of oxygen in the body, and it stimulates the production of red blood cells from the bone marrow. Erythropoietin stimulating agents (ESAs) are used to treat anemia in dialysis patients. Renin is an enzyme secreted by the kidneys that helps maintain aldosterone and regulate blood pressure. An activated form of vitamin D is secreted by the kidneys to promote the absorption of calcium in the gastrointestinal tract. Rockwell also has a product known as Calcitriol that is a vitamin D supplement.

**Iron (Fe) Metabolism.** Iron is necessary for the production of RBCs, which have many functions, primarily delivery of oxygen to the body. On average a person requires approximately 20 mg of iron per day for the production of RBCs. When the amount of iron in the body deviates from equilibrium it may cause a variety of life-threatening diseases, so careful monitoring and maintenance is important for patients, such as those on dialysis, whose bodies can’t properly regulate iron homeostasis.

Several molecules that exist in the human body are responsible for the regulation of internal iron levels, including hemoglobin, transferring, ferritin, and hepcidin.

- Hemoglobin is an iron-binding protein located in the body’s RBCs and accounts for greater than 95% of their total dry weight. It can increase the blood’s oxygen by 70-fold. Non-normal amounts of iron can affect internal hemoglobin levels causing a variety of diseases. Most common is iron deficiency, or anemia, which is directly associated with dialysis and leads to decreased hemoglobin. Measuring hemoglobin concentration is one of the most commonly performed blood tests.
Transferrin is a glycoprotein that has the ability to bind iron. Transferrin-bound iron is important because it is most efficiently transferred to the bone marrow for RBC production. Transferrin’s iron binding capacity decreases as with decreasing pH. When an individual becomes hypoxic or lacks oxygen, carbon dioxide will build up in the body and decrease biological pH, allowing iron to then be released for the immediate production of RBCs.

Ferritin is a globular protein that is the primary intracellular iron-storage protein in all living things. Its main biological function is to store iron in a safe and non-toxic form, so that it may be released to transferring in a timely fashion to maintain iron homeostasis.

Hepcidin is a small peptide produced in the liver and is the body’s main regulator of systemic iron homeostasis. Hepcidin levels are increased by inflammation and elevated body iron levels, and reduced by erythropoietin activity and hypoxia. Hepcidin inhibits the release of iron from the liver to be taken to the bone marrow for the production of red blood cells.

CKD and Associated Diseases

Some of the most prevalent diseases involving iron homeostasis include chronic kidney disease (CKD), end-stage renal disease (ESRD), and iron deficiency anemia. Typical causes of CKD include diabetic nephropathy, hypertension, or inflammation of blood vessels in the kidney. These problems are diagnosed using a blood test of creatinine, urinalysis for protein and RBCs, medical imaging, and renal biopsies. Patients with CKD often suffer from atherosclerosis, leading to increased risk of cardiovascular disease. Other conditions that may result from decreased kidney function are anemia, acidosis, cholesterol and fatty acid disorders, and bone disease. Iron deficiency anemia is a disease that may cause some similar symptoms, but is typically due to a decrease in the dietary intake or adsorption of iron. If iron levels are abnormally low, then less hemoglobin is being made and oxygen transport suffers. This disease can lead to malfunctioning organ systems and treatment requires some form of iron supplementation.

There are 5 stages of CKD disease that are characterized by symptoms of increasing seriousness with stage 1 being the least serious and stage 5 being the most. Stage 5 CKD is also classified as end-stage renal disease (ESRD), where the kidney stops functioning and there is a dangerous accumulation of water and toxic substances in the body. In the early stages of CKD, drugs like angiotensin-converting enzyme (ACE) inhibitors or angiotensin II receptor blockers (ARBs) may slow the progress of the disease, but are not a sufficient treatment. As the disease worsens patients can be supplemented with recombinant human erythropoietin, vitamin D3, and calcium. Phosphate binders can also be used to control elevated serum-phosphate levels in CKD. Once a patient reaches stage 5 CKD, renal replacement therapy, consisting of either dialysis or organ transplant, is the only option.

CKD Treatment & Dialysis. Due to the shortage of organ donors, dialysis has become a very common procedure for serious chronic kidney disease. Only 4% of patients with end-stage renal disease received donated kidneys in 2008. Dialysis replaces the normal function of a kidney when the patient has ESRD. Even though dialysis can replace some of the kidney functions like diffusion (waste removal) and ultrafiltration (fluid removal), it does not replace the endocrine functions of the kidney, which must be managed separately. While there are multiple types of dialysis, we focus only on hemodialysis, which is used to treat CKD.

The process of dialysis is based on the principle of diffusion of solutes and the ultrafiltration of liquid across a semi-permeable membrane. Once the blood enters the dialyzer, it flows in an opposite direction across a semi-permeable membrane from the dialysate solution to maximize the concentration gradient and maintain efficiency of dialysis. The dialysis solutions are designed to draw toxins from the blood through diffusion while adding other things that the
patients lack, such as calcium, back into the blood. Fluid is removed from the blood through hydrostatic pressure. Triferic is the only way to replenish lost iron each session via the dialysate.

A nephrologist must prescribe the patient-specific treatment, which varies based on treatments per week, length of treatment, blood and dialysis solution flow rates, and the size of the dialyzer apparatus. Routine dialysis, usually three times per week, is commonly performed on an outpatient basis at a stand-alone clinic. Medicare and Medicaid will generally only reimburse up to three dialysis sessions a week. Different and more convenient methods of dialysis are constantly being introduced, but all rely on the same underlying science and a change in instruments or exact procedures aren’t likely to decrease patients’ need for iron supplementation.

Anemia Management for Hemodialysis Patients

ESAs. Nearly all ESRD patients who undergo hemodialysis have anemia or low red-blood cell count since the kidneys secrete erythropoietin, a hormone that is responsible for keeping normal red-blood cell count. As a result, most hemodialysis patients receive intravenous erythropoietin stimulating agents (ESAs). The most common ESAs are Amgen’s (NasdaqGS: AMGN) Epogen (epoetin alfa) and Aranesp (darbepoetin alfa) and Johnson & Johnson’s (NYSE: JNJ) Procrit (epoetin alfa). Sales for these three drugs alone were over $5 billion ending 2014, as detailed in the next section. However, they are also expensive; for example the treatment cost for one year of Epogen is approximately $8,4471 and at about $3 billion annually, it is one the costliest drugs for Medicare. There have also been questions relating to its safety and possible over-use.

Concern about erythropoietin therapy has attracted considerable attention recently in the clinical community. Epidemiologic and clinical trial evidence in patients with ESRD and chronic kidney disease suggests that liberal administration of erythropoietin is associated with a slight but statistically significant increase in mortality. As a result of this finding, ESA dosing has been on the decline. The National Kidney Foundation updated its practice guideline to target hemoglobin levels in the range of 11.0 to 12 g/dL and not greater than 13 g/dL.

