

# Rockwell Medical's innovative drug Triferic will impact iron deficiency therapy around the world

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Wixom-based [Rockwell Medical](#) is preparing to release its industry-changing iron maintenance and replacement therapeutic drug treatment Triferic to the market later this year, positioning itself as a global leader in its field.

[Rockwell Medical](#) got its start in Founder, Chairman, and CEO Rob Chioini's garage in 1995.

Admittedly that's a bit of hyperbole – it wasn't *technically* a garage, though it might as well have been.

After graduating from Michigan State University, Chioini went to work as a salesman in the medical industry, selling different products to hospitals that primarily included sterile instrument tray kits. The kits were a more efficient way for hospitals to utilize instrument trays that would otherwise get sent back to a central supply department for sterilization and re-distributed to various wards like the ER and ICU. Chioini would also work with different doctors and nurses to customize the trays to best suit their needs.

After that he worked in the field of dialysis selling hemodialysis concentrates (solutions and powders), where he also introduced his kit concept. Shortly thereafter he went off on his own, taking over a 10'x10' room in his dad's commercial cleaning space. Chioini would go out and sell the kits, come back and build them with help from his mother and younger brother, and then his dad would then deliver them in his spare time.

Within a year customers were looking for concentrates as well, so in 1996 Rockwell Medical partnered with two doctors, moved to Wixom, and started manufacturing. Later Chioini was able to buy out his partners and take company public, grow from one to three manufacturing plants, and made the strategic decision to become a drug company.

Flash forward 20 years from those early days in his dad's commercial space, and Chioini is now the head of a company that is a world leader in therapeutic dialysis products with over 300 employees and \$50 million in revenue. Now his company is about to introduce an innovative new therapeutic dialysis drug to the market, Triferic, with \$150 million in funding to back it.

Triferic offers iron replacement and maintenance of hemoglobin in hemodialysis patients through concentrates. In 2002 Rockwell licensed the technology for delivering iron through concentrates, and in 2004 they made the decision to rebrand as a biopharmaceutical company and take the drug to the market themselves in order to get the full value. They raised money and went all the way through the clinical process including clinical trials, eventually receiving FDA approval for the drug more than 10 years later (a pretty standard amount of time for a drug to go through the full clinical process). Now Rockwell is just a few months away from the proprietary drug being released into the market, where there is no other competing product currently in existence.

"There is no other iron delivery method that can do what this drug can do," Chioini says. "Every [dialysis patient] gets [iron replacements] through an IV in the bloodline, but IV iron isn't approved by the FDA as a maintenance therapy, it's a repletion therapy. It's being used that way because there

is nothing else available."

Dialysis patients lose five to seven milligrams of iron with every treatment and typically receive intravenous iron to help maintain sufficient iron store. But IV iron is stored in the liver, causing inflammation and increased risk of infection, and very little of that iron gets out of the liver and into the bone marrow where it is needed to create healthy red blood cells. Triferic safely and effectively delivers sufficient iron directly to bone marrow in a non-invasive manner through concentrates, maintaining hemoglobin without increasing iron stores. It is the only viable drug treatment to replace ongoing iron losses and maintain hemoglobin levels.

While Triferic already has FDA approval, it likely won't launch until sometime mid-year. As Chioini, even after receiving FDA approval there are a number of other circumstances to handle before the drug is ready for the market, including packaging and getting production ramped up to meet demand, which is expected to be significant.

"This drug will go global and we are in negotiations with several companies to manufacture and market it worldwide," Chioini says.

Rockwell is already conducting studies with total parenteral nutrition patients and is also looking at the cancer market, as cancer patients exhibit the same functional iron deficiency as dialysis patients.

"Rockwell Medical is an example of the growing, diverse life sciences cluster we have here in the [Medical Main Street](#) region," says Irene Spanos, Director of Economic Development & Community Affairs for Oakland County. "There is no place in the USA that has the strong resources and support that Medical Main Street offers companies wanting to grow their company globally from their Oakland County home."

In addition to their proprietary Triferic drug, Rockwell is also introducing a generic Vitamin D injection to the market later this year.

"Back in '94 I didn't envision all of this," says Chioini. "As you grow and build a business you're constantly trying to stay ahead of everything and secure proprietary products, in our industry it's doing that with the patient in mind. If you can come up with product or drug that is clinically superior that improves a patient's life and fits within reimbursement scheme you might have success. It's not easy, nothing is, but you've got a solid foundation or good opportunity for success."

He jokes, "We don't feel like we've won the championship yet. We're in the Final Four right now; we're getting close!" Never one to rest on his laurels, he says he hasn't really sat back and thought, "Wow, this is great," about how much his company has grown over the last two decades. "There's just so much work to do to get the drug to the market, then thinking, 'What else are we working on, what's next?'"

Still, he says, "We want to make Rockwell one of the biggest biotech companies in the world."