



Pål Ryfors,
CEO

Message from the CEO

Dear shareholders,

We are continuing to be optimistic on Episurf Medical's progress. First and foremost, our business in Europe is growing, driven by Germany which now starts to show signs of real commercial progress. In parallel, we have developed a robust clinical strategy targeting a US FDA approval and have taken a significant step in US by the filing of our IDE application. Moreover, our excellent clinical results are becoming well known among orthopaedic surgeons in Europe. All of this, topped with a growing interest for mini implants in the orthopaedic industry and an interesting development in new markets outside of Europe and the US, indicates that our positioning in the orthopaedic industry is very good.

Key highlights during the quarter

During the second quarter, the company achieved one of its biggest milestones when we filed our IDE application to the US Food and Drug Administration (FDA). An approved IDE application will allow Episurf Medical to initiate a clinical trial in the US that will form the basis for a future final application for FDA approval. We are expecting feedback

analysed the demographic factors driving the US orthopaedic market, and our conclusion is that the Episealer® knee implant meets a significant unmet and a major commercial opportunity. An FDA approval would also have big positive impact for us outside of the US because many other countries look to FDA for regulatory guidance.

During the quarter we took the important step of appointing Dr. Michael A Kelly, currently Chairman of the Department of Orthopaedic Surgery at the Hackensack University Medical Center in New Jersey, as special study advisor. Dr. Kelly has extensive experience in the global orthopaedic markets, and was previously President of the American Knee Society. We want to "hit the ground running" once we receive clearance to go ahead with the clinical trial, and Dr. Kelly plays an important role in positioning us for this.

Another key highlight in the quarter was the performance of our German business, which now stands out as a great market example, and promises to be a commercial success. More than 50 surgeries were planned in Germany alone during the first six months of the year, which barely

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from the FDA on our IDE application shortly, and we hope to conclude the study design and all the study details soon. The preparations have been intense and we have discussions with several potential study sites, both in the US as well as in Europe. The interest to participate in our study has been very positive.

The US market represents the biggest orthopaedic market in the world, and the knee segment is the single biggest market segment, with an estimated market value of USD 9 billion annually. Further, there are about 30,000 certified orthopaedic surgeons in the US, of whom about a third have knee as their main sub-speciality. We have also

scratches the surface of the market potential. Our peer reviewed clinical results were only recently published and we are still only working with a small fraction of all the surgeons that we think we will now be able to reach with our data in hand.

Germany is the country in which we have come the farthest in terms of clinical acceptance, re-imburement and market penetration, and we are starting to see that in the numbers. Germany will continue to be a highly important market for us and it's starting to act as a proof of concept that the Episealer® technology is a viable part of the treatment algorithm.

► **New opportunities**

Readers may recall that earlier in 2018 we visited several Asian countries to assess their potential as markets for our products. After careful review we have worked through our priorities. We announced that we were launching in Hong Kong with a local partner in April 2018, and I am now happy to announce that the next country in which we will initiate activities is India. India represents an attractive opportunity for us. All the major international orthopaedic players are already present in India, which has an orthopaedic market growing more quickly than the US and Western European markets. The Indian population is aging and the potential osteoarthritis patient base is growing. A few weeks ago, we held a workshop with about 35 orthopaedic surgeons from India, who showed great interest in our technology. We have initiated the process of establishing a legal entity in India which is a necessary first step and the regulatory filing is expected to take several months.

Continued clinical progress

When we updated our strategy earlier in 2018, we emphasized the importance of clinical data supporting the Episealer® technology, and this remains our most important strategic activity. In line with this, in the second quarter it was announced that no fewer than three scientific abstracts had been accepted for presentations at important clinical congresses.

The first one was the scientific abstract "Clinical results of an individualized mini-metal implant for focal cartilage lesions in the knee" by Johannes Holz, Tim Spalding, Karl Eriksson, Tobias Jung, Peter Verdonk and Clemens Kösters. This abstract covers interim results from a European multicentre study and was accepted for presentation at the 7th Annual Congress of the Deutschen Kniegesellschaft (DKG, the German Knee Society). Further, the abstract "Clinical 2 years results after implantation of patient-specific mini-metal implants in the middle-aged patients after previous frustrane cartilage surgery" by Priv.-Doz. Dr. med. Clemens Kösters was also accepted for presentation at the same meeting. In June, it was also announced that clinical results from the use of Episealer® were to be presented at the annual meeting of the Swedish Orthopaedic Association, as the scientific abstract "Clinical results of an individualized mini-metal implant" by Ass. Prof. Karl Eriksson was accepted for presentation.

One cannot overstate the importance of this to Episurf Medical, and the fact that more and more 2-year follow-up

data is being presented is extremely encouraging. We are also continuing to see a growing interest in the industry for mini implants as an alternative for patients in the treatment gap, which was best exemplified during the quarter by the publication of the agenda for the upcoming "Combined Bristol & Oxford Unicompartmental Knee Arthritis Symposium 2018". This is a very important meeting and the founders and organisers are closely tied to the arrival and growth of partial knee replacements in the world. Mini implants for isolated defects are an important topic for discussion this year, and we have been happy to see Episealer® on the agenda. As a last point on our clinical process, we note that as of now 45 patients have had their implant for more than 3 years and 15 patients have now had the implant for more than 4 years.

What do we have ahead of us?

In the coming months, we look forward to publication and presentation of additional clinical evidence supporting the Episealer® technology. We are also expecting to receive feedback and ultimately a decision from the FDA on our proposed IDE study. We are expecting continued growth in Europe, especially in Germany. We hope that the regulatory review of our ankle implant will be concluded and we have planned surgeon meetings in our new markets in Israel and Hong Kong. We have previously announced that we are running preliminary discussions regarding potential partnerships for the US market, and these discussions are continuing and we will update investors once anything is formalised.

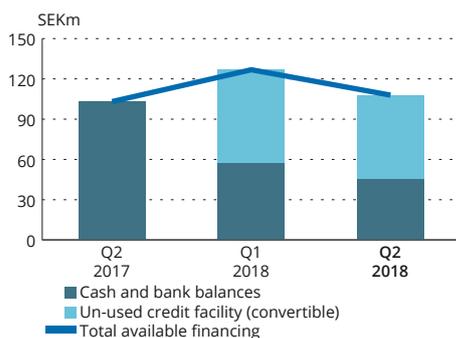
The financial results for the first six months are SEK 2.4 million better than the same period last year and we are continuing to work with a disciplined expense strategy. The result in the second quarter was negatively impacted by expenses related to the IDE filing. We are continuing to experience a growing order book, and we expect growth to continue. We have a total of SEK 107.9 million in available financing.

Stockholm, July 2018



Pål Ryfjors, CEO

Available financing



Gross order intake