Studies done to determine the magnitude of erythropoietin stimulating agent (ESA) sparing have shown that dosing IV iron drugs 3-times weekly in small doses (off-label) can reduce ESA doses by up to 35%. Due to their high cost and safety concerns, the percentage of patients receiving an ESA prior to initiation of dialysis decreased from 33% in 2002 to about 18% in 2011. Since the introduction of the bundling system for dialysis patients in 2011, intravenous ESA use has decreased even further in favor of IV iron.

IV Iron. Iron needs to be present in order to make new RBCs, and due to the loss during dialysis about 90-95% of hemodialysis patients need supplements. Oral tablets are not very effective because there is generally not enough iron orally bioavailable to replace the iron lost.

The market size in the US for intravenous iron used in dialysis is between $550 to $600 million per year, and approximately $1 billion globally. The top five products include Venofer (iron sucrose injection), Feraheme (ferumoxytol), Ferrlecit (sodium ferric gluconate complex in sucrose injection), INFeD (iron dextran injection), and Dexferrum (iron dextran injection). Venofer, sold by American Regent (a subsidiary of Daiichi Sankyo, OTC: DSNKY), and Sanofi’s (NYSE: SNY) Ferrlecit have the largest shares in terms of sales. After the introduction of the new bundling

payment system, IV iron use increased as providers have sought ways to reduce costs per treatment by reducing ESA use. This has led, in turn to renewed safety concerns surrounding the use of IV iron.

All IV iron products contain language on their label – some in the form of a boxed warning – regarding the possibility of anaphylactic reactions. Patients who receive IV iron must be observed for 30 minutes following infusion for signs of a reaction, and IV iron is recommended to only be administered when facilities for rescuing patients are available. IV iron also carries a risk of iron overload, and is known to increase ferritin levels. The human body has a complex system for managing iron, which is a toxic oxidative element. Ferritin increases when the body can’t use the iron available. Instead of maintaining proper iron and hemoglobin levels, IV iron puts patients on a roller coaster ride where they experience iron overload and then become anemic over time, before receiving another bolus of iron. *Triferic* delivers iron in a bio-available fashion that mimics dietary delivery of iron, and maintains patients’ hemoglobin leading to better quality of life.

**Triferic** Possess Clear Safety Advantage Over IV Iron and ESAs. The Phase III CRUISE trials clearly demonstrate that *Triferic* is a safe and physiologically available form of supplemental iron. This stands in strong contrast to intravenous iron, which carries a boxed warning for anaphylactic reactions. SFP has not caused a single anaphylactic reaction in approximately 100,000 human doses. Additionally, the Phase II PRIME clinical trial demonstrated that using SFP significantly reduces the need for ESAs, by 35%. Reducing ESA use will be valuable for patient safety as ESAs also carry a boxed warning concerning the risk of death, myocardial infarction, stroke, venous thromboembolism, thrombosis of vascular access, and tumor progression or recurrence.

**Dialysis Treatment Market**

**Market Information**

The global ESRD population was estimated to be over 2.8 million patients at the end of 2011, growing approximately 6-7% annually. According to the United States Renal Data System, there were approximately 409,000 dialysis patients in the United States at the end of 2012. Total Medicare expenditures totaled almost 30 billion in 2011. While there is a move to home or other alternative treatments, most dialysis treatments still occur in freestanding clinics or hospitals. There are about 6,300 Medicare-certified dialysis clinics in the US. The two largest dialysis clinics, Fresenius Medical Care (NYSE: FMS) and DaVita HealthCare Partners (NYSE: DVA, control about 70% of the hemodialysis market. The top 10 providers cover more than 90% of the market. There are two types of dialysis modality – hemodialysis and peritoneal dialysis. Hemodialysis (HD) accounts for over 90% of all dialysis administered. However in 2011, the number of new patients starting therapy with hemodialysis decreased by 1.5%, the first decrease in more than three decades. In contrast, patients starting with peritoneal dialysis has grown to 8% and now accounts for 6.6% of total dialysis patients. The biggest cause for this shift is the change in financial incentives for providers under the new bundling system for routine dialysis treatments and peritoneal dialysis is the least expensive option of the two – one year of hemodialysis cost approximately $88,000 in 2011 versus $72,000 for peritoneal dialysis.3

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2 USRDS 2014 Annual Data Report. Volume 2, ESRD, Chapter 1, Table D.1.
Recent Revenues for Iron Therapy

The table in Figure 2 shows recent revenues for leading ESA and IV iron products. As detailed in the table, revenue for ESAs has been falling due to both safety concerns and pricing pressure due to bundled payments.

**Figure 2. Revenue for Iron Management Products, in Millions**

<table>
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<tr>
<th>ESA Product Name</th>
<th>Company</th>
<th>2014</th>
<th>2013</th>
<th>2012</th>
<th>2011</th>
<th>2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epogen (epoetin alfa)</td>
<td>Amgen</td>
<td>$2,031</td>
<td>$1,953</td>
<td>$1,941</td>
<td>$2,040</td>
<td>$2,524</td>
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<td>Aranesp (darbepoetin alfa)</td>
<td>Amgen</td>
<td>$1,930</td>
<td>$1,911</td>
<td>$2,040</td>
<td>$2,303</td>
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<tr>
<td>Procrit (epoetin alfa)</td>
<td>Johnson &amp; Johnson</td>
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<td>$1,364</td>
<td>$1,462</td>
<td>$1,623</td>
<td>$1,934</td>
</tr>
<tr>
<td>Micera (epoetin beta pegol)</td>
<td>Galenica</td>
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<td>$459</td>
<td>$404</td>
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<td>$246</td>
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<tr>
<td>NeoRecormon (epoetin beta)</td>
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<td>$465</td>
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<td>$741</td>
<td>$953</td>
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<table>
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<th>Company</th>
<th>2014</th>
<th>2013</th>
<th>2012</th>
<th>2011</th>
<th>2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dexferrum (iron dextran)</td>
<td>Luitpold</td>
<td>$86</td>
<td>$71</td>
<td>$60</td>
<td>$52</td>
<td>$59</td>
</tr>
<tr>
<td>Ferrlecit (sodium ferric gluconate)</td>
<td>Sanofi-Aventis</td>
<td>$110</td>
<td>$110</td>
<td>$110</td>
<td>$110</td>
<td>$110</td>
</tr>
<tr>
<td>INFeD (iron dextran)</td>
<td>Watson</td>
<td>$38</td>
<td>$32</td>
<td>$32</td>
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<td>$32</td>
</tr>
<tr>
<td>Venoferr (iron sucrose)</td>
<td>Daiichi Sankyo</td>
<td>$345</td>
<td>$345</td>
<td>$375</td>
<td>$408</td>
<td>$408</td>
</tr>
<tr>
<td>Feraheme (ferumoxytol)</td>
<td>AMAG Pharma</td>
<td>$86</td>
<td>$71</td>
<td>$59</td>
<td>$38</td>
<td>$27</td>
</tr>
<tr>
<td>Injectfer (ferric carboxymaltose)</td>
<td>Daiichi Sankyo</td>
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<td>$183</td>
<td>$135</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Nulecit (iron gluconate)</td>
<td>Watson</td>
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<td>$23</td>
<td>$25</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

