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Ortho RTi developing biologic scaffold for soft issue injuries

Ortho Regenerative Technologies is developing a “sticky scaffold” biologic that has the potential to be best in class to repair symptomatic lesions in shoulder tendons, knee meniscus and articular cartilage.

DR. BRENT NORTON
CEO AND EXECUTIVE CHAIRMAN

“The timeline to market of our first product, Ortho-R, for rotator cuff tendon repair is short, with clear and manageable endpoints,” Dr. Brent Norton, executive chairman and CEO, says in an interview with BioTuesdays.

“With standard surgical repair of rotator cuff, there is a 50% failure rate within the first year,” he adds. “Clinical trials in this indication could have a follow-up as short as six months to a year against the comparative failure of operative repair.”

Dr. Norton explains that Ortho-R is a freeze-dried biopolymer that when mixed with a small amount of a patient’s platelet-rich plasma (PRP) forms a sticky scaffold in about five minutes and “fits seamlessly into current surgical procedures without any additional equipment required.” The powder biopolymer has a shelf life of three years at room temperature, he adds.

Dr. Norton notes that in preclinical models, the sticky scaffold has been shown to stabilize the PRP in an injury, impede its shrinkage and stick to the lesion surface. “We have demonstrated increased vascularization of tissues after two weeks, and later on, improvement of tissue repair and regeneration.”

Founded in 2015 to commercialize technology developed by Drs. Michael Buschmann and Caroline Hoemann at the Ecole Polytechnique in Montreal, Ortho RTi expects to begin trading soon on the Canadian Securities Exchange under the symbol, ORH.

In addition to shoulder rotator cuff repair, the company is developing technology for knee meniscus and articular cartilage repair, and other commonly injured joints, such as the elbow, ankle and hip.

IN ADDITION TO SHOULDER ROTATOR CUFF REPAIR, THE COMPANY IS DEVELOPING TECHNOLOGY FOR KNEE MENISCUS AND ARTICULAR CARTILAGE REPAIR, AND OTHER COMMONLY INJURED JOINTS, SUCH AS THE ELBOW, ANKLE AND HIP

“Clinical trials for meniscus and cartilage repair require multi-year safety follow-up studies, which is why, as a way to build a small company, we selected the shorter rotator cuff repair route,” Dr. Norton points out.

The company received a U.S. patent last August for PRP/biopolymer compositions and has patents pending for additional compositions of matter and use. It also has a legal opinion affirming its freedom to operate without infringing any valid IP.

At the end of last month, Ortho RTi’s technology platform was front and center at the 2017 Orthopaedic Research Society annual meeting in San Diego. The company presented four key scientific studies validating Ortho-R’s ability to improve repair of three distinct joint tissues: rotator cuff tendons, meniscus and articular cartilage.

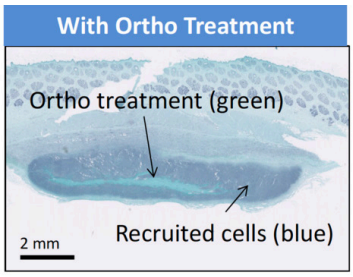
“This type of third-party scientific validation, where four of our studies were reviewed by external experts and selected for broad exposure at this, the most important event of its kind worldwide, is incredibly energizing,” Dr. Norton points out.

According to Dr. Norton, the market for soft tissue injuries is growing at an average of 8% a year, driven in part by “weekend warriors.”

Some 25% of U.S. adults over the age of 40 will develop a rotator cuff tear, with aging. In addition, he says four million people in the U.S. with rotator cuff injuries are at risk for disability as 50% of rotator cuff tears progress in size in three years.

“There are approximately 600,000 rotator cuff surgeries performed each year, with 50% failing within six-to-12 months,” he adds.

In addition, Dr. Norton points to two million meniscal injuries annually, making up 16% of all orthopedic surgeries. “These first two indications represent a potential market of $1.75-billion,” he suggests.



Cells present after 7 days: promotes residency and cell recruitment

Cells gone after 7 days: no cell residency or recruitment

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Based on Ortho RTi’s tissue healing evidence in a rotator cuff large animal model at three months after surgery with Ortho-R and anchors, Dr. Norton says the tendon is mostly organized in bundles with small areas of tendon-like repair tissue, which is “what we see in a normal tendon.”

Histology at the tendon attachment site three months after surgery also indicates an abundant expression of glycosaminoglycan and remodeling, which is implicated in wound repair at the insertion site of Ortho-R, he adds. “This suggests that bone remodeling through endochondral ossification is still ongoing at the tendon and bone interface.”

The company has had a pre-IND meeting with the FDA and obtained feedback about its development plan and how it will be regulated as a biologic.

Later this year, Ortho RTi plans to release final preclinical data and move into a clinical rotator cuff pilot study in the first half of 2018 to measure safety and unexpected adverse events.

The company also plans to begin a registration trial in 2019 with about 200 patients at 15-to-25 clinical sites in the U.S. and Canada. Primary outcomes will be pain and function at six months following surgery. Health economic outcomes for payers also will be part of the study.

“There is strong R&D partnering and strategic interest from larger medical device companies in this space, which we hope to tap as we go forward,” Dr. Norton says.