



### Hy2care

At the campus: Since 2019 Ecosystem: Biomedical products Dimensions: Health, Society

Founded in 2014 by Sanne Both and Professor Marcel Karperien, Hy2Care is a spin-off from the TechMed Centre at the University of Twente. Their unique CartRevive™ hydrogel implant as a solution for knee cartilage defects is now being tested in patients. In 2022, the European Commission awarded Hy2Care €6 million in funding through the European Innovation Council Accelerator program. This financial injection will allow Hy2Care to complete clinical studies to obtain European approval for the hydrogel implant. Preparations are underway for a clinical trial in the U.S.

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Microscopic image of healthy cartilage tissue consisting entirely of small groups of cartilage cells.



# Polymer in knee repairs cartilage

Sanna Severins COO of Hy2care Long ago, Sanna Severins dreamed of becoming a rheumatologist, in part because she comes from a family of people with rheumatism and is all too aware of how profound and painful this disease is. She has experienced first hand how much of a social burden chronic cartilage damage (leading to osteoarthritis) can be.

"Now that I'm at Hy2care, everything has kind of come full circle for me. We treat cartilage defects that, without proper treatment, come with a high risk of chronic osteoarthritis. Our product is a hydrogel implant for the repair of defective cartilage, and our initial focus is on knees. If someone has cartilage damage, we fill the hole with our hydrogel implant. Immediately afterwards, cartilage cells from the environment can migrate into the gel. These cells reproduce in the implant, regenerating cartilage in an almost completely natural manner. The body's own substances in the implant dissolve in the body. After a year, only new cartilage remains.

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## "We will still have to convince people that our product is a cost-effective and high-quality alternative to the existing techniques"

#### **Clinical tests**

Since this is a new technology, we had to do a comprehensive battery of biocompatibility tests to make sure there are no negative effects. In this, we succeeded magnificently. We have proved in animal studies that the newly generated cartilage is almost as good as the existing cartilage and comparable in quality to that resulting from current, much more expensive therapies. We are now in the clinical phase, an important step for a startup, and the UMC Utrecht\* medical center is taking the lead. There are already ten patients walking around with the product and who are doing well. After following these first ten patients for three months, we will be able to move on to the second phase, with another 36 patients receiving treatment at three different hospitals. Patients eleven and twelve have now also undergone surgery, and we will monitor them for a year to see how it goes. What are the pain scores, how mobile are they? We also use an MRI to check the status of the new tissue with a so-called MOCART(2.0) score.

#### **Research at CHILL**

It's great that Hy2care can use all of the facilities and expertise available at Brightlands Chemelot Campus. This is where you want to be if you run into challenges involving materials, knowledge, R&D, scaling up and so on. We have a good network and important production partners at or near the site, and have also built a very nice lab of our own at the campus. We also call on Chemelot Innovation and Learning Labs, or CHILL, for certain specific studies. They have very high-quality facilities that startups like us don't have to lay out the investment for.

#### Priorities

We're still a startup, so right now the main issue is to secure sufficient funding. We have a nice group of our own investors who support us through thick and thin. In addition, we can rely on a 2.5-million-Euro subsidy from the EIC Accelerator, with an option for 3.5 million Euros in equity. We can cash that option in during the next round of financing with a new investor. This is what we are looking for now. A second priority is the trial. We are looking for a total of 36 physically fit patients with acute knee trauma. We will treat them and then follow them for a year. Depending on the results, we can move forward to the acceptance phase so that we can sell the technology in Europe. The last important step is acceptance in the U.S., where you need separate approval from the Food and Drug Administration (FDA). We are trying to figure out

how to incorporate the European results, but that doesn't detract from the need to do clinical trials locally, too.

#### **Diversity scores high**

Hy2care's impact is obviously in the healthcare sector, but I think we also score well for diversity, for example. Leo and I form the management, he's the CEO and I'm the COO, and we run the company on the basis of a full co-directorship. Our team now has 15 people that make up around 10 FTEs in total, coming from the business community and the University of Twente. A very diverse group, both in terms of background as well as age and gender. It's clear that the large proportion of women is received very well, including, for example, the time we were in Brussels at the European Innovation Council. I personally would love to see more young talents, both men and women, becoming visible in a director role as well.

The biggest challenge for the near future will primarily be financial. We can probably launch the product on the market around 2025, but we will still have to convince Zorginstituut Nederland (ZIN) and healthcare insurers that our product is a cost-effective and high-quality alternative to the existing techniques. All of this means that we will still have to endure a second 'Valley of Death' as it's known, the gap between market acceptance and the first real sales. What you don't want is a situation in which your product checks all the boxes yet the whole project still goes under at the last minute. We are already working with parties to ensure that we come out of that phase unscathed too. All in a day's work for a startup. If you can handle the uncertainty, it does give you incredible energy!" ■

\* Candidates for this study must satisfy strict criteria.

#### **About Sanna Severins**

After completing her Master's degree in Chemical Engineering, Sanna Severins went to work in consumer marketing for Unilever. In 2003, she transferred to DSM's Pharma Chemicals division, and joined the brand-new DSM Biomedical group four years later where she researched the application of DSM materials and products in the medical field. This was also where she met Leo Smit, the father of Dyneema Purity<sup>™</sup> surgical suture fiber. In 2018, she was put in charge of clinical programs, operations and product launches at Corporis Medical, a startup that develops products for laparoscopic surgery. In 2020, Leo Smit asked her to join Hy2care as Chief Operations Officer.