Source: Company Reports and LifeSci Capital Estimates

Bundled Prospective Payment System for Dialysis

Since 1983, reimbursement for hemodialysis was billed on a per-treatment basis that included the dialysates as well as add-ons for separately billable medications that were administered during the dialysis session. Facilities and providers also sent separate bills for ESAs. This led to rapid growth in dialysis spending as providers were incentivized to use and bill extra for these additional items. Since 2011 the Centers for Medicare and Medicaid Services (CMS) have been using a comprehensive bundled payment for dialysis that caps the total reimbursement for dialysates and other items used for each treatment session. Products generally required for dialysis that are included in the bundle are:

- All dialysates.
- ESAs.
- Vitamin D.
- Intravenous iron.
- Laboratory tests.
- Oral medications with IV equivalents.
The CMS recalculates the bundled reimbursement amount each year based on a formula that includes wages, the cost of supplies, and budgetary concerns. In 2015, the base payment was $239.43 per treatment. However, the rate is expected to decrease to $230.20 per treatment in 2016, which will put renewed pressure on payers to reduce the cost of treatment within the bundle. In addition, the proposed rule will also implement a Drug Designation Process to determine if the all applicable drugs relating to renal dialysis services will be included in the bundled payment.

**Triferic Has Multiple Potential Advantages in the Bundled Payment Environment**

The existence of the bundled payment system for dialysis providers creates constant pressure to reduce costs related to the materials and drugs need for treatment as well as nursing time. *Triferic* has the potential to deliver savings in both areas. First, *Triferic* led to a significant decrease in both IV iron and ESA use in the Phase II PRIME trial. IV iron costs up to $700 per patient annually in addition to the significant nursing time needed to administer the drug. ESAs are expensive biologic drugs that cost up to $5,000 per patient per year. Overall in the PRIME trial *Triferic* reduced ESA usage by 35% and IV iron usage by 51% relative to placebo. In ESA hypo-responders, patients who use much more than the average amount of ESAs, *Triferic* reduced ESA usage by 74% compared to placebo.

The economic potential of using *Triferic* is clear. Simply reducing ESA use by 2% would save providers $1 per patient per dialysis session, and there are about 75 million dialysis procedures in the US each year. Moreover, the PRIME study results suggest a potential savings in ESA and IV iron use alone due to *Triferic* of more than $2,000 per patient per year. To further put the ESA sparing affect in context, just a 2% reduction in ESA equates to an estimated $1 reduction in per treatment cost for each dialysis patient, which adds up to $156 per year per patient, or approximately $60 million in annually savings. The size of the US market for ESA in dialysis is approximately $2 billion, meaning significant savings potential for patients receiving hemodialysis. Taken together, the benefits of reducing ESA in both the overall and hypo-responsive population should improve the market prospects for *Triferic*.

**Triferic and the CMS Quality Incentive Program**. In addition to setting the bundled price for dialysis each year, the Centers for Medicare and Medicaid Services (CMS) also maintain a program to encourage providers to constantly improve their services. The Quality Incentive Program or QIP provides payments of up to 2% of the bundle price when certain measures are met. One of the primary components of the QIP is effective iron management, including using agents such as ESAs according to FDA approved labeling, meaning *Triferic* has the potential to impact clinics’ ability to achieve these extra payments. If we assume a $500 per year cost per patient of *Triferic* annually, it breaks down to about $3 per patient per session. A 2% rebate for the QIP would give providers about $5 per patient per session. Making it easier for providers to achieve the QIP and the subsequent payment is another incentive that could help drive adoption.

**Triferic Sales Potential - Scenario Analysis**

Considering the potential cost savings that *Triferic* may help providers achieve, we can understand the potential pricing power of *Triferic*. We assume that approximately $500 is spent per dialysis patient on IV iron per year and $5,000 is spent on ESAs, and then consider the potential reductions in their use due to *Triferic* of 51% and 35%, respectively. This would lead to $255 plus $1,750 or over $2,000 in annual savings. This type of analysis could be used to determine the value of *Triferic* to dialysis providers and also Rockwell Medical.

Since *Triferic* may save providers up to $2,000 per patient annually, the scenario analysis in Figure 3 assumes prices of $500, $850, and $1,200 per patient per year. The table shows the given annual revenue for Rockwell at each point.
assuming the number of patients shown. In 2015 and 2016 there are a half-million dialysis patients in the US, and the population is growing about 4-6% annually. For this analysis we assume a patient population of 500,000 and show the revenue potential for Triferic based on the given market penetration. As seen in the table, Triferic has a reasonable expectation of annual revenue in the range of $200 to $400 million before factoring in population growth. It is also important to remember that Triferic is expected to have a very low cost of goods, which would translate to a healthy gross margin for this product.

**Figure 3. Triferic Revenue Potential Based on Market Penetration and Price, in Millions**

<table>
<thead>
<tr>
<th>Price</th>
<th># of Patients:</th>
<th>Market Penetration:</th>
</tr>
</thead>
<tbody>
<tr>
<td>$500</td>
<td>150,000</td>
<td>30%</td>
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<tr>
<td></td>
<td>200,000</td>
<td>40%</td>
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<tr>
<td></td>
<td>250,000</td>
<td>50%</td>
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<td></td>
<td>300,000</td>
<td>60%</td>
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<tr>
<td></td>
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<td>70%</td>
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<td></td>
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<td>$850</td>
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<td>30%</td>
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<td></td>
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<td>40%</td>
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<tr>
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<tr>
<td></td>
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<tr>
<td></td>
<td>$200</td>
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</tr>
<tr>
<td>$1,200</td>
<td>$128</td>
<td>Revenue Potential:</td>
</tr>
<tr>
<td></td>
<td>$170</td>
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<td>$298</td>
<td></td>
</tr>
<tr>
<td></td>
<td>$340</td>
<td></td>
</tr>
</tbody>
</table>

*Source: LifeSci Capital*

**Clinical Data Discussion**

The late stage clinical program for Triferic included the Phase II PRIME trial, which demonstrated the drug's ESA sparing effects, and the Phase III safety and efficacy trials known as CRUISE I and CRUISE II. Rockwell announced in February 2013 that the Phase II PRIME study met the primary endpoint of change in ESA dose from baseline, setting the stage for the two Phase III CRUISE trials that also met their primary endpoints of mean change in hemoglobin. Positive results from the CRUISE trials were released in the summer of 2013. Full results of the PRIME study, notably that Triferic led to an overall 35% decrease in ESA use and 74.4% decrease in ESA hyporesponders, were recently published in the journal *Kidney International*.4

**Phase II Prime Study**

**Trial Design.** The Phase II PRIME trial was a placebo controlled, double blind study conducted in the US and completed in early 2013.5 A total of 108 patients were randomized 1:1 to dialysis treatment using dialysate that included Triferic at 11 μg/dL or standard dialysate. 103 patients received treatment or placebo (Triferic = 51, placebo = 52). During the trial, the objective was for both groups to keep hemoglobin between 9.5 and 11.5 g/dL. All patients were eligible, under the same guidelines, to receive erythropoiesis-stimulating agents (ESA) and rescue iron in order to maintain Hgb in the target range. The primary endpoint measurement was the difference between treated and placebo groups in change from baseline ESA usage over the course of 9 months. Secondary endpoints included the amount of IV iron needed to maintain hemoglobin and safety.

