Pål Ryfors,
CEO

Message from the CEO

Dear shareholders,

At the very end of 2017, the first peer-reviewed article with results from a multicenter study on the Episealer® knee implant was published. The primary objective was to assess **implant safety profile, surgical usability of the implant and instruments, and implant migration**. As previously communicated, the patient-related outcome measures showed good-to-excellent results, the surgical usability of implants and instruments was good and no implant migration was seen. Since then, additional clinical results from the use of Episealer® have been presented, most recently at **two important clinical congresses**; the annual BASK meeting (British Association of Surgery of the Knee) as well as at the annual meeting of ICRS (International Cartilage Regeneration & Joint Preservation Society). In the med-tech world, presentation of Episealer® data at clinical congresses is precisely what we need, in addition to publication of peer-reviewed articles in scientific journals. In this context, the last months clearly represent a break-through for Episurf Medical. We have several important milestones ahead of us when it comes to demonstrating the clinical performance of the Episealer®, and I encourage our shareholders to follow this development closely.

We are concluding an exciting first quarter and we have had a high level of activity across our business. Before accounting for the development in the first quarter, I would like to go directly to the core of what we are doing, by asking the question: **Have we solved an orthopaedic problem?**

Focal cartilage lesions in the knee joint for middle-aged patients, patients in the so called "treatment gap" are notoriously difficult to treat. There is no given or automatic healing process, instead, the end-point is all too often fully developed osteoarthritis and surgery with a total knee replacement. Millions of knee replacement surgeries take place every year and the forecasts for the future points to a significant increase in the need for knee replacements on a global basis. The most common treatment for focal cartilage lesions is the biologic bone marrow stimulation procedure often referred to as microfracturing. Each year, **an estimated 75,000 microfracturing procedures are performed in the knee joint in the US alone**. If new cartilage is actually generated through microfracturing, this cartilage is made of a replacement tissue of lower quality compared to the original cartilage, leading to sub-optimal results. A high portion of these patients are subject to further surgical treatments within 2–3 years.

Our method is another way of dealing with focal lesions, and in our coming FDA study, we will compare the Episealer® technology to microfracturing. Already communicated results indicate that Episealer® performs better than microfracturing, and our 3 years' revision rate is less than 5%. When comparing published results for microfracturing with Episealer® results, our conclusion is that it is most likely that this study will show advantageous results for Episealer® at 24 months. Going back to the original question, whether we have solved and orthopaedic problem or not – **it certainly looks very promising**.

In the first quarter, we continued our work in the US and we aim at submitting our IDE application during the second quarter of 2018. We are also progressing with our discussions with US as well as European study clinics and surgeons and a lead investigator site is likely to be appointed and communicated shortly. **In the US, we are also continuing with our industrial partnership discussions concomitantly.** We are approaching these discussions in a cautious way. We have a successful technology which is covered by an efficient and extensive IP portfolio, addressing a global orthopaedic problem of significant size. Clearly, this generates interest from the industry.

In the first quarter, we also performed a road show in Asia, meeting local distributors, Key Opinion Leaders and regulatory experts in India, Taiwan, South Korea, Japan and Hong Kong. We look back at this road show as a success, and we

will continue our work in the Asian markets. In Hong Kong, our technology is ready to be marketed and we have entered into a distribution agreement with a local distributor. Following the above-mentioned countries, the next step in Asia will be to look at the south east Asian countries, but this region is a second priority. During the first quarter, we also received approval to market our technology in Israel and in Spain. We are working with distributors in these countries and these markets are important in our long-term business planning. **Preparing for the future through initiatives aimed at securing access to international markets through early regulatory work remains a key strategy for us.**

Looking ahead, we are continuing the work on our ankle implant for the talus bone. We are meeting a solid interest from our counterparties as these lesions in the ankle joint represent a treatment gap, just like in the knee joint. We are also advancing rapidly in the development of our proprietary imaging product Epioscopy®. We are confident that our diagnostic tool represents a cutting-edge technology and with the help of artificial intelligence, we have taken significant steps in our product development. This product will not only represent an interesting business opportunity on a standalone basis, it will also reduce the production time and costs of our Episealer® implants.

Concluding remarks

During the first quarter, first-time Episealer® users performed surgeries in, among others, Antwerp, London and Stockholm. Every new patient surgery is of course equally important, but each numeric milestone – now well over 350 sold implants – increases the size of our patient base as well as our confidence and the confidence of our surgeons to whom we offer a unique and effective solution to a major clinical problem, for which few if any treatment alternatives exist. **We can conclude that for a certain type of indication, we have solved a clinical problem**, which is surely good news for both our patients and our shareholders. We have in the past reported our implant population benchmarks at intervals of 50, but we are now confident enough of our data base and growth prospects that we no longer see the need for such announcements, and we will in the future report our increasing patient population quarterly, as part of our regular company reports.

We are well-funded, we have just started to prove that our technology works and we are executing on our global strategy. We are in a strong position.

Stockholm, April 2018

Pål Ryfors, CEO