Pål Ryfors,
CEO

Message from the CEO

Dear shareholders,

2017 was a successful year for Episurf Medical in which we reached a number of important milestones and overcame some important challenges. We concluded the year with a highly satisfactory trend, given the 41.3 percentage growth of gross order intake, a financial result which was SEK 2.9m better than the same quarter previous year, and we also saw a stable increase in the number of Episealer® orders.

In the orthopaedic industry new products and procedures are not usually accepted overnight: orthopaedic surgeons want to bring their patients back to motion, but first they want to see evidence of long-term efficacy. Once innovations gain acceptance, however, treatment algorithms and the market landscape can change quickly. Episurf Medical has a clear and ambitious strategy to address this challenge and in 2017 we made significant progress with this strategy. Our strategy has four key components and summarising these will be the main theme of this annual review.

1. Produce clinical and health economic data supporting the Episealer® technology

Close to 300 patients in Europe have now been treated with the Episealer device and we have had our first patient passing the 5-year follow-up with excellent results. We had our first peer-reviewed multicenter study results published in late 2017, showing good to excellent results. Further, we have a fully recruited multicenter study involving more than 100 patients, where interim results are expected shortly. During the year, the Episealer® was presented at a number of podium presentations at clinical congresses, where prominent surgeons talked about their experience of using the Episealer® technology. It is fair to say that the Episealer® technology gained significant attention during 2017 and encouragement to produce further clinical evidence remains a top priority for the company. I am particularly happy with the continuous interest from clinics across the globe to participate in clinical studies of the Episealer® technology, and investors should expect additional news and progress on this front.

2. Establish the Episealer® technology with a large user base of orthopaedic surgeons and Key Opinion Leaders globally

We now have a solid and growing user base in Europe. The sales cycle in these early days is quite lengthy, although it is steadily being shortened as we develop our processes and as our technology gains acceptance. Germany, UK, the Benelux and the Nordic region remain our core markets, and these markets will be instrumental in driving revenues for the coming years. In line with our international growth strategy, we started to execute on our expansion plan for new markets in late 2017. There are additional countries in Europe which are of great interest to us, such as Spain where we are close to finalizing product registration. Our network in Europe is strong and we will continue to target Key Opinion Leaders in new European markets. These new markets are likely to constitute a mix between direct sales markets and distribution markets.

We are also working on the Middle East (ME) region. We have recently received regulatory approval in Israel and we have appointed a distributor. One Israeli patient has been treated with an Episealer® and there are additional patients in the pipeline. We have engaged in distributor discussions in several other ME countries and we have started the processes of achieving regulatory approval. The regulatory timelines in the ME region are generally shorter than in many other regions, and we will market in the ME through distributors.

As we speak, we are further engaging in distributor and surgeon discussions in a number of Asian countries. An initial regulatory review in these countries has been performed. We are looking at these markets with great interest and we look forward to taking the next steps in 2018.

Next up, there are certain carefully selected markets where we are looking at potential distributor opportunities. They constitute important markets in our long-term planning, but we do need to analyse them further before taking the next steps. In this group we are primarily referring to Australia, South Africa and Canada.

Moving on to the US – by far the largest orthopaedic market in the world – I would like to start by saying the we have come far in our preparations. The US Food and Drug Administration is, after long discussions, classifying our Episealer® knee technology as a Class III device requiring a Premarket Approval (PMA) application. Such an application generally follows on a clinical study performed under an Investigational Device Exemption (IDE). We have spent a good part of 2017 investigating and reviewing our regulatory pathway options and, ultimately, the IDE study design. We are now in a position where we have a study design completed, we are in discussions with a potential principal investigator site and we have other sites ready to sign up for the study. The study will be performed both at sites in the US and in Europe. We see a great interest in the Episealer® technology and our ambition is that the first surgeries in the US shall take place during late 2018. The clinical trial is also designed to meet requirements on health economic considerations and this study will be of tremendous value to Episurf Medical. We are really starting to execute on our strategy for obtaining FDA approval for the US market.

From a commercial perspective we continue to assess the execution of our US strategy. As we have communicated, execution of our strategy might best be pursued together with a partner, and Episurf Medical is currently in early collaborative discussions. In the past, when Episurf Medical has discussed future opportunities with US market participants, it has been very clear that two prerequisites must be met before such discussions can advance. First, there must be clarity regarding the regulatory pathway for the Episealer® device into the US market. Second, there must be clinical evidence in place. We are very happy to conclude that the first criterion is now met, and the second is partly met and there is a clear route forward to meet it completely. Episurf Medical has put itself in a much stronger position with respect to the US market.

3. Secure production and reimbursement enabling high margins

We are consciously deferring for now any capital expenditures in the actual Episealer® production chain. Our strategy is to make these investments once demand drives production requirements to higher volumes. For now, capital expenditures are directed mainly towards the software side of our business and our IT platform, as we are improving efficiency in the web-based order and production flow.

Naturally, we are getting quite a lot of questions from investors on our reimbursement situation, and I would like to say the following. Our list prices are in the region of EUR 3,000, which we work hard to defend, notwithstanding challenges typical for novel products entering the market. When you bring a totally new technology to the market, it is quite normal to use a slightly softer approach to price discussions for the first cases. Moreover, many of our surgeries take place within clinical studies, a situation where medical technology companies often provide the goods without charge. In Belgium, which is important to us for clinical reasons, we have a very low reimbursement amount which was fixed and determined by authorities many years ago. Despite all of this, and even though we up to November 2017 operated without any published study results published, I am pleased to report we have been able to charge very close to our list prices. Why is this? Simply because we have a superior product.

4. Ensure technological relevance and a high degree of innovation

At Episurf Medical, we take pride in being at the forefront technologically. A constant discussion has been whether our technology can be applied to other joints, and in 2017, our product development efforts were primarily focused on the development of an ankle implant. We updated the market on this in February 2018, and we look forward to communicating more on this very interesting product soon. The development of our imaging technology further continues within this very interesting field.

The treatment of smaller joints and the development of imaging technologies constitute fast growing key segments for the orthopaedic industry, and Episurf Medical's solutions are at the forefront of this development.

Concluding remarks

IIn 2017, we continued to deliver on our strategy and we did this with a smaller organisation than in 2016. We worked very hard to optimize our allocation of resources and to ensure strong cost discipline and efficiency in everything we do. This will contribute to continued improvement of the profitability and we are convinced that this development will continue to create shareholder value. The strength of our organisation was evident during 2017 and we are prepared for another year of challenges overcome and goals achieved. Today, we have also announced that we are strengthening our finances by a credit facility. This credit facility works perfectly for us as it provides financial flexibility and allows existing shareholders to participate in our growth journey through a warrant structure. 2018 promises to be a very exciting year for Episurf Medical.

Pål Ryfors, CEO
Stockholm, February 2018