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5 [https://clinicaltrials.gov/ct2/show/NCT01286012](https://clinicaltrials.gov/ct2/show/NCT01286012)
**Triferic Led to a 35% Reduction in ESA Use in the PRIME Study.** The full results of the PRIME trial, including analyses of the secondary endpoints, were recently published in the journal *Kidney International*. The paper is entitled, “Ferric pyrophosphate citrate administered via dialysate reduces erythropoiesis-stimulating agent use and maintains hemoglobin in hemodialysis patients”.

Most importantly, data from the PRIME trial demonstrates *Triferic*’s ability to significantly reduce patients’ need for ESAs. This is an important feature considering the safety and cost considerations associated with ESA use. Overall, patients receiving *Triferic* were administered 35% less ESA than patients receiving placebo (p=0.045). This is a significant reduction however a pre-defined sub-population analysis of patients that were ESA hypo-responders indicated that *Triferic* led to a 74.4% reduction in ESA use compared to placebo. Hypo-responsive patients represent a significant portion of ESA expense. The most common causes of ESA resistance are non-compliance, absolute or functional iron deficiency, and inflammation. IV iron does not cause ESA resistance but also does not help to correct it. This analysis illustrates the dramatic potential in savings and clinical advantages of *Triferic* over currently available iron replacement therapies.

The change in ESA from baseline is shown in **Figure 4** from the beginning of the study until the end of treatment. The amount of ESA trended upwards for patients receiving placebo starting at approximately week 16, whereas the amount of ESA remained stable across the treatment period for patients receiving *Triferic*.

**Figure 4. Triferic Reduces ESA Usage**

![](image)

*Source: Gupta, A. et al., 2015*

The lower, dotted lines in the graph in **Figure 5** show hemoglobin levels for patients receiving either *Triferic* or placebo. These data demonstrate that patients in the active treatment arm were able to maintain hemoglobin levels with *Triferic* while patients in the control arm experienced a decrease until ESA dose increased. This graph is very important relative
to the above graph showing ESA usage. When viewed together, the placebo arm shows a rapidly rising ESA dose and declining hemoglobin level while patients in the active treatment arm maintain hemoglobin levels without an increase in ESA dose. These data, taken together, clearly demonstrate Triferic’s ability to maintain hemoglobin while sparing ESA. The solid graphs in Figure 5 indicate patients’ ferritin levels. Patients on placebo initially maintained their hemoglobin by depleting their ferritin reserves. The important thing to notice here is that patients administered Triferic were able to maintain hemoglobin without increasing or decreasing ferritin levels. IV iron, on the other hand, leads to unsafe increases in ferritin.

**Figure 5. Triferic Maintains Hemoglobin without Increasing Ferritin**

![Graph showing hemoglobin and ferritin levels](image)

*Source: Gupta, A. et al., 2015*

**Notable 74.4% ESA Sparing Effect in ESA Hypo-Responders.** A sub-population analysis of PRIME data was presented during an oral session at the 2013 American Society of Nephrology meeting. The data demonstrated the impact of Triferic on ESA use in patients who are hypo-responsive to ESA. The presentation was entitled “Soluble Ferric Pyrophosphate (SFP) Administered via Dialysate Reduces ESA Requirements in CKD-HD Patients with ESA Hypo-Response.”

ESA hypo-responders are individuals with resistance to ESAs, defined as those receiving greater than 13,000 units of ESA per week. As shown in Figure 6. The analysis revealed 23 patients who received greater than 13,000 units of ESA per week at baseline. Of these, 12 received Triferic and 11 were assigned to placebo. Here the mean percent change from baseline in the Triferic arm decreased 8.5% while in the placebo arm ESA increased 65.9%. Triferic was able to reduce the amount of ESA between Triferic and placebo patients an impressive 74.4%.

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These data suggest that *Triferic* has the ability to provide an additional benefit to hypo-responders in terms of reducing their dependence on ESA. In addition to the economic benefit, reducing ESA use is important for patient safety as ESAs carry a boxed warning concerning the risk of death, myocardial infarction, stroke, venous thromboembolism, thrombosis or vascular access, and tumor progression or recurrence. The lack of response to ESA intensifies hypo-responding patients’ difficulty in maintaining proper hemoglobin levels, but the ready bioavailability of *Triferic*, which is utilized directly by the bone marrow to make new red blood cells, partially obviates the need for ESA.

**Phase III CRUISE Clinical Trials**

For Rockwell, the successful conclusion of the CRUISE Phase III clinical program represented the culmination of years of research and development, and was also a key step on the path to approval for *Triferic*. For hemodialysis (HD) providers and patients, the first product with the ability to safely help patients maintain hemoglobin (Hgb), the CRUISE trials brought this breakthrough product one step closer to the market. On July 13, 2015, full results from the Phase III CRUISE 1 and 2 trial results were published in the journal *Nephrology Dialysis Transplantation.*

**Well-Planned CRUISE Trials Used an Innovative Design.** The Phase III program for *Triferic*, which included CRUISE-1 and CRUISE-2, was unlike any other clinical trials run in the dialysis space, because the drug is an innovative product used to consistently deliver iron every treatment and maintain hemoglobin in hemodialysis patients who lose iron every treatment. *Triferic* is designed to maintain iron and hemoglobin so that patients do not become anemic. The trials were longer than trials for IV iron products, giving Rockwell evidence for the utility of long-term administration of *Triferic*, as well as its safety.

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8 https://clinicaltrials.gov/ct2/show/NCT01320202

9 https://clinicaltrials.gov/ct2/show/NCT01322347
The CRUISE studies were randomized, placebo-controlled, patient-blinded studies of Triferic in patients with chronic kidney disease who are receiving dialysis. Each trial enrolled 300 patients. The primary endpoint for each trial was mean change from baseline in Hgb. Fundamentally, the trial was designed to show that patients receiving Triferic experience a smaller decrease in hemoglobin levels during the study period than patients taking placebo. By design, patients were moved from the randomization stage of the trial to the open-label extension stage when they met pre-specified safety criteria. Hemoglobin values from all patients in the randomization stage were then included in the final data analysis, which confirmed statistical significance. The pre-defined safety criteria were:

- A need to change erythropoietin stimulating agent (ESA) dose due to low (90 g/L) or high (120 g/L) hemoglobin values.
- Rapidly rising hemoglobin, which is defined as hemoglobin greater than 115 g/L and an increase of 10 g/L over 4 weeks.
- Serum ferritin greater than 200 μg/L and less than 800 μg/L over the two most recent consecutive every-other-week measurements prior to randomization.

