LSI Alumni Innovator Spotlight: Hy2Care's Leo Smit

Leo Smit (Source: LSI USA '24)

Armed with a joint-mimicking hydrogel and a track record of engineering success, Leo Smit is leading Hy2Care into a new era of orthopedic care, where restoring true cartilage is no longer a costly dream but a scalable solution. With IDE approval now in hand and CE mark submission underway, Hy2Care is preparing to enter pivotal markets in the U.S., Europe, and beyond.

Engineering a *Better Outcome*

For **Leo Smit**, the mission behind **Hy2Care** is personal. "My mother lived with chronic pain from arthritis until the end of her life," he shared. "It's deeply rewarding to create something that gives people their lives back."

Smit brings decades of medtech experience to his role, including the creation of high-strength polyethylene fibers now used in implantable sutures across orthopedics. But his decision to join Hy2Care as CEO in 2019 was sparked by something more: a belief that cartilage repair could, and should, be simpler, more affordable, and more widely accessible.

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That belief is shared by Dr. **Sanne Both**, Hy2Care's co-founder and current Director of Clinical Applications. Before she turned 24, Both had undergone three failed cartilage surgeries and knew firsthand the shortcomings of current treatments. Her decision to pursue a PhD in regenerative biology and develop a new solution led to the founding of Hy2Care in 2014 alongside Prof. **Marcel Karperien**. Smit and COO **Sanna Severins**, who had worked together previously at **DSM Biomedical**, joined the company during its early funding stages in 2019 to bring that solution to life.

"We don't just have the science," said Smit. "We have a team that knows how to deliver on time, on budget, and with heartfelt dedication, even through two and a half years of intermittent lockdowns during the COVID-19 pandemic."

Rebuilding from Within

The company's lead product, *CartRevive,* is a hydrogel implant designed to restore natural cartilage in focal knee defects. Unlike conventional implants that require cutting and fixation, CartRevive is delivered as a liquid that molds perfectly to the defect before solidifying into a tissue-integrating scaffold within 60 seconds.

A clinical illustration provided by Hy2Care *(see below)* shows this process in action. Smit explained, "When cartilage is damaged, it creates a defect in the smooth joint surface, leading to pain and reduced mobility. Our in-situ forming hydrogel precisely fills that defect, adheres to the surrounding tissue, and forms a protective matrix. This matrix supports the body's natural healing process and creates an ideal environment for chondrocytes to migrate, proliferate, and build new, healthy cartilage while the gel resorbs naturally."

The result is a seamless fit within the joint's delicate architecture. "The knee is like a Swiss clock," Smit explained. "Any mismatch throws it off. Because CartRevive molds exactly to the shape of the defect, the clockwork keeps running."

Real Results, *Real Lives*

That biological precision is paying off. In a European clinical trial, 46 patients have been treated with CartRevive. Results show significant improvement in KOOS scores, a measure of pain and mobility, reaching 2.5 times the threshold for clinical relevance after just 12 months. Patients are not only pain-free, but many are returning to sports within a year.

At LSI Asia '25, Smit shared the story of Bob, a 35-year-old patient who had been told to "learn to live with the pain" after an MRI indicated a severe cartilage injury. "After nine months with CartRevive, Bob was running again, and after a year, he was back to playing football and tennis," Smit told the audience. "That's what we want, for every patient."

What sets CartRevive apart is its performance relative to cost. "We match the tissue quality of cell therapies," said Smit. "This efficiency comes from a fundamentally different approach, but at 15% of the cost. It's a return to biology, made scalable."

Path to Market and *Global Expansion*

Hy2Care's regulatory progress reflects its momentum. The company secured FDA Breakthrough Device Designation in 2023 and received IDE approval in April 2025 to begin its U.S. clinical trial. A CE mark submission is already underway in Europe, with market approval targeted for 2026.

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In May 2025, Hy2Care closed a €4.5 million funding round, led by **Brightlands Venture Partners** and supported by the **European Innovation Council Accelerator**. This round fuels preparations for the U.S. trial and supports early commercial planning.

To fully fund the U.S. trial and global expansion, the company is currently raising €35 to €40 million, with an initial €15 million tranche targeted for completion this year.

"We're a small team with global ambitions," said Smit. "We're looking for partners to help us scale, whether distributors or licensees. Our mission is to make this technology available to everyone who needs it."

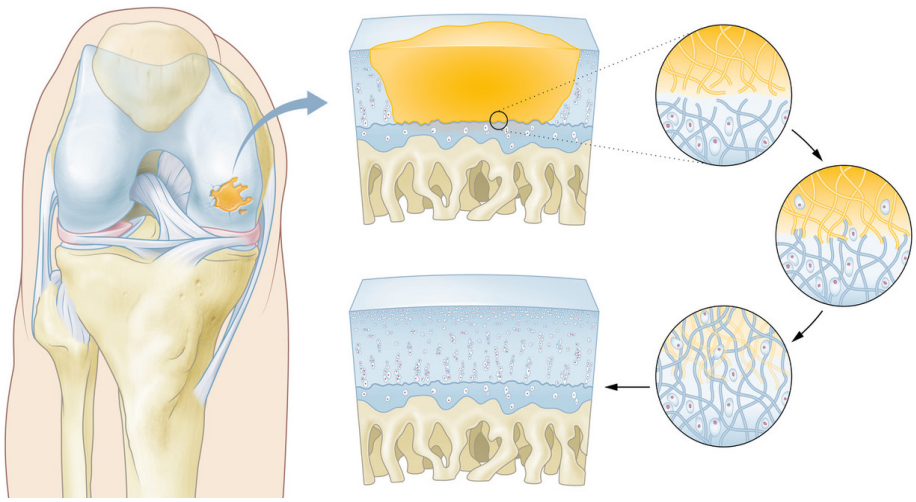
Building the Right Team for Disruption

Hy2Care's leadership isn't just technically strong; it's intentionally diverse. "We're balanced across age, gender, nationality, and expertise," said Smit. "You'll find Baby Boomers and Gen Z working side by side here, and that's not an accident. It's a strength."

That cohesion has helped the team hit every major milestone, despite launching just before the COVID-19 pandemic. "We've never missed a deadline," said Smit. "That's a testament to the people behind the product."

Looking ahead, Hy2Care sees broader potential for its platform. Future applications could include larger defects, patellar defects, and eventually other joints and orthopedic indications. LSI

Cartilage Repair with CartRevive



Source: Hy2Care website