

ROCKWELL POSITIONS IRON DRUG IN AGE OF THE BUNDLE

by Keith Chartier , Editor Renal Business TODAY

WIXOM, Mich. August 12, 2010 —Rockwell Medical finds itself in an interesting position—it has a profitable core business while it is developing a new product for the competitive iron drug market, both of which are in the rapidly changing economic environment of dialysis reimbursement.

Right now, the company's main business is focused on producing and delivering dialysis products, such as hemodialysis concentrates in solutions and powders as well as other ancillary products.

During the second quarter for this year, Rockwell's sales increased to \$15.5 million, up 19.2 percent compared to the second quarter of 2009. And the company's gross profit increased to \$2.8 million, up 49 percent or \$900,000 compared to the second quarter of 2009. In addition, gross profit margins increased to 17.9 percent, compared to 14.3 percent in the second quarter of 2009.

During the same time period, R&D expense was \$400,000, compared to \$2 million in the second quarter of 2009. And Rockwell's net income was \$100,000, compared to a loss of \$1.7 million in the second quarter of 2009.

"We are pleased with our strong second quarter earnings, reflecting our best quarterly results to date," Robert L. Chioini, chairman and CEO of Rockwell, said in a statement. "Our performance was in line with our expectations and we expect that our operating business will continue to generate cash to support the funding of our phase III clinical development."

That clinical development is for soluble ferric pyrophosphate (SFP), which is an iron-replacement therapy delivered through dialysate and designed to treat iron deficiency anemia in hemodialysis patients.

This places Rockwell in a rare category of drug developers that have an existing business in place with a developed customer base. "I always like it when a company has direct access to basically the end users of a product when they're moving into product development," said Charles C. Duncan, PhD, an analyst with JMP Securities. "I feel they have a source of good information on how to appropriately develop that product. That may seem pretty obvious, but in biotech land it's actually a pretty uncommon event in that many biotech products are kind of disparate products."

Rockwell is in a very interesting time in its evolution, said Duncan, who specializes in studying hybrid business models, such as Rockwell. "The customers that they currently serve are some of the same customers that would be benefitted by the product that is their future growth engine, that's SFP."

One challenge with SFP is the economic reality of the time it is being developed and potentially launched, namely the new era of bundling in dialysis where pharmaceuticals and dialysis services are being bundled into one lump sum per treatment. This could lead dialysis providers to look for cheaper drug alternatives in order to maintain their business models.

Another challenge is the competitive landscape. Market research company Global Industry Analysts Inc. recently forecast that the global IV iron market will be worth \$1.6 billion by 2015. In addition to Rockwell, the major players included AMAG Pharmaceuticals, Fresenius Medical Care, Galenica Ltd., Vifor Pharma Ltd, Luitpold Pharmaceuticals Inc, American Regent, Pharmacosmos A/S, Sanofi-Aventis, Syner-Med Pharmaceutical Products, and Watson Pharmaceuticals Inc.

"We expect Rockwell to be ideally situated," Chioini said during an Aug. 5 conference call with investors. "We are certain that dialysis providers will aggressively look to utilize products and drugs that lower their costs due to the new reimbursement system."

Dialysis patients receiving SFP in place of IV iron will be expected to use fewer erythropoietin-stimulating agents (ESA) reducing the ESA cost for providers—a powerful incentive for adoption, Chioini said during the call.

“We believe SFP fits perfectly in the new bundled reimbursement world as it is expected to reduce the need for ESA,” he added. “ESA drug cost is extremely expensive at approximately \$12,000 per patient annually.”

Duncan agreed that the dialysis bundle could actually be part of the solution for SFP’s launch and not part of the problem. “Historically, dialysis centers made money giving Epogen, and that’s changing,” he said.

For example, BioTrends Research released survey results in April that found safety issues in clinical reports on erythropoietin-stimulating agents have changed the way nephrologists are prescribing anemia drugs. One potential change from that could be physicians using anemia drugs, like Amgen’s Epogen, more sparingly while increasing the use of iron drugs.

It seems Rockwell is attempting to take advantage of this nexus of clinical and economic changes in anemia management. “The cat’s meow would be that they are able to show not only good clinical benefit, but Epogen sparing,” Duncan said.

During the investor call, Chioini revealed that Rockwell is taking part in a National Institutes of Health-funded study regarding SFP. The study will include approximately 30 patients and will compare SFP to Fresenius’s iron drug Venofer. The study is designed to generate bundle-related data, as well as data on ESA reduction.

“In a bundled environment we believe any product that enables dialysis providers to lower their costs and is part of the bundle should do well commercially,” Chioini said during the investor call.

The next step is the phase-III clinical trial that could pave the way for approval. Earlier this summer, Rockwell met with the U.S. Food and Drug Administration and said it solicited input on the company’s planned phase III clinical program for SFP. As a result of those conversations, Rockwell confirmed a change in hemoglobin is an approvable end point for the phase III trial design.

“We intend to use a primary efficacy endpoint in the phase III study that is identical to a secondary efficacy endpoint we had in our phase IIb study, which achieved a statistically significant p-value, demonstrating an excess of 0.5 g/dL difference in hemoglobin between placebo and the SFP 10 µg/dl dose group,” Chioini said in a news release. “Our regulatory path for SFP is now clear and we expect to submit our phase III protocol design to the FDA shortly. We remain on track to start the pivotal phase III program later this year.”