When patients in the randomization stage met any of the safety criteria above, they were eligible to continue in the open-label safety extension study. The mean treatment duration was 23 weeks, or about 6 months. Patients were eligible for treatment up to 12 months, and up to 18 months in combined treatment between randomization and open-label stages of the trial. The assessment of hemoglobin for the primary endpoint was made based on measurements from the last 1/6th of the treatment period for patients, no matter when they left the randomization stage. This 1/6th average of final measurement actually makes the magnitude of effect even more robust.

**Strong Phase III CRUISE Safety and Efficacy Data Supported FDA Approval.** The full safety and efficacy analyses from the two Phase III CRUISE trials were presented in a poster entitled “Continuous, Maintenance Iron Therapy Using Soluble Ferric Pyrophosphate Citrate Chelate (SFP, Triferic) Infusion via Hemodialysate in CKD-HD: Phase III CRUISE Studies.” Hemodialysis (HD) patients were randomized to placebo or Triferic and remained in the study for up to 48 weeks. Both trials met the primary endpoint of change from baseline in hemoglobin. The results, highlighting the tight correlation between CRUISE-1 and CRUISE-2, are displayed in Figure 7. Triferic was able to maintain hemoglobin levels across the 48 weeks of treatment, whereas patients receiving placebo experienced a statistically significant decline in hemoglobin.
CRUISE-1 was the first of two identical Phase III trials comparing SFP to placebo in adult patients with chronic kidney disease who are on dialysis. The mean difference in hemoglobin between the SFP and placebo groups was a statistically significant 3.6 g/L in favor of SFP (p=0.011). Overall, patients treated with SFP experienced a 0.6 g/L increase in hemoglobin levels while patients in the placebo group experienced a 3.0 g/L decrease in hemoglobin. CRUISE-2 also met its primary endpoint as Triferic demonstrated a statistically significant change in hemoglobin from baseline compared to placebo. Patients randomized to SFP experienced a mean decrease of 0.5 g/L of hemoglobin from baseline while placebo patients saw a 4.0g/L decline in hemoglobin. The difference of 3.6 g/L in favor of SFP was statistically significant, with a p-value of 0.011. This result confirms the positive outcome of CRUISE-1.

Additional efficacy data were presented including the maintenance or slight decrease in ferritin levels with Triferic treatment. Ferritin is an iron storage molecule and also a marker of inflammation. An increase in ferritin suggests that the body is storing newly delivered iron instead of utilizing the iron for hemoglobin production, and may additionally indicate inflammation. Patients in the Triferic arms of the CRUISE trials did not experience an increase in ferritin, indicating that the iron delivered by Triferic is not stored but actively used to make hemoglobin instead of causing inflammation. This is an important contrast to other iron therapies, as available data shows that IV iron increases inflammation.

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Positive Results Achieved for Secondary Endpoints

In addition to achieving the primary efficacy endpoint, SFP also met important secondary endpoints. For example, there was a statistically significant difference between SFP and placebo groups in reticulocyte hemoglobin. At the end of treatment, the difference was 0.97% (p=0.017) in favor of Triferic, as treated patients maintained reticulocyte hemoglobin but placebo patients experienced a significant decrease. This is an important biomarker because it is a measure of the effectiveness of erythropoiesis and of iron in a person’s body that is readily available for use in the making of red blood cells.

Serum ferritin is another important biomarker for monitoring anemia in hemodialysis patients is it measures stored iron and inflammation in the patients’ body. In CRUISE-1 Triferic patients experienced a decline of 14.8%, compared to a decline of 28.5% for placebo (p<0.001). In CRUISE-2, patients taking Triferic experienced a decline in serum ferritin of 11.6%, compared to 21.7% for placebo. This result is important in two ways. First, it showed that iron stores were not depleted for patients receiving Triferic, compared to those on placebo who saw a significant decline. Equally important is that serum ferritin did not increase for patients taking Triferic. If the iron from Triferic was being stored by the body instead of being used to make hemoglobin, then serum ferritin would increase. Coupled with the fact that Triferic patients maintained reticulocyte hemoglobin, this result shows that the iron is bioavailable and is being used by patients’ bodies to make hemoglobin, and is not being unnecessarily stored.

Reticulocyte hemoglobin (CHr) measured showed that patients receiving Triferic remained stable and near the baseline levels, while placebo patients experienced a statistically significant 2.1% decrease from baseline (p<0.001). This CHr result is an important metric that shows Triferic is getting to the bone marrow and is being utilized in RBC production.

Correlation of CRUISE-1 and CRUISE-2 Results Provide Strong Evidence of Triferic’s Clinical Activity. In addition to the strong topline data values, the CRUISE-2 data is an important validation and confirmation of the CRUISE-1 trial. The two studies were run according to the same trial design and produced very similar results. A summary of the key data from each trial that has been released is shown in Figure 8.

<table>
<thead>
<tr>
<th>Clinical Parameter</th>
<th>CRUISE-1 Result</th>
<th>CRUISE-2 Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change in Hgb from baseline – Triferic</td>
<td>+0.6 g/L</td>
<td>-0.5 g/L</td>
</tr>
<tr>
<td>Change in Hgb from baseline - placebo</td>
<td>-3.0 g/L</td>
<td>-4.0 g/L</td>
</tr>
<tr>
<td>Difference between Triferic &amp; placebo in change in Hgb</td>
<td>3.6 g/L (p=0.011)</td>
<td>3.6 g/L (p=0.011)</td>
</tr>
<tr>
<td>from baseline</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change in reticulocyte hemoglobin from baseline – Triferic vs. placebo</td>
<td>2.1% (p&lt;0.001)</td>
<td>0.97% (p=0.017)</td>
</tr>
<tr>
<td>Serum ferritin – decrease from baseline for Triferic</td>
<td>-14.7%</td>
<td>-11.6%</td>
</tr>
<tr>
<td>Serum ferritin – decrease from baseline from placebo</td>
<td>-28.2%</td>
<td>-21.7%</td>
</tr>
<tr>
<td>Difference between Triferic and placebo in serum ferritin</td>
<td>13.5% (p&lt;0.001)</td>
<td>10.1% (p&lt;0.001)</td>
</tr>
</tbody>
</table>

Source: LifeSci Capital
Triferic’s Safety Profile was Consistent and Benign for both CRUISE Trials. Equally important to the strong efficacy results for Triferic produced by the CRUISE clinical program is the safety profile. Triferic was designed to replace the 5-7 mg iron loss that HD patients experience during every treatment. As a product that will be used frequently and over the long-term, it is extremely important that the drug is safe for patients. The primary take-away from the CRUISE trials regarding safety is that Triferic has a similar safety and adverse event profile as placebo. There were no significant differences between the treatment and control arms when it came to safety. A full accounting of the safety data released to date from CRUISE 1 and CRUISE-2 is shown in Figure 9.

Figure 9. CRUISE Clinical Trials Safety Data

<table>
<thead>
<tr>
<th>Adverse Events</th>
<th>CRUISE-1</th>
<th>CRUISE-2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>SFP (n=149)</td>
<td>Placebo (n=151)</td>
</tr>
<tr>
<td>Procedural (Intradialytic) Hypotension</td>
<td>43 (28.9%)</td>
<td>41 (27.2%)</td>
</tr>
<tr>
<td>AVF complication</td>
<td>17 (11.3%)</td>
<td>17 (11.3%)</td>
</tr>
<tr>
<td>Hemodialysis induced symptom</td>
<td>7 (4.7%)</td>
<td>5 (3.3%)</td>
</tr>
<tr>
<td>AVF Hemorrhage or Thrombosis</td>
<td>8 (5.4%)</td>
<td>6 (4.0%)</td>
</tr>
<tr>
<td>AVG complication or Thrombosis</td>
<td>6 (4.0%)</td>
<td>4 (3.3%)</td>
</tr>
<tr>
<td>Infections</td>
<td>29 (19.5%)</td>
<td>31 (20.5%)</td>
</tr>
<tr>
<td>Cardiac Disorders</td>
<td>14 (9.4%)</td>
<td>21 (13.9%)</td>
</tr>
<tr>
<td>Device Thrombosis</td>
<td>3 (2.0%)</td>
<td>5 (3.3%)</td>
</tr>
</tbody>
</table>

Source: LifeSci Capital

Long-Term Safety Trial Results for Triferic. The safety profile of any iron drug is very important, and Triferic has been tested in the largest and longest cohorts of any iron product to date. The gathered data demonstrate no acute safety signals or anaphylaxis. Triferic has produced a consistently strong and benign safety profile. Safety has been consistent across the PRIME and CRUISE trials, supporting the long-term use of Triferic in HD patients. An additional safety study, including patients from the CRUISE trials, was conducted in 703 patients to further assess the drug’s safety. The trial was a Phase III, randomized, double-blind, placebo-controlled, crossover study and the results were presented on in November 2013 at the American Society of Nephrology Annual Meeting in a poster entitled “Soluble Ferric Pyrophosphate (SFP) Administered via Dialyate Shows No Acute Safety Signals.” Patients with CKD undergoing dialysis were enrolled and randomized to placebo or Triferic. Patients were treated with placebo or Triferic for 2 weeks, followed by a 1 week washout period. The treatment was switched for the last 2 weeks, so that those receiving placebo now received Triferic, and vice versa. The primary endpoint was safety and tolerability.

The number of adverse events (AEs) was similar in placebo and Triferic treated patients. Furthermore, the number of serious AEs was also similar between placebo and Triferic. Importantly, after more than 100,000 doses not a single anaphylactic event has been attributed to Triferic. Figure 10 shows the number of treatment-emergent serious AEs and the number of subjects with greater than 1 treatment-emergent serious AE both placebo and Triferic.

11 http://clinicaltrials.gov/ct2/show/NCT01503021
Figure 10. Serious Adverse Events

<table>
<thead>
<tr>
<th>Serious Adverse Events</th>
<th>Triferic (N=693)</th>
<th>Placebo (N=687)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number of treatment-emergent serious AEs</td>
<td>37</td>
<td>51</td>
</tr>
<tr>
<td>Number of subjects with ≥ 1 treatment-emergent serious AE, n (%)</td>
<td>30 (4.3)</td>
<td>35 (5.1)</td>
</tr>
</tbody>
</table>

Source: Guss, C. et al., 2013

The following list summarizes the key findings from the long-term safety trial:

- *Triferic* reliably delivers iron via dialysate.
- There were no specific adverse events directly attributable to *Triferic*.
- The adverse events during *Triferic* administration were those common in CKD-HD patients.
- No difference in type, frequency, severity or resolution of adverse events between *Triferic* and placebo.
- No anaphylaxis or hypersensitivity attributable to *Triferic*.
- No evidence of changes in hepatic enzymes between *Triferic* and placebo.
- No evidence of first use events or an increase in intradialytic hypotension.

**Calcitriol – A Generic Vitamin D Supplement for Dialysis Patients**

Rockwell is expected to launch *Calcitriol* in 2015 in concert with the introduction of *Triferic*. The most important factor to understand about this product is that most hemodialysis patients require this supplement, and it is billed as part of the bundle. Rockwell intends to sell *Calcitriol* at a discount relative to all other vitamin D supplements available. Therefore, within the bundled billing system, providers will be able to achieve savings on every patient treated by switching to this product. Rockwell also has the potential to combine this product with *Triferic* for sales and marketing purposes. Despite the expected price of this product, the Company still expects *Calcitriol* to achieve good profit margins relative to its other products.

**Vitamin D.** *Calcitriol* is an injectable generic form of active vitamin D indicated for use in managing hypocalcemia in chronic hemodialysis patients. The kidneys have numerous vitamin D receptors and play a major role in activating vitamin D, which controls calcium and phosphorus levels in the blood. Vitamin D also regulates the activity of the parathyroid hormone (PTH), which pulls calcium out of the bones and into the blood. When kidneys become non-functional, excess PTH may be secreted causing hyperparathyroidism that can lead to weak and frail bones.

Some dialysis patients develop high PTH and as a result, will be administered high vitamin D. An analysis consisting of 908 dialysis patients in 37 different states found that 79% were vitamin D deficient. The three major therapies in


this space include Calcitriol, Hectoral, and Zemplar. Sales of Hectoral and Zemplar together were $425 million in 2014. Of the three, Zemplar is the most expensive while Calcitriol is the least expensive. There is a general consensus that these three drugs have equal clinical outcomes. Under the new bundle system, where cutting costs is critical, Calcitriol is well positioned to gain market share the other two branded drugs.

**Vitamin D Market Information.** The leading vitamin D supplements for hemodialysis patients are AbbVie’s (NYSE: ABBV) Zemplar (paricalcitol) and Sanofi’s (NYSE: SNY) Hectorol (doxercalciferol). Recent sales for these products are detailed in Figure 11.

![Figure 11. Recent Annual Revenue for Leading Vitamin D Supplements, in Millions](image)

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Company</th>
<th>2014</th>
<th>2013</th>
<th>2012</th>
<th>2011</th>
<th>2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zemplar (paricalcitol)</td>
<td>AbbVie</td>
<td>$225</td>
<td>$188</td>
<td>$383</td>
<td>$409</td>
<td>$596</td>
</tr>
<tr>
<td>Hectorol (doxercalciferol)</td>
<td>Sanofi</td>
<td>$200</td>
<td>$190</td>
<td>$180</td>
<td>$185</td>
<td>$190</td>
</tr>
</tbody>
</table>

*Source: Company Reports*

**Rockwell’s Core Dialysis Concentrate Business**

While many are currently focused on the launch of Triferic, Rockwell Medical has been successfully selling its products into the dialysis market for almost 2 decades, and has an established distribution network. The Company successfully launched four new products, three of which have become the standard-of-care in the hemodialysis industry. The Company already has established relationships with the dominant dialysis providers and the necessary distribution agreements in place to penetrate the bundled dialysis market. This is supported by the five year extension, in May of 2013, of Rockwell’s supply agreement with dialysis giant DaVita (NYSE: DVA). The DaVita agreement calls for a significant increase in new concentrate business, and for a conversion to Rockwell’s industry-changing CitraPure concentrate product.

Rockwell has built a successful brand in the dialysis market and cultivated strong relationships with key service providers. The US market is very concentrated, where just 9 service providers control approximately 83% of the dialysis centers. DaVita alone controls approximately 35% of the market. Because they already have an efficient sales and distribution network in place for this consolidated market, we expect Rockwell to launch Triferic without hiring additional sales representatives. This means the product launch should have minimal impact on SG&A expense.

**Rockwell’s Exclusive Licensing Agreement with Baxter International**

On October 3, 2014, Rockwell Medical announced an exclusive licensing agreement with Baxter International (NYSE: BAX) for Rockwell’s hemodialysis product line. The deal includes a $20 million up-front cash payment and a $15 million equity investment in Rockwell at a premium to the stock price at the time ($11.39/share) by Baxter. In addition to the upfront payment and equity investment, the Company is eligible to receive an additional $10 million for the

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expansion of manufacturing capabilities. Rockwell has indicated an intention to open a new manufacturing facility in Las Vegas, NV. We believe this entry to the west coast and open up significant additional future sales. The agreement has a 10 year lifespan with the option for Baxter to extend the term by 5 years for an additional $7.5 million payment. Notably, the deal did not include Calcitriol or Triferic.

Baxter purchases Rockwell’s concentrate products at a predetermined price per unit that will lock in a higher gross margin than the Company achieved before the deal and will trend higher over the course of the deal. Topline sales dollars may be reduced initially with the deal, but Rockwell is expected to increase profit margins immediately and in the years ahead. Additionally, Rockwell will continue to manage customer service and delivery operations and pass that cost onto Baxter, charging a slight mark-up. Rockwell’s freight cost, which has been the greatest expense in its gross margin, has now been eliminated and transferred to Baxter.

**Intellectual Property**

Rockwell has a US delivery and composition of matter patent covering Triferic delivered via dialysate until 2021, with potential for a 5 year Hatch-Waxman extension, with additional patent protection in Europe and Japan and other countries. The Company also has patents covering the method of manufacture and composition of matter for soluble ferric pyrophosphate that provide protection through 2029. Additional patents have been either issued or are pending in the US, EU, and additional countries. An issued US packaging and method of use patent provides protection for Triferic until 2027. Additional patents related to the formulation and potential ESA sparing effects of Triferic have also been filed.

**Management Team**

**Robert L. Chioini**  
*Founder, Chairman, CEO, and President*

Robert L. Chioini is the Founder, Chairman, Chief Executive Officer and President of Rockwell Medical, Inc. He has served as the Chairman since March 2000, and as the President and Chief Executive Officer since January 1995. In addition, Mr. Chioini is a Board Member of Medical Mainstreet, an alliance of world-class hospitals, universities, medical device and biopharmaceutical companies creating a global center of innovation in health care, research and development, education and commercialization in the life sciences industry in Oakland County, Michigan. Prior to founding Rockwell, Mr. Chioini served as Regional Sales Manager for Dial Medical of Florida, Inc., from 1993 to 1995, which was then acquired by Gambro HealthCare, Inc. Earlier in his career, He served in sales, management and marketing capacities with medical manufacturing companies. Mr. Chioini is a graduate of Michigan State University and earned his Bachelor's degree in 1987.

**Thomas E. Klema**  
*Vice President, CFO, and Secretary*

Thomas E. Klema, CPA/MBA is the Vice President of Finance, Chief Financial Officer and Secretary of Rockwell Medical and has served in that position since January 1999. Prior to joining Rockwell, Mr. Klema served as the Vice President of Finance and Administration for Whistler Corporation. Previously, he held senior management roles at
Molson's Diversey subsidiary, which was acquired by Unilever. While at the Molson Companies and Unilever, Mr. Klema served as Vice President of Finance, Administration and Business Development. He earned his Bachelor's Degree in 1976 and his Master of Business Administration Degree in 1977 from Michigan State University.

**Ajay Gupta, MD**  
*Chief Scientific Officer*

Ajay Gupta, MD is the Chief Scientific Officer and has served in that position since he joined the company in June of 2009. He has been a member of Rockwell's Scientific Advisory Board since November, 2005. From 2002 to 2009, Dr. Gupta was an Associate Professor of Medicine at UCLA and Charles Drew University Schools of Medicine in Los Angeles; while at UCLA, he has had an active nephrology practice. Dr. Gupta is the inventor of dialysate iron therapy using *Triferic* (Soluble Ferric Pyrophosphate) as well as the inventor of intravenous (IV) iron therapy using slow continuous infusion of *Triferic*. He has filed a number of patents in the areas of drugs, medical devices and diagnostic tests. Dr. Gupta earned his MBBS degree and completed his residency in Internal Medicine from All India Institute of Medical Sciences (AIIMS), New Delhi. In 1990, he completed a Nephrology Clinical/Research Fellowship from Washington University, St. Louis, Missouri. He has served on the faculty at Washington University, St. Louis; State University of New York, Syracuse; University of Alabama, Birmingham and Henry Ford Hospital, Detroit; MI. Dr. Gupta is the founder and Chairman of the Indian Society for Bone and Mineral Research and has completed a clinical fellowship in Nephrology from Wayne State University, Detroit, Michigan and a research fellowship in Nephrology from Washington University, St. Louis, Missouri.

**Raymond D. Pratt, MD**  
*Chief Medical Officer*

Raymond D. Pratt, MD has been the Chief Medical Officer of Rockwell since he joined the Company in April, 2012. Dr. Pratt was Vice President R&D and the scientific leader in the Emerging Business and Renal Business Units at Shire PLLC. Previous roles at Shire included Vice President Global Clinical Medicine, Global Clinical Affairs, and head of US Clinical Development. Dr. Pratt was instrumental in the FDA approval of *Farenol* for the ESRD and CKD non-dialysis indications in the European Union and United States. He was responsible for three new drug applications as well as multiple EU applications. Dr. Pratt has managed ten different drugs through all stages of global development for renal and other indications and has extensive experience appearing before the FDA. Prior to Shire, Dr. Pratt was Senior Director, Clinical Research and Development at Eisai Medical Research from 1994 to 2003, where he was head of CNS and Internal Medicine clinical development. Dr. Pratt received his MD degree from the University of Illinois College of Medicine. He served six years in the U.S. Army Medical Corps including a period as Director, Dialysis Services at the Walter Reed Army Medical Center. He has served as an Assistant Professor at Cornell Medical College from 1993 to 1994 and at Johns Hopkins University School of Medicine from 1990 to 1993.

**Risk to an Investment**

We consider an investment in Rockwell Medical to be a high-risk investment. Although Rockwell has received FDA approval for *Triferic* and is planning a commercial launch, regulatory approval to market and sell a drug does not guarantee that the drug will penetrate the market. The Company may require incur substantial costs during the launch of *Triferic* and sales may not recoup these costs or meet the expectations of investors. Rockwell has not reached
profitability or positive cash flow and may need to seek additional financing in the future. The dialysis market is competitive and susceptible to pricing pressures, and unknown competitors may emerge.
## Rockwell Medical

7/21/2015

<table>
<thead>
<tr>
<th>In Millions</th>
<th>FY09A</th>
<th>FY10A</th>
<th>FY11A</th>
<th>FY12A</th>
<th>FY13A</th>
<th>1Q14A</th>
<th>2Q14A</th>
<th>3Q14A</th>
<th>4Q14A</th>
<th>FY15A</th>
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<td><strong>REVENUES</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Sales</td>
<td>54.7</td>
<td>59.6</td>
<td>49.0</td>
<td>49.8</td>
<td>52.4</td>
<td>13.0</td>
<td>13.0</td>
<td>13.7</td>
<td>14.5</td>
<td>54.2</td>
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<tr>
<td><strong>Total Revenues</strong></td>
<td>$54.7</td>
<td>$59.6</td>
<td>$49.0</td>
<td>$49.8</td>
<td>$52.4</td>
<td>$13.0</td>
<td>$13.0</td>
<td>$13.7</td>
<td>$14.5</td>
<td>$54.2</td>
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<td>% growth</td>
<td>N/A</td>
<td>8.9%</td>
<td>-17.8%</td>
<td>1.7%</td>
<td>5.2%</td>
<td>-0.4%</td>
<td>5.9%</td>
<td>5.0%</td>
<td>3.4%</td>
<td>7.1%</td>
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<td>Cost of Sales</td>
<td>46.8</td>
<td>49.7</td>
<td>43.3</td>
<td>43.1</td>
<td>45.7</td>
<td>11.3</td>
<td>11.0</td>
<td>11.5</td>
<td>11.8</td>
<td>45.6</td>
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<tr>
<td><strong>Gross Profit</strong></td>
<td>$7.9</td>
<td>$9.9</td>
<td>$5.6</td>
<td>$6.7</td>
<td>$6.7</td>
<td>$1.7</td>
<td>$2.0</td>
<td>$2.3</td>
<td>$2.6</td>
<td>$8.6</td>
</tr>
<tr>
<td>Gross Margin</td>
<td>14.4%</td>
<td>16.6%</td>
<td>11.5%</td>
<td>13.5%</td>
<td>12.8%</td>
<td>13.0%</td>
<td>15.5%</td>
<td>18.2%</td>
<td>15.9%</td>
<td>16.5%</td>
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<tr>
<td>SG&amp;A</td>
<td>6.9</td>
<td>9.3</td>
<td>9.5</td>
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<tr>
<td>R&amp;D</td>
<td>6.4</td>
<td>3.4</td>
<td>17.8</td>
<td>48.2</td>
<td>39.4</td>
<td>4.6</td>
<td>0.2</td>
<td>1.3</td>
<td>1.7</td>
<td>7.8</td>
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<tr>
<td><strong>Total Operating Expense</strong></td>
<td>$13.3</td>
<td>$12.7</td>
<td>$27.3</td>
<td>$60.9</td>
<td>$53.7</td>
<td>$8.7</td>
<td>$4.4</td>
<td>$5.4</td>
<td>$7.6</td>
<td>$26.1</td>
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<tr>
<td>Operating Income (loss)</td>
<td>$(5.4)</td>
<td>$(2.9)</td>
<td>$(21.7)</td>
<td>$(54.2)</td>
<td>$(47.0)</td>
<td>$(7.0)</td>
<td>$(2.4)</td>
<td>$(3.1)</td>
<td>$(5.0)</td>
<td>$(17.5)</td>
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<tr>
<td>Interest Income (expense)</td>
<td>-</td>
<td>0.0</td>
<td>0.0</td>
<td>0.2</td>
<td>(1.7)</td>
<td>(0.8)</td>
<td>(0.8)</td>
<td>(0.8)</td>
<td>-1.4</td>
<td>(3.8)</td>
</tr>
<tr>
<td>Other income (expense)</td>
<td>-</td>
<td>0.2</td>
<td>0.2</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
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<tr>
<td><strong>Total Other Income (expense)</strong></td>
<td>$-</td>
<td>$0.2</td>
<td>$0.2</td>
<td>$0.2</td>
<td>$(1.7)</td>
<td>$(0.8)</td>
<td>$(0.8)</td>
<td>$(0.8)</td>
<td>$(1.4)</td>
<td>$(3.8)</td>
</tr>
<tr>
<td>Net Income (loss) Before Taxes</td>
<td>$(5.4)</td>
<td>$(2.7)</td>
<td>$(21.4)</td>
<td>$(54.0)</td>
<td>$(48.7)</td>
<td>$(7.8)</td>
<td>$(3.2)</td>
<td>$(4.0)</td>
<td>$(6.3)</td>
<td>$(21.3)</td>
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<tr>
<td>Income Tax</td>
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<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>Net Income</strong></td>
<td>$(5.4)</td>
<td>$(2.7)</td>
<td>$(21.4)</td>
<td>$(54.0)</td>
<td>$(48.7)</td>
<td>$(7.8)</td>
<td>$(3.2)</td>
<td>$(4.0)</td>
<td>$(6.3)</td>
<td>$(21.3)</td>
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<tr>
<td>EPS - Basic</td>
<td>$(0.38)</td>
<td>$(0.16)</td>
<td>$(1.21)</td>
<td>$(2.65)</td>
<td>$(1.48)</td>
<td>$(0.20)</td>
<td>$(0.08)</td>
<td>$(0.10)</td>
<td>$(0.15)</td>
<td>$(0.51)</td>
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<tr>
<td>EPS - Diluted</td>
<td>$(0.38)</td>
<td>$(0.16)</td>
<td>$(1.21)</td>
<td>$(2.65)</td>
<td>$(1.48)</td>
<td>$(0.20)</td>
<td>$(0.11)</td>
<td>$(0.10)</td>
<td>$(0.15)</td>
<td>$(0.51)</td>
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<tr>
<td>Shares Out - Basic</td>
<td>14.9</td>
<td>17.2</td>
<td>17.8</td>
<td>20.4</td>
<td>32.9</td>
<td>40.0</td>
<td>29.9</td>
<td>40.1</td>
<td>41.4</td>
<td>41.4</td>
</tr>
<tr>
<td>Shares Out - Diluted</td>
<td>14.9</td>
<td>17.2</td>
<td>17.8</td>
<td>20.4</td>
<td>32.9</td>
<td>40.0</td>
<td>29.9</td>
<td>40.1</td